• REPAIR
• REGENERATE
STEM CELL • RESTORE

Therapy Protocol Series

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Therapy Protocol Series

Overview

To date, R3's Centers nationally have completed over 11,000 regenerative procedures and over 40,000 PRP therapies. The enclosed protocols are what constitutes "best practices" as reported by our Centers.

Each protocol is not considered "black and white". In addition, we reserve the right to change these protocols from time to time based on additional information received from our Centers.

Disclaimer: You will notice that each Protocol comes with a disclaimer that reads as follows.

This protocol from R3 Stem Cell has been put together as a “best practice” document based on feedback from our provider user base. As with any medical procedure, R3 Stem Cell does not guarantee any particular outcome. Also, the protocol provided is not meant to provide definitive advice, but simply a guide based on feedback from users. Make sure to view the Pre- and Post-Procedure protocols as well.

Reliance on any information provided by R3 Stem Cell is solely at your own risk. R3 Stem Cell is not responsible for the outcome of therapy, and each practice should have plans in place for treating an allergic reaction. No protocol or specific biologic indication has been evaluated or approved by the FDA, and these protocols are NOT meant to treat or cure any condition.

Therapy Protocol Series

Biologic Handling Protocol

Whether using amniotic or umbilical cord tissue, the handling of the biologics is the same. The tissues are regulated under the same FDA regulations.

If a practice has a cryogenic freezer on site, it should be set at a minimum of -80 degrees Celsius. The biologics can be stored as low as -192 degrees Celsius, which is typically what liquid Nitrogen achieves.

When a practice receives the biologic through overnight mail, it will be on dry ice at -80 degrees Celsius. The dry ice is enough for 3 days typically. We like to have it arrive the day before the procedure if possible to avoid any shipping delays on the day of the order.

The vials themselves are not sterile, only aseptic. The product is meticulously processed in an aseptic environment, every precaution was taken and exercised to insure the absence of any bioburden. Testing has been completed according to USP71 sampling on bioburden. The best labs like we use do NOT use radiation, which is why the vials themselves are not sterile.

Here are excerpts from the General instructions from the insert (not word for word):

1. For use on a single visit for a single patient, it can not be shared between patients or stored after thawing.

2. Remove the tube containing vial from plastic bag, Inspect the packaging and labeling materials carefully.

3. Do not use past expiration date on the label.
   - Do not use if the packaging is damaged.
   - Do not use if there are discrepancies in label info.
   - Notify R3 if the labeling is wrong info.
   - Use sterile technique for preparation and implantation.
   - Do not sterilize or re-freeze.
   - Report ANY adverse events to R3 right away.
   - Take photographs to document ANY concerns.

4. Open outer vial, remove inner vial, hold upright.

5. Thaw allograft by holding inner vial in your hand. Do not turn upside down or shake. Some providers will roll the vial between their gloved hands for a few minutes.

6. Packaging is NOT sterile. If used in a surgical environment, use a sterile 18g needle to withdraw the allograft out of the vial into a sterile syringe. The contents of the vial are aseptic, the outer vial was prepared in an aseptic environment but it is not sterile.

7. Mix with preservative free saline preferably, can be mixed with BMA, PRP, patient's blood.

8. Make sure to complete the tissue tracking record card. Even if the allograft was discarded.

When it comes to lidocaine, we do not recommend mixing the biologic with it. There is concern over cytotoxicity. For superficial numbing, use it preservative free.

Needle size - There is concern that using a needle size of 27g or smaller may be cytotoxic. So best to use needles larger than that if possible.

What if a case gets delayed? Don't panic. Simply place more dry ice on the biologic. It can be purchased at most supermarkets and it is inexpensive. Another option is to join our Cryogenic Freezer program!

R3 Stem Cell Informed Consent

Regenerative Medicine Treatment with Amniotic and Umbilical Cord Tissue

Name of Patient: _____

Name of Provider: _____

1. **Overview:** The biologic material is derived from the amniotic fluid, placenta and umbilical cord tissue of live consenting donors and there is nothing embryonic (fetal). The tissue is regulated by the FDA and it is processed according to the FDA's Current Good Tissue Practices (CGTP) in an ISO certified lab. The risk profile to date has been excellent with minimal adverse effects reported. Having said this, any procedure has risks associated with it as outlined below. Of note – these biologics are regulated by the FDA in accordance with CFR21, Part 1271. They are not regulated as drugs, therefore, cannot be FDA Approved or Denied – ONLY regulated.

2. **Procedure:** You will receive an injection or infusion of the regenerative biologics along with numbing medicine with the specific technique according to the clinic provider. Your procedure may also include a vitamin infusion and/or mannitol as well.

Specific procedure being administered:

_____

_____

_____

3. **Risks and Discomforts:** Risks of these treatments include but are not limited to: infection, bleeding, allergic reactions, nerve injury, lidocaine complication (such as heart attack), blood clots, pneumonia, and failure to alleviate your symptoms. Your treating physician will address these issues should they occur and if serious enough, direct you to an emergency room.

The following information has been discussed with me about the Procedure listed above: (a) the nature and intended purpose; (b) the potential risks, benefits and side effects, (c) the reasonable alternatives, including the potential risks, benefits and side effects related

to those alternatives; (d) the risks and consequences of not receiving the Procedure; and (e) the possible or likely results of the Procedure, including my likelihood of achieving treatment goals.

4. **Acknowledgement.** I understand the practice of medicine and surgery is not an exact science, and that the procedure may not have the benefit or results intended. I acknowledge that no guarantees or assurances have been made to me concerning the benefits or results of the Procedure.

Patient Signature:

I have read and understand the information in this informed consent form. The information referred to in this informed consent form has been explained to me by my Practitioner.I have had the opportunity to ask and have had answered to my satisfaction all of my questions about the Procedure, including any questions about anesthesia. I believe that I know enough about the Procedure to make an informed decision and that by signing below, I give my consent for the Procedure

_____ _____

PATIENT DATE AND TIME

Physician Signature:

I certify that I have had the informed consent discussion with the patient or patient's representative and have answered any questions related to the Procedure.

_____ _____

PHYSICIAN'S SIGNATURE DATE AND TIME

R3 Stem Cell Non Cancer Forming Notice
Informed Consent Regarding Malignancy

Hearing the words "you have cancer" is something no one ever wants to hear. The unfortunate reality in America is that one in two men and one in three women may expect a cancer diagnosis (American Cancer Society).

These statistics are important for several reasons. One is that there is always a chance you may have cancer cells currently in your system and not know it. A second reason is that no foolproof screening system exists to tell whether you currently have cancer cells in your system, whether they are active or not.

Treatment with mesenchymal stem cells from an amniotic or umbilical source has not been shown to cause cancer in humans, or worsen a pre-existing cancer diagnosis.

Through many studies, we know that mesenchymal stem cells are not tumorigenic, which means they don't form or exacerbate tumors (R3's affiliated centers do NOT use embryonic cells). **R3's Centers use multipotent stem cells (not pluripotent), which have not been shown to either start or promote a cancer growth.**

Several references showing this are below. By signing this, you acknowledge receiving this information and understand what the current body of evidence shows, that mesenchymal stem cell therapy has not been shown to form or promote cancer in humans.

Patient Name (printed): _____

Patient Signature: _____

Date: _____

References:

1. Tumorigenicity Evaluation of Umbilical Cord Blood-derived Mesenchymal Stem Cells, Park et al., Toxicol Res, 2016.
2. Bone Marrow Mesenchymal Stem Cell Has Poor Proliferation but Non-Tumorigenicity in Cancer Environment, Xie et al., Laboratory Medicine, 2010.
3. Human Wharton's jelly stem cells and its conditioned medium enhance healing of excisional and diabetic wounds, Fong et al, J Cell Biochem 2014.
4. Potential antitumor therapeutic strategies of human amniotic membrane and amniotic fluid-derived stem cells, Kang et al, Cancer Gene Ther, 2012.
5. Bone-marrow-derived mesenchymal stem cell therapy for neurodegenerative diseases, Sadan et al, Expert Opin Biol Ther, 2009.
6. Muse cells, newly found non-tumorigenic pluripotent stem cells, reside in human mesenchymaltissues, Wakao et al, Pathol Int, 2014.
7. Extra-embryonic human Wharton's jelly stem cells do not induce tumorigenesis, unlike human embryonic stem cells, Gauthaman et al, Reprod Biomed Online, 2012.
8. Unique multipotent cells in adult human mesenchymal cell populations, Kuroda et al, Proc Natl Acad Sci USA, 2010.
9. Wharton's jelly derived mesenchymal stem cells: future of regenerative medicine? Recent findings and clinical significance, Kalaszczyka et al, Biomed Res Int, 2015.

Anti Aging (Wellness) Protocol

Introduction

According to Dr. Arnold Caplan at Case Western University, infused stem cells are able to go to where they are needed in the body. As the "Father of MSC's", Dr. Caplan is well published about the topic such as his recent article in the April 2017 issue of Stem Cells and Translational Medicine titled: **Mesenchymal Stem Cells: Time to Change the Name!**

The bottom line with IV therapy is that the biologic will go to the area of organ damage and assist with the issue. As a person ages, tissue deterioration inevitably occurs. Throughout the natural process of aging, your stem cells actively work to help replenish your body. If some of your organs are damaged or destroyed, these repair stem cells "home" to the damaged parts of the body to begin repair. Unfortunately, as people age, the production of your stem cells also diminishes over time.

After the age of 50, the ability of one's own bone marrow to generate stem cells decreases exponentially. Therefore, anti aging therapy at R3 Stem Cell Centers of Excellence incorporates amniotic and/or umbilical cord tissue therapy. These biologics contain a veritable "orchestra" of cell types including stem cells, cytokines, exosomes, secretomes, micro RNA and over eighty growth factors!

Initial studies have shown both safety and effectiveness of IV regenerative therapy for anti aging. Disclaimer – We do not use the words "heal" or "cure", as that is an unrealistic claim. You also should not tell patients this will "turn back the clock" as that is unrealistic.

To date, R3 Stem Cell's providers have not reported any adverse events as a result of an IV procedure. Amniotic and umbilical tissue obtained from R3's suppliers have not produced any rejections or deep infections to date.

Protocol

1. For patient comfort, best to have him/her in a reclining comfortable chair or laying down on a treatment table. Sometimes people get lightheaded when receiving an IV!
2. Start an IV in the usual sterile manner, secure it to prevent it from falling out.
3. Prior to the regenerative biologic infusion, providers infuse a vitamin cocktail which is essentially a "Myers Cocktail". A significant amount of providers include glutathione with the vitamin cocktail, which is an important antioxidant reversing the effect of free radicals (see #4 about glutathione). **(R3 offers the vitamin cocktail as a kit that is**

ready to go, which includes the IV tubing, saline bag and vitamins/minerals with instructions).

4. You can start infusing at full rate. After half the bag is infused, that is the best time to place the glutathione in with the mix and then slow the bag down to half rate. Providers have seen issues with lightheadedness when the glutathione is placed and full rate is continued.
5. When 2/3 of the multi-vitamin bag has been infused, place the stem cells into the 2nd port. Most providers will use 2ml's of amniotic fluid or 2 cc's of umbilical cord tissue product.
6. Make sure to infuse the biologic into the 2nd port (very important). Once the biologic is in, the rest of the "Myers Cocktail" will flush it through. If the bag has already finished, the biologic should be flushed through with some saline.

The whole procedure takes approximately two hours.

Post-Procedure – Activity is important. The amount is relative to the individual's baseline. But being sedentary is one of the main reasons for treatment failure. Walking, exercising, etc will facilitate the biologic to activate and should be encouraged.

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Autism and CP Protocol

Introduction

In the U.S., millions of children have a diagnosis of CP or autism. Initial studies are showing small but statistically significant improvements for CP with use of stem cells (Novak et al, Stem Cells Transl Med. 2016), and Duke University's Phase I study showed safety of umbilical cord tissue infusions for children aged 2-5 (Dawson et al, STEM CELLS TRANSLATIONALMEDICINE 2017;6:1332–1339). In addition, both of these studies displayed very low risk profiles for IV umbilical cord therapy.

In reality, the human brain doesn't finish forming until the age of 25. So while the studies were completed in younger children, there is a possibility of improvements in patients older than five.

What follows is a protocol culled from existing studies along with best practices from our existing providers. Please note our disclaimer with regard to usage and outcomes.

Protocol

1. Because the procedure is being done on a child, it may be necessary to provide something to relax the child like Benadryl or even IV sedation. One of the obvious concerns is that the child may become agitated and remove the IV. So there is no "standard" sedation protocol and should be decided upon case by case.
2. The procedure should be performed with the patient in a reclining seat or with the patient laying on a table.
3. Prior to the regenerative biologic infusion, providers infuse a vitamin cocktail which is essentially a "Myers Cocktail". A significant amount of providers include glutathione with the vitamin cocktail, which is an important antioxidant reversing the effect of free radicals. (R3 offers the vitamin cocktail as a kit that is ready to go). This includes the saline bag, tubing AND the vitamin tubes.
4. Approximately 30 minutes later, the patient should receive mannitol first to open the blood brain barrier. According to the mannitol safety paper published in 2014 (Gonzales-Portillo et al, Cell Transplant. 2014 ; 23(0): 531–539.), the dosing is as follows: "In humans, the adult dose is 1.5–2.0 g/kg, while the pediatrics dose is 0.25–1.0 g/kg, both administered intravenously. In children of all ages for treatment of cerebral edema, a 200 mg/kg dose is recommended (88)." So for a 20 kg child at 1g/kg, the math would be 20 grams.
5. Keep in mind this is not a "black and white" protocol for IV stem cell therapy. Our providers have significant variation. Thankfully all have been shown to be safe to date

with the overriding recommendation to use mannitol for blood brain barrier and glutathione is also unanimously recommended too.

6. Approximately 30-60 minutes later, the stem cell portion is administered. Dosing of umbilical cord tissue in the various studies ranges considerably for CP or Autism. The Duke study used 1-5 x 10^7 stem cells/kg. So for a 20kg child, using the midpoint number would mean 50 million stem cells. That would be 4cc's of Stemvive. In the meta-analysis study referenced in the intro for CP, dosing is VERY similar for CP. So for most kids, the dose will be around 4cc's umbilical.
7. This should be infused through the 2nd port of the IV and flushed with saline.

The whole procedure takes approximately 2-3 hours.

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Therapy Protocol Series

Autoimmune Therapy Protocol

Introduction

According to Dr. Arnold Caplan at Case Western University, infused stem cells are able to go to where they are needed in the body. As the "Father of MSC's", Dr. Caplan is well published about the topic such as his recent article in the April 2017 issue of Stem Cells and Translational Medicine titled: **Mesenchymal Stem Cells: Time to Change the Name!**

The bottom line with IV therapy is that the biologic will go to the area of damage and assist with the issue. With regards to autoimmune disease, essentially the body begins to damage itself.

These biologics contain a veritable "orchestra" of cell types including stem cells, cytokines, exosomes, secretomes, micro RNA and over eighty growth factors!

Initial studies have shown both safety and effectiveness of IV therapy for autoimmune disease. Disclaimer – We do not use the words "heal" or "cure", as that is an unrealistic claim, and nothing in this protocol should be construed as a treatment for any specific condition, as stem cell therapy is considered experimental.

To date, R3 Stem Cell's providers have not reported any adverse events as a result of an IV procedure. Amniotic and umbilical tissue obtained from R3's suppliers have not produced any rejections or deep infections to date.

Protocol

1. Prior to the regenerative biologic infusion, providers infuse a vitamin cocktail which is essentially a "Myers Cocktail" and primes the body for the regenerative biologic. A significant amount of providers include glutathione with the vitamin cocktail, which is an important antioxidant reversing the effect of free radicals. **(R3 offers the vitamin cocktail as a kit that is ready to go, which includes the IV tubing, saline bag and vitamins/minerals with instructions).**
2. Approximately 30 minutes later, the stem cell portion is administered. This is at the point when 2/3 of the multi-vitamin bag has been infused. Most providers will use 2ml's of amniotic fluid or 2 cc's of umbilical cord tissue product.
3. Make sure to infuse the biologic into the 2nd port (very important). Once the biologic is in, the rest of the "Myers Cocktail" will flush it through. If the bag has already finished, the biologic should be flushed through with some saline.

The whole procedure takes approximately two hours.

Post-Procedure – Activity is important. The amount is relative to the individual's baseline. But being sedentary is one of the main reasons for treatment failure. Walking, exercising, etc will facilitate the biologic to activate and should be encouraged.

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Therapy Protocol Series

COPD Protocol

Introduction

According to Dr. Arnold Caplan at Case Western University, infused stem cells are able to go to where they are needed in the body. As the "Father of MSC's", Dr. Caplan is well published about the topic such as his recent article in the April 2017 issue of Stem Cells and Translational Medicine titled: **Mesenchymal Stem Cells: Time to Change the Name!**

The bottom line with IV therapy is that the biologic will go to the area of organ damage and assist with the issue. This includes treatment for COPD. However, this protocol also recommends use of a nebulizer, as the biologics can reach the lungs more directly as well.

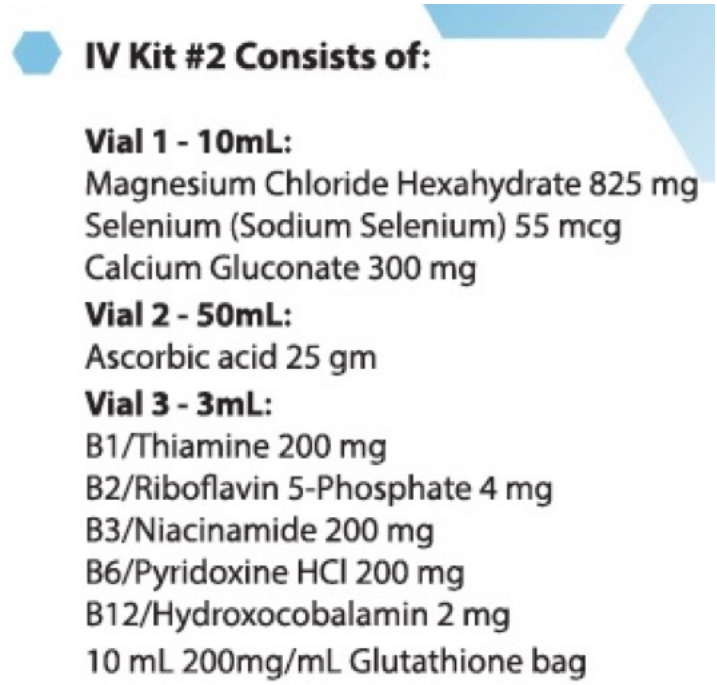
Disclaimer – We do not use the words "heal" or "cure", as that is an unrealistic claim, and nothing in this protocol should be construed as a treatment for any specific condition, as stem cell therapy is considered experimental.

To date, R3 Stem Cell's providers have not reported any adverse events as a result of an IV or nebulized procedure. Amniotic fluid and umbilical cord tissue obtained from R3's suppliers has not produced any rejections or deep infections to date.

Protocol

With COPD, the provider should obtain baseline labs and indices such as amount of oxygen, medications being used, saturations and activity level. That way, objective improvement can be monitored along with subjective improvement. R3 has an IRB approved study which includes data acquisition instruments. R3's Partner Practices have access to these outcome instruments.

1. Prior to the regenerative biologic infusion, providers infuse a vitamin cocktail which is essentially a "Myers Cocktail" and primes the body for the regenerative biologic. A significant amount of providers include glutathione with the vitamin cocktail, which is an important antioxidant reversing the effect of free radicals. **(R3 offers the vitamin cocktail as a kit that is ready to go, which includes the IV tubing, saline bag and vitamins/minerals with instructions).**



2. Approximately 30 minutes later, the stem cell portion is administered. This is at the point when 2/3 of the multi-vitamin bag has been infused. Most providers will use 2ml's of amniotic fluid or 2 cc's of umbilical cord tissue product. However, for more severe cases of COPD, then 3 cc's or 4 cc's may be appropriate.

Amount of amniotic or umbilical cord tissue – provider opinions vary. The most common amount to utilize for a patient with COPD is 2cc's of either product. We have had providers safely use 4cc's of product in severe cases. Adverse events have not been reported to R3 with the usage of these increased amounts.

Whether 2cc or 4cc is used, then 0.5cc's for either amount should be placed into a nebulizer machine along with 2-4 cc's of saline and inhaled. MOST COPD patients will have their own nebulizer machine. Usage of a nebulizer machine is seen here: https://www.youtube.com/watch?v=UKUClmyRC2Q

They can be obtained inexpensively and the tubing parts are obtained as a kit and disposable.

Post-Procedure – Activity is important. The amount is relative to the individual's baseline. But being sedentary is one of the main reasons for treatment failure. Walking, exercising, etc will facilitate the biologic to activate and should be encouraged.

A repeat procedure may become necessary for the condition. This will vary from patient to patient. COPD improvements usually start within a couple weeks, and may last anywhere from 6 months to 3 years. Repeat treatments are typically necessary more often than with arthritis.

Therapy Protocol Series

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Therapy Protocol Series

Diabetic Neuropathy Protocol

Pre-Procedure

Prior to the procedure, it is recommended to check the patient's bloodwork. A HgbA1C under 8 is advised prior to moving ahead with the procedure along with a fasting blood sugar under 200. Providers should also implement a nutritional protocol including supplements and a strict anti-inflammatory diet.

Consideration should be given to provide IV therapy prior to the procedure including a Myer's Cocktail, given once or twice. Additional considerations:

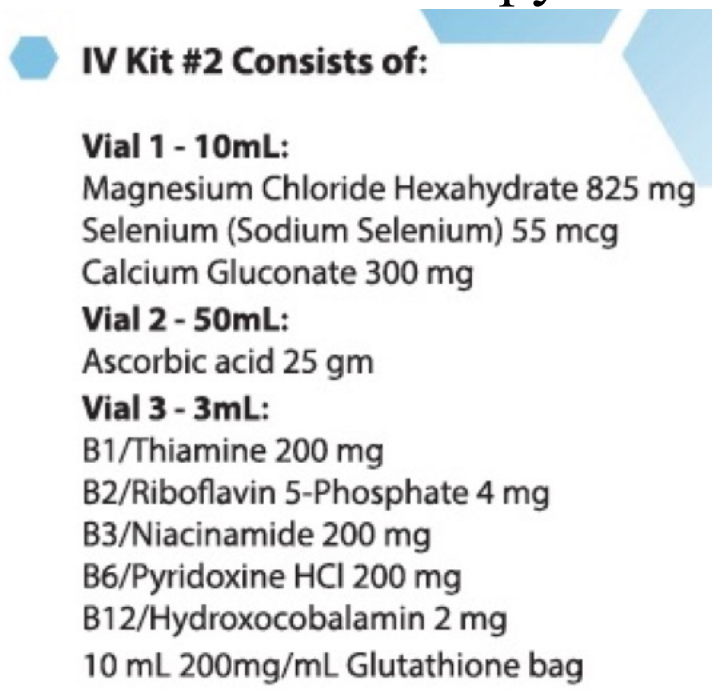
- Gait Evaluation
- Rule out other potential diagnoses
- Test 2 point discrimination – gives baseline.
- Consideration of a punch biopsy – can show baseline neuropathy level. Consider repeating 6-8 months after treatment.
- See our Pre-procedure instructions for all pts – stop NSAIDs for 5 days prior to the procedure and work with PCP on meds like Lovenox/Coumadin.

Disclaimer – We do not use the words "heal" or "cure", as that is an unrealistic claim, and nothing in this protocol should be construed as a treatment for any specific condition, as stem cell therapy is considered experimental.

IV and/or Injection Protocol?

It is unclear which is best. It appears both work well. This protocol showcases both, which we call a hybrid protocol.

1. Prior to the regenerative biologic infusion, providers infuse a vitamin cocktail which is essentially a "Myers Cocktail" and primes the body for the regenerative biologic. A significant amount of providers include glutathione with the vitamin cocktail, which is an important antioxidant reversing the effect of free radicals. **(R3 offers the vitamin cocktail as a kit that is ready to go, which includes the IV tubing, saline bag and vitamins/minerals with instructions).**



2. Approximately 30 minutes later, the stem cell portion is administered. This is at the point when 2/3 of the multi-vitamin bag has been infused. Most providers will use 1 or 2ml's of amniotic fluid (or umbilical).

Injection:

There are two main recommended injection sites.

1. CPN – Inject 0.5cc's amniotic or umbilical (diluted 1:1 with sterile preservative free saline for a total of 1cc's) along the common peroneal nerve below the area of the fibular head. NOT into the nerve, but around it. Use a 23 gauge needle, either 1 inch or 1.5 inches in length. Ultrasound is very helpful for the procedure, but plenty of providers have success without it. Without U/S it is advisable to use a Tinel's test to see if the nerve can be located to avoid injecting into it.
2. Tibial – Inject 0.5cc's amniotic or umbilical (diluted 1:1 with sterile preservative free saline for a total of 1cc's) along the tibial nerve in the area prior to where the nerve splits. A good landmark is along the medial border of the peroneal tendon.

Total amniotic or umbilical used for both legs = 2cc's which becomes 4cc's after dilution.

Post-Procedure

1. See the R3 Post Procedure instructions.
2. For neuropathy, it is helpful to incorporate electrical stimulation. The device providers have had success with is Quell worn below fibular head area, worn 12 hrs/day on each leg. A TENS unit may help if the Quell is not feasible. The goal is to provide the additional stimulus for the growth factors and stem cells to "do their thing". It also can

increase blood flow, neovascularization and facilitate the sodium channel gate theory. Light treatment can help as well.

3. Heat is ok, but no ice or NSAIDS for weeks.

Results: Our providers have seen results in as little as 96 hours or as much as 12 weeks. Patients differ considerably in their response.

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Therapy Protocol Series

Erectile Dysfunction Protocol

Pre-Procedure

Prior to the procedure, it is recommended to figure out the potential cause of the ED. In essence, the procedure works well for ED resulting from microvascular disease. This includes diabetes and hypertension. For instance, a post prostatectomy patient may not benefit since it's not a microvascular issue.

Procedure

First and foremost, it should be understood that this protocol only refers to what has worked well for some of our providers immensely well. They report exceptional safety and efficacy.

Injection:

Initially, PRP is used for the procedure. Only a few cc's is needed for the procedure, but it depends on the size of the anatomy. Initially, a numbing cream (e.g BLT) should be used to numb the areas along with appropriate sterilization.

The injections are placed intracavernosal bilaterally. One cc of amniotic material is typically used and diluted with 3cc's of PRP. The material is then split between Left and Right. The amount of material used will vary based on the size of the patient's penis. Four cc's total may be appropriate or it can be up to double that.

Some providers will add shock wave therapy to the treatment. SWT is extremely beneficial as an adjuvant, but the equipment costs approximately $25,000. The exact protocol for these shock wave devices will need to defer to manufacturer's instructions. It should include an initial treatment and several afterwards for a few weeks. In actuality, the machine may serve as a significant "value add" for patients. The procedure pricing may include the SWT, and then keeps the patient coming back for treatment which develops rapport.

Because the shock wave devices are expensive and require continual office visits, when this is not possible, providers will simply use a vacuum penis enlargement device. These should be used several times daily to stimulate the neovascularization process for a few weeks.

While results will vary, over 80% will respond within two weeks of the treatment, with results often lasting six months or more. A great result may consist of spontaneous erections without the need for medications, or medication adjuvants working where they didn't work before.

Special Note:

Be careful not to over-inject. More is not always better.

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Therapy Protocol Series

Large Joint Protocol

Pre-Procedure

See our Pre-procedure instructions for all pts – stop NSAIDs and H2 Blockers for 5 days prior to the procedure and work with PCP on meds like Lovenox/Coumadin.

Injection:

The amniotic or umbilical material arrives on dry ice and is good for 3 days (including shipping time). The vial only needs 15-20 minutes to thaw out prior to the procedure. Once thawed, the material should be used within two hours (do not refreeze). If the procedure gets delayed, simply place more dry ice on the biologic or put into a cryogenic freezer.

Dilution – Most providers will dilute the product in a 3:1 ratio. You don't have to dilute at all however. Dilution is most commonly performed with sterile preservative free saline. While you could use PRP as the dilution, most providers do a separate PRP injection. Lidocaine is not recommended into the joint being treated as it may affect cell viability. Plenty of providers will use numbing medicine superficially though and/or numbing spray.

Amount – Most providers utilize a 1cc vial for a knee, hip or shoulder joint. When diluted 3:1, the total to be injected is 4cc's. Steroid should NOT be injected at the same time and if the patient has had a previous injection it is best to wait at least 30 days before a regenerative biologic procedure. The actual injection technique for a knee such as peri-patellar tendon, supra-patellar, etc, is not mandated and is up to personal preference.

When it comes to whether or not to utilize image guidance, the providers we work with use ultrasound, c-arm, or none at all. It is up to physician preference and training, however, for a joint that has significant soft tissue between the skin and the joint it can be very helpful (e.g. hip, shoulder, spine).

Once the injection has been performed, most providers will have the patient move the joint around for a few minutes to circulate the fluid throughout the joint.

Post-Procedure

1. See the R3 Post Procedure instructions.
2. The principal that is appropriate for all large joint procedures is to create an inflammatory signal. If one is dealing with an acute injury, the signal is already present. For chronic issues (e.g. arthritis), it is a great idea to incorporate a TENS unit, laser or light therapy to provide a stimulus ramp up for the regenerative material. As mentioned, adding in the PRP is great for the stimulus. Even with a second spin to reduce WBC's there is still some inflammation created!

3. Heat is ok, but no ice or NSAIDS for weeks.
4. A lot of providers will incorporate a post-procedure brace for the knee which allows for limited ROM including flexion/extension but not lateral/medial motion for a couple weeks.

Results: Our providers have seen results in as little as 24 hours or as much as 8 weeks. Patients differ considerably in their response. Even bone on bone patients have seen excellent responses.

There have been some large studies done on knee treatment with amniotic. Please see our video titled “Stem Cell Therapy for Knee Arthritis” where those studies are discussed.

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Therapy Protocol Series

Lyme Disease Protocol

Introduction

Annually, state health departments in America report thirty thousand Lyme cases to the CDC. However, the CDC says the actual number is probably ten times higher than that.

While most cases of Lyme disease respond to antibiotic treatment, the problem is that 20% of patients end up with Post Treatment Lyme Disease Syndrome. This is where regenerative therapy enters the picture and has been markedly effective. Symptoms of the Syndrome include extended fatigue, pain, and joint and muscle aches, according to the National Institute of Allergy and Infectious Diseases (NIAID).

Based on provider feedback, R3 Stem Cell has put together this Lyme Disease stem cell therapy protocol. Various scientific studies are showing how important the variety of cell types are to Lyme recovery including stem cells, exosomes, secretomes and others.

Disclaimer – We do not use the words “heal” or “cure”, as that is an unrealistic claim, and nothing in this protocol should be construed as a treatment for any specific condition, as stem cell therapy is considered experimental.

Protocol

1. Prior to the regenerative biologic infusion, providers infuse a vitamin cocktail which is essentially a “Myers Cocktail” and primes the body for the regenerative biologic. A significant amount of providers include glutathione with the vitamin cocktail, which is an important antioxidant reversing the effect of free radicals. **(R3 offers the vitamin cocktail as a kit that is ready to go, which includes the IV tubing, saline bag and vitamins/minerals with instructions).**

IV Kit #2 Consists of:

Vial 1 - 10mL:
Magnesium Chloride Hexahydrate 825 mg
Selenium (Sodium Selenium) 55 mcg
Calcium Gluconate 300 mg
Vial 2 - 50mL:
Ascorbic acid 25 gm
Vial 3 - 3mL:
B1/Thiamine 200 mg
B2/Riboflavin 5-Phosphate 4 mg
B3/Niacinamide 200 mg
B6/Pyridoxine HCl 200 mg
B12/Hydroxocobalamin 2 mg
10 mL 200mg/mL Glutathione bag

2. Approximately 30 minutes later, the patient should receive mannitol first to open the blood brain barrier (if neurological symptoms are present). Typically it involves 80g (plus or minus 40g) being put into a saline bag and infused over half an hour. According to the mannitol safety paper published in 2014 (Gonzales-Portillo et al, Cell Transplant. 2014 ; 23(0): 531–539.), the dosing is as follows: "In humans, the adult dose is 1.5–2.0 g/kg." For an individual who weighs 175 pounds, that equates to about 80kg. According to the calculation from the paper, a dose of 120gm would be appropriate and safe. For a patient who weighs 120 pounds (about 60kg), that's 60 x 1.5 = 90gms.
Keep in mind this is not a "black and white" protocol for IV stem cell therapy. Our providers have significant variation. Thankfully all have been shown to be safe to date with the overriding recommendation to use mannitol for blood brain barrier and glutathione is also unanimously recommended too.

3. Approximately 30 minutes later, the stem cell portion is administered. Most providers will use 2ml's of amniotic fluid or 2 cc's of umbilical cord tissue product along with a smaller amount for intranasal A saline bag is hung of 150ml's or so and infused slowly. The stem cell material is placed into the 2nd port and then let the rest of the saline bag flush it through the tubing. This process takes 30-60 minutes. *The 2nd port part is VERY important. If it goes into the bag, we've seen issues with restricted IV flow.
4. In addition to the IV regenerative therapy, a small amount is given via a nasal pump as well. Usually a lidocaine swab is administered first for numbing. Either 0.5 or 1.0cc's of

the stem cell material is used, with saline dilution. The nasal pump providers have used is the Sphenocath which is easy to use. We can help obtain one.

The whole procedure takes approximately 3 hours.

Post-Procedure – Activity is important. The amount is relative to the individual's baseline. But being sedentary is one of the main reasons for treatment failure. Walking, exercising, etc will facilitate the biologic to activate and should be encouraged.

A repeat procedure may become necessary for the condition after 6 to 18 months. This will vary from patient to patient.

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Migraine & Tension Headache Protocol

Introduction

Chronic migraine and tension type headaches affect over 2% of the population. A significant amount of patients do not respond to traditional therapies such as medications and Botox injections.

Several recent studies have shown that stem cell therapy may be very effective for chronic migraines and/or tension type headaches. In small cohorts of patients, regenerative therapies have been shown to potentially be life changing. This would be called anecdotal.

Disclaimer – We do not use the words “heal” or “cure”, as that is an unrealistic claim, and nothing in this protocol should be construed as a treatment for any specific condition, as stem cell therapy is considered experimental.

To date, R3 Stem Cell’s providers have not reported any adverse events as a result of an IV procedure. Amniotic and umbilical cord tissue obtained from R3’s supplier has not produced any rejections or deep infections to date.

Protocol

In the studies to date, there have been two methods for the administration of the regenerative biologics. In reality, a combination of the two methods may be the better option.

IV Infusion

1. Prior to the regenerative biologic infusion, providers infuse a vitamin cocktail which is essentially a “Myers Cocktail” and primes the body for the regenerative biologic. A significant amount of providers include glutathione with the vitamin cocktail, which is an important antioxidant reversing the effect of free radicals. **(R3 offers the vitamin cocktail as a kit that is ready to go, which includes the IV tubing, saline bag and vitamins/minerals with instructions).**

2. Approximately 30 minutes later, the patient should receive mannitol first to open the blood brain barrier. Typically it involves 80g (plus or minus 40g) being put into a saline bag and infused over half an hour. According to the mannitol safety paper published in 2014 (Gonzales-Portillo et al, Cell Transplant. 2014 ; 23(0): 531–539.), the dosing is as follows: “In humans, the adult dose is 1.5–2.0 g/kg." For an individual who weighs 175 pounds, that equates to about 80kg. According to the calculation from the paper, a dose of 120gm would be appropriate and safe. For a patient who weighs 120 pounds (about 60kg), that's 60 x 1.5 = 90gms.

Keep in mind this is not a "black and white" protocol for IV stem cell therapy. Our providers have significant variation. Thankfully all have been shown to be safe to date with the overriding recommendation to use mannitol for blood brain barrier and glutathione is also unanimously recommended too.

3. Approximately 30 minutes later, the stem cell portion is administered. Most providers will use 2ml's of amniotic fluid or 2 cc's of umbilical cord tissue product along with a smaller amount for intranasal A saline bag is hung of 150ml's or so and infused slowly. The stem cell material is placed into the 2nd port and then let the rest of the saline bag flush it through the tubing. This process takes 30-60 minutes. *The 2nd port part is VERY important. If it goes into the bag, we've seen issues with restricted IV flow.

4. In addition to the IV regenerative therapy, a small amount is given via a nasal pump as well. Usually a lidocaine swab is administered first for numbing. Either 0.5 or 1.0cc's of the stem cell material is used, with saline dilution. The nasal pump providers have used is the Sphenocath which is easy to use. We can help obtain one.

Injection Option

1. For this option, a total of 8-10 cc's is injected into the temporalis, occipitalis, neck, and trapezius. This may consist of either 2cc's of amniotic or 2cc's of umbilical cord stem cell material diluted 3:1 for a total of 8cc's.
2. These injections are basically trigger point injections – if lidocaine is used, make sure it is preservative free and make sure the needle is no smaller than a 23 gauge.

Combination Option

Studies to date have shown efficacy with either systemic infusion of injections. In reality, the optimal protocol may be to simply combine the 2 options.

This may include 1cc of IV usage along with 1cc of injection with 3:1 dilution. More material may be used for both mediums, however, cost may become a factor.

Post-Procedure – Activity is important. The amount is relative to the individual's baseline. But being sedentary is one of the main reasons for treatment failure. Walking, exercising, etc will facilitate the biologic to activate and should be encouraged.

A repeat procedure may become necessary for the condition after 6-18 months. This will vary from patient to patient.

References:

J Med Case Rep. 2014; 8: 237.

Published online 2014 Jun 30. doi: 10.1186/1752-1947-8-237
PMCID: PMC4088303

Migraine and tension-type headache treated with stromal vascular fraction: a case series

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Case Rep Neurol. 2017 May-Aug; 9(2): 149–155.
Published online 2017 Jun 14. doi: 10.1159/000477393
PMCID: PMC5498934

Stem Cells in the Treatment of Refractory Chronic Migraines

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Disclaimer:

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Therapy Protocol Series

Multi-Vitamin Preparation Instructions

Introduction: The multi-vitamin infusion utilized by most R3 providers is a vital component of an IV procedure. Because it has so many different vitamins and minerals, we view it as "priming" the body for the regenerative biologic.

Known as a "Myers Cocktail", it was named after a physician who compiled a plethora of vitamins and minerals together in an IV solution for the treatment of a wide range of clinical conditions. After Dr. Myers passed away in the 1980's, a subsequent physician Dr. Gaby built on his work and subsequently published an excellent review of a Modified Myers Cocktail. (Altern Med Rev. 2002 Oct;7(5):389-403. **Intravenous nutrient therapy: the "Myers' cocktail".** Gaby AR.)

In his conclusion, Dr. Gaby wrote "The Myers' has been found by the author and hundreds of other practitioners to be a safe and effective treatment for a wide range of clini- cal conditions. In many instances this treatment is more effective and better tolerated than conven- tional medical therapies."

R3's providers have incorporated the IV infusion of a Modified Myers Cocktail as a precursor to the regenerative biologic. **R3 Stem Cell offers these kits to providers**! Here are the components and instructions.

IV Kit #2 Consists of:

Vial 1 - 10mL:
Magnesium Chloride Hexahydrate 825 mg
Selenium (Sodium Selenium) 55 mcg
Calcium Gluconate 300 mg

Vial 2 - 50mL:
Ascorbic acid 25 gm

Vial 3 - 3mL:
B1/Thiamine 200 mg
B2/Riboflavin 5-Phosphate 4 mg
B3/Niacinamide 200 mg
B6/Pyridoxine HCl 200 mg
B12/Hydroxocobalamin 2 mg
10 mL 200mg/mL Glutathione bag

Preparation of Solutions:

1. Aseptic technique must be followed in preparing the infusion solution.
2. Kit comes with 500ml of 0.9% Sodium Chloride (NS) Infusion solution and 4 vials of medication.
3. Withdraw the entire contents (10ml) from MgCl/Selen/CaGluc and inject into the infusion bag.
4. Mix gently and check to see that the contents have dispersed completely.
5. Withdraw the entire contents (50ml) from Ascorbic Acid and inject into the infusion bag.
6. Mix gently and check to see that the contents have dispersed completely.
7. Withdraw the entire contents (1ml) from B-Complex and inject into the infusion bag.
8. Mix gently and check to see that the contents have dispersed completely.
9. Final infusion solution should be inspected visually for particulate matter prior to administration.
    a. If visibly opaque particles or other foreign particulates are observed, the solution should not be used.
    b. The final infusion solution is clear and light yellow colored. If it is cloudy, the solution should not be used.
    c. The compatibility of this infusion solution with other drugs has not been established. Hence, infusion solution should not be mixed with or physically added to solutions containing other drugs.
10. Administer the infusion solution immediately after preparation.
11. Once the IV drip has completed, extract all 10 ml of the glutathione and administer it to the bag to be infused into the patient.

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Therapy Protocol Series

Post Stroke Protocol

Introduction

In the U.S., almost 800,000 people have a stroke each year and more than 140,000 people die of their stroke. It is the leading cause of serious, long-term disability in the U.S.

According to the National Stroke Association, 10 percent of people who have a stroke recover almost completely, with 25 percent recovering with minor impairments. Another 40 percent experience moderate to severe impairments that require special care. This means that there is a type of disability that affects your daily function, whether at work or in your personal life. And 10 percent require long-term care in a nursing home or other facility.

Recovery may be due to:

- Your brain may be able to resume functioning by changing the way tasks are performed.
- If blood flow to the affected area of your brain was restored, some of your brain cells may be damaged instead of destroyed. As a result, these cells will be able to resume functioning over time.
- One area of your brain may take control of the functions that used to be performed by the affected area.

We know that for the first 18 months after a stroke, the human body does have the capacity to heal somewhat. Unfortunately, as the above statistics show there are often persistent deficits.

Studies are showing that for ischemic stroke, IV therapy is not only safe, but often effective for assisting in recovery of areas in the brain that were previously thought to be "dead".

As an example, here is an excerpt from a study out of India that was presented at the 2012 International Stroke Conference:

"The stem cell group experienced significant improvement in daily living activities such as feeding, dressing and mobility, using the modified Barthel Index (P=.05), as compared with controls. There was also an increase in brain activity in areas of the brain responsible for movement planning and motor function."

Based on provider feedback, R3 Stem Cell has put together this post stroke stem cell therapy protocol. Various scientific studies are showing how important the variety of cell types are to stroke recovery including stem cells, exosomes, secretomes and others.

Therapy Protocol Series

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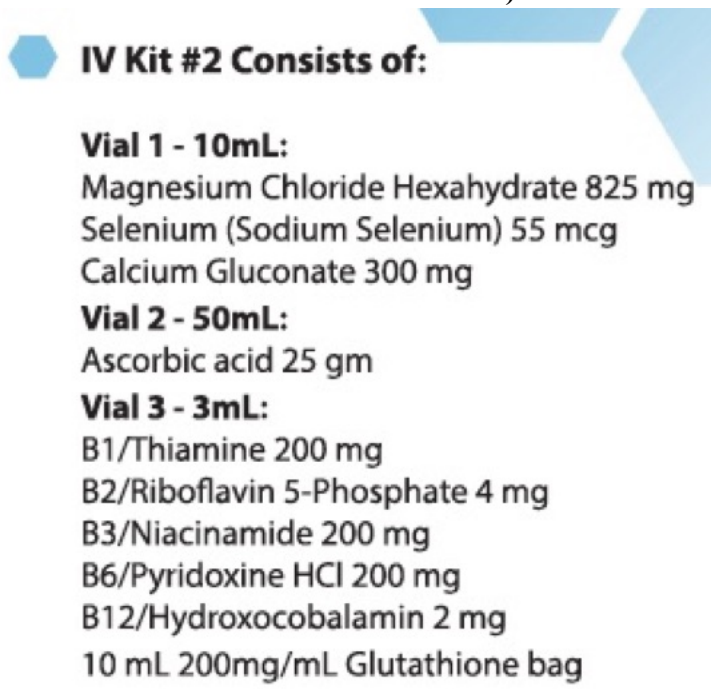
Protocol

1. Prior to the regenerative biologic infusion, providers infuse a vitamin cocktail which is essentially a “Myers Cocktail” and primes the body for the regenerative biologic. A significant amount of providers include glutathione with the vitamin cocktail, which is an important antioxidant reversing the effect of free radicals. **(R3 offers the vitamin cocktail as a kit that is ready to go, which includes the IV tubing, saline bag and vitamins/minerals with instructions).**



2. Approximately 30 minutes later, the patient should receive mannitol first to open the blood brain barrier. Typically it involves 80g (plus or minus 40g) being put into a saline bag and infused over half an hour. According to the mannitol safety paper published in 2014 (Gonzales-Portillo et al, Cell Transplant. 2014 ; 23(0): 531–539.), the dosing is as follows: “In humans, the adult dose is 1.5–2.0 g/kg." For an individual who weighs 175 pounds, that equates to about 80kg. According to the calculation from the paper, a dose of 120gm would be appropriate and safe. For a patient who weighs 120 pounds (about 60kg), that's 60 x 1.5 = 90gms.
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with the overriding recommendation to use mannitol for blood brain barrier and glutathione is also unanimously recommended too.

3. Approximately 30 minutes later, the stem cell portion is administered. Most providers will use 2ml's of amniotic fluid or 2 cc's of umbilical cord tissue product along with a smaller amount for intranasal A saline bag is hung of 150ml's or so and infused slowly. The stem cell material is placed into the 2nd port and then let the rest of the saline bag flush it through the tubing. This process takes 30-60 minutes. *The 2nd port part is VERY important. If it goes into the bag, we've seen issues with restricted IV flow.
4. In addition to the IV regenerative therapy, a small amount is given via a nasal pump as well. Usually a lidocaine swab is administered first for numbing. Either 0.5 or 1.0cc's of the stem cell material is used, with saline dilution. The nasal pump providers have used is the Sphenocath which is easy to use. We can help obtain one.

The whole procedure takes approximately 3 hours.

Post-Procedure – Activity is important. The amount is relative to the individual's baseline. But being sedentary is one of the main reasons for treatment failure. Walking, exercising, etc will facilitate the biologic to activate and should be encouraged.

A repeat procedure may become necessary for the condition after 12 to 24 months. This will vary from patient to patient.

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Therapy Protocol Series

Small Joint Protocol

Pre-Procedure

See our Pre-procedure instructions for all pts – stop NSAIDs and H2 Blockers for 5 days prior to the procedure and work with PCP on meds like Lovenox/Coumadin.

Injection:

The amniotic or umbilical material arrives on dry ice and is good for 3 days (including shipping time). The vial only needs 15-20 minutes to thaw out prior to the procedure. Once thawed, the material should be used within two hours (do not refreeze). If the procedure gets delayed, simply place more dry ice on the biologic or put into a cryogenic freezer.

Dilution – For small joints, most providers will either not dilute the product or only use a 2:1 ratio since there is typically not a lot of intra-articular space. Dilution is most commonly performed with sterile preservative free saline, however, more providers lately are actually using PRP from the patient. Lidocaine is not recommended into the joint being treated as it is unclear its effect on cell viability. Plenty of providers will use numbing medicine superficially.

Amount – Most providers utilize a 0.5 - 1cc vial for a thumb (CMC), finger, toe or similar joint. For a larger small joint like elbow, wrist, ankle, etc – typically a 1cc vial is utilized. Steroid should NOT be injected at the same time. If the patient has had a steroid injection prior, the regenerative procedure should be delayed at least a month.

When it comes to whether or not to utilize image guidance, the providers we work with use ultrasound, c-arm, or none at all. It is up to physician preference and training, however, for a joint that has significant soft tissue between the skin and the joint it can be very helpful (e.g. hip, shoulder, spine). For smaller joints, it still may be helpful especially if there has been significant degeneration which may make it tough to get into.

Once the injection has been performed, most providers will have the patient move the joint around for a few minutes to circulate the fluid throughout the joint.

Post-Procedure

1. See the R3 Post Procedure instructions.
2. The principal that is appropriate for all joint procedures is to create an inflammatory signal. If one is dealing with an acute injury, the signal is already present. For chronic issues (e.g. arthritis), it is a great idea to incorporate a TENS unit, laser or light therapy to provide a stimulus ramp up for the regenerative material. As mentioned, adding in the

PRP is great for the stimulus. Even with a second spin to reduce WBC's there is still some inflammation created!

3. Heat is ok, but no ice or NSAIDS for weeks.

Results: Our providers have seen results in as little as 24 hours or as much as 8 weeks. Patients differ considerably in their response. Even bone on bone patients have seen excellent responses.

There are several larger studies on large joints such as the knee. Our providers have reported exceptional results on smaller joints as well including big toe joint, ankle, elbow, CMC, wrist, etc but no statistically significant study has been put together yet.

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Stem Cell Facelift Protocol

Procedure

1. Prep: this involves simply a face mask, cleansing, etc to prepare the face for the needling.
2. Micro or nano needle the face per physicians technique with PRP. This will involve something like a Dermapen.
3. While the needling is being performed, start to thaw out 1cc at least of the amniotic RHEO product. Do not thaw out the Rheo too soon. You want it to be very "fresh" for application.
4. Put on a surgical sterile glove.
5. Then put a drop of RHEO on gloved finger and paint onto the needled portion of face. No need to dilute the Rheo.
6. Repeat until whole face has been painted with RHEO. Then let it dry for about 5minutes
7. Some providers are repeating the micro needling again at this point.
8. Many providers send patient home with their own serum formulation.

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Stem Cell Hair Restoration Protocol

Procedure

1. Prep: thankfully the scalp has a very good blood supply and infection is rare. Having said that, sterilizing with alcohol swab prior to each injection is recommended.

2. Draw blood for PRP with the smallest kit, as the treatment involves 3 ml of PRP. The two spin technique should be used.

3. Mix the 3cc of PRP with amniotic (our Rheo product) (1-2ml). The amount of amniotic depends on the amount of scalp being treated. Add Vitamin B4 (0.25 - 0.5 mL) and B5 (0.25 - 0.5mL) once again volume dependent on area being treated.

4. Divide the scalp area being treated into quadrants, and implant mix equally into each.

5. Have patient use a Micro Cold Laser Treatment (red LED) helmet 3-4 times per day for 20-30 minutes each time. These are available online.

6. After the initial treatment, repeat with PRP alone at 6-8 weeks to continue potentiation. PRP by itself has been shown to work well as a series of treatments, but the amniotic definitely adds another level when done initially.

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