



Regenexx-SD What to Expect Guide The Regenexx® Patented Same Day Stem Cell Protocol

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What Is a Same Day Stem Cell Procedure?

Our Regenexx Same-Day stem cell protocol is called a same-day procedure because the stem cells are harvested and reinjected on the same day. However, for most patients the complete protocol is actually a series of injections that happen over the course of about a week, depending on your unique situation. These injections include a pre-injection, the same-day stem cell extraction and re-injection procedure, followed by a post-injection of multiple proprietary platelet mixes a few days later.

The first day of the treatment is prolotherapy - a regenerative injection technique that uses an irritant, such as dextrose, to produce a natural inflammatory response which can help regenerate tendons, ligaments, and joint injuries. It is used prior to the stem cell injection to create an acute inflammatory reaction which begins the healing process. In simpler terms, it is analogous to tilling the soil prior to planting the seed.

The second day of the treatment is the stem cell injection. You will first be prepared for the bone marrow aspiration which entails taking bone marrow from the back of each of your hips (iliac crest). This is different than a bone marrow biopsy, which can be painful. The bone marrow aspiration process is often described by patients as being only mildly uncomfortable and well tolerated. You will lie on your stomach on the procedure table and an area at the back of your hip will be numbed. A special needle will be used to draw marrow blood out of this area. X-ray or ultrasound will be used to ensure the optimum location. This will be done on both sides of your hips.

A few hours later you will receive your stem cell injections. The doctor will reinject your stem cells and natural growth factors from your blood platelets using advanced imaging guidance into the area in need of repair (real time fluoroscopy or musculoskeletal ultrasound, using your MRI as a map for the injection). This allows the doctor to pinpoint the exact location of the injection, as well as the dispersion of the cells into the tissue.

The third day of the treatment will be a super concentrated platelet (SCP) and platelet lysate (PLM) injection. The purpose of this is to add an extra boost of growth factors which can help optimize the regenerative potential of the stem cells.

Pre-Procedure

- Please carefully review the medication guidelines printed on page 5.
- It is very important that you drink plenty of fluids (64 oz./day) and are well hydrated beginning 48 hours prior to your blood draw and bone marrow aspiration.
- Please fast (no food, water only) for six hours prior to your bone marrow aspiration procedure and your blood draw.
 - If you are having and intraosseous procedure, with sedation, no food after
 9:00pm the evening prior, and no water for four hours prior to sedation.
- Please refrain from taking any anti-inflammatories beginning three weeks prior to procedure and 6-8 weeks post procedure, as they will block the body's natural ability to heal. A list of anti-inflammatory alternatives can be found below.
- If you have pre-arranged to take Valium or another sedative prior to bone marrow aspiration, you must be accompanied to the procedure by an adult (18 or older). Driving while on a sedative medication is unsafe and can result in a DUI.
 - A driver is required for all intraosseous procedures
- Please review information on improving the quality of your stem cells. See: https://regenexx.com/blog/8-ways-improve-your-stem-cells-prior-treatment/

If you have multiple joints that are requiring treatment (non-intraosseous), we have discovered a minimum number of cells that we need in order to maximize the odds of any given patient having a good result with a Regenexx-SD™ stem cell procedure. Based on that cell count obtained after your bone marrow sample has been processed we can determine if we have an adequate number of cells to treat multiple joints versus only being able to treat one joint. For patients who want two joints treated at once you will either have enough cells to treat one joint only and the other joint can be treated with our super concentrated platelet mix only; enough cells to treat one joint adequately and maybe a partial dose to the second joint; or enough cells to treat two joints adequately. Based on our data the chances of an average patient obtaining enough cells to treat 2 joints adequately is between 20% and 40%.

After the procedure you may eat and drink as tolerated. Please refer to the POST-PROCEDURE INSTRUCTIONS for activity after your procedures.

Pre-Procedure Recommendations to Optimize Results

Nutrition

Eat low glycemic index foods, close to a Paleo diet. The mainstay of the diet should be plenty of vegetables and fruits. Moderate amounts of nuts, legumes, whole grains, organic grass-fed meats if not vegetarian. Decrease sweets, conventional meat, wheat, processed foods, fried foods, dairy. No artificial sweeteners. Drink mostly water and teas, decrease sugary beverages. Cut down on alcohol. No more than 1 glass of red wine/day if you drink. No more than two 8 oz. cups of coffee/day.

Read **Nutrition 2.0**: Nutrition 2.0 is a concise guide to eating and living healthy, written by Regenexx regenerative medicine doctor, John Pitts. The book gives a basic foundation of information on mostly diet, but also supplements, physical activity, and stress-relief to improve your life.

https://regenexx.com/resources/ebooks/nutrition-2-0/

Alcohol and Marijuana

Alcohol can have profound negative impacts on stem cell function, so this should be avoided for the 6 weeks before and after your procedure. A glass of red wine or white wine with dinner is not a problem, but more than that could pose a risk to the cells. Cannaboids such as marijuana can also promote bone formation over cartilage (not what we want in this case), so should be avoided.

Supplements

Regenexx supplements are available for sale at our clinic.

Regenexx Stem Cell Support Formula: We suggest that you take the Regenexx™ Advanced Stem Cell Support Formula supplement during the course of your treatment (approximately 4 weeks or more before your bone marrow draw and at least 4-6 months post-procedure). There is certainly no harm in taking this supplement for a longer period of time. This is a proprietary blend of vitamins, herbs and supplements developed by the Regenexx™ research team that helps support healthy stem cell function and cartilage production.

Regenexx Turmeric Curcumin Complex: Physicians also recommend Regenexx Curcumin in addition to the Advanced Stem Cell Support Formula to control inflammation while undergoing the procedure as it has been found to be as effective as over the counter NSAIDS for relief of osteoarthritis pain. Patients can take 750-1500 mg or 1-2 capsules 2-3 times per day in conjunction with the Advanced Stem Cell Support Formula.

**** Medication Restriction List ****

Certain medications may interfere with your stem cell procedure. Please inform us of all medications, supplements, and hormones you are taking. This is reviewed to ensure that there are no contraindications and to confirm whether you need to adjust or withhold certain medications for a specified period prior to, during, or after your procedure.

Through our research and experience we have found certain medications that can inhibit cell growth or have a detrimental effect on healing. In an effort to optimize your outcome, please follow the below recommendations.

Stop taking all medications and supplements that can be stopped.

Do not stop any prescribed drug without speaking to a physician.

- Some medications may not be safe to abruptly discontinue, so you must check with your Regenexx doctor, who may have you contact your prescribing physician as well.
- For the medications listed below, we recommend stopping for at least **2-4 weeks** before and **4-6 weeks** after your procedure.
- Medications/products listed have been shown to be particularly problematic either in our clinical experience, or, are suspected to be, based on what is published in the medical research about their impacts on cells or stem cells and must be stopped.
- For all other medications and supplements stop (if able) at least **3-5 days before** any blood or bone marrow draws, and stay off for **2-5 days after** your procedure as an extra layer of precaution.
- If you take the Regenexx Stem Cell Support Supplement, Regenexx Turmeric/Curcumin Complex, or hormone therapy, you can continue taking these.

1. Steroid drugs

- You should discontinue use of these drugs for at least *6 weeks prior* to your procedures Note, this is more than two weeks outlined above.
- <u>This is very important!</u> Oral steroids (such as prednisone, methylprednisolone, etc.), steroid injections (i.e. for knee or joint arthritis or sciatica such as cortisone, dexamethasone, triamcinolone), topical steroid creams and any other forms, such as eye drops, skin creams, etc. must all be discontinued *for at least 6 weeks*.
- Stop inhaled steroids taken for asthma (Advair, Beclomethasone, Budesonide, Flovent, Fluticasone, Mometasone, Nasonex, Pulmicort, QVAR, etc...) for at least **2 weeks before** and **2 weeks after** your procedure.

2. NSAID (Non-steroidal anti-inflammatory) drugs

• <u>This is very important!</u> Anti-inflammatory medications such as: Aleve, Aspirin, Bayer, Cataflam, Cox-2 inhibitors (Celebrex, Voltaren, Feldene, Piroxacam) and Indomethacin, Ibuprofen, Motrin, Naprosyn or Naproxen **must be stopped**. Asthma medications such as Montelukast, Singulair, etc. must also be stopped.

- If you think you will have intolerable pain with stopping these drugs, then please let us know.
- The physician may have other pain medication alternatives that can be prescribed.
- We encourage you to read and utilize the <u>"Anti-inflammatory Alternatives"</u> in the next section.

3. Statin cholesterol lowering drugs

- Including Advicor, Altocor, Atarvostatin, Caduet, Crestor, Lescol, Lipex, Lipitor, Lipostat, Livalo, Mevacor, Pitava, Pravachol, Pravastatin, Rosuvastatin, Selektine, Simvastatin, Torvast, Vytorin, Zocor, etc...
- If you have a history of heart disease, you must get approval from your prescribing cardiologist or internist to temporarily stop these drugs.
- Ask your prescribing doctor about ezetimibe (Zetia), high dose fish oil, red yeast rice, or Niacin as temporary alternatives.

4. ACE inhibitor blood pressure drugs

- Accupril, Altace, Enalapril, Lisinopril, Prinivil, etc...
- If you take these medications, consult with your prescribing doctor about switching to a different blood pressure drug such as a diuretic or calcium channel blocker.

5. Beta Blockers

- Atenolol, Carvedilol, Labetalol, Metoprolol, Nadolol, Propranolol, Sotalol, etc...
- If you take these medications, consult with your prescribing doctor about switching to a different blood pressure drug such as diuretic or calcium channel blocker.

6. Angiotensin receptor blockers

- Losartan, Olmesartan, Telmisartan, Valsartan, etc....
- If you take these medications, consult with your prescribing doctor about switching to a different blood pressure drug such as diuretic or calcium channel blocker.

7. Blood Thinners

- Medications such as Apixaban, Coumadin, Eliquis, Rivaroxaban, Warfarin, Xalralto, etc....
- These medications increase the risk of bleeding from your procedure. Stop these 48 hours prior to the procedure.

8. Testosterone Inhibitors

• Dutasteride, Finasteride, Proscar, Propecia, etc.

9. Proton Pump Inhibitors

- Used to reduce gastric acid (examples Aciphex, Nexium, Prevacid, Prilosec, Protonix)
- The following medications are ok to take as an alternative, but should be discontinued <u>3</u> days before any blood or bone marrow draw: Axid, Famotidine, Pepcid, Ranitidine, Tagamet, Tazac, Zantac.

10. Antibiotics

- You should not take the following antibiotics 2-4 weeks prior to your procedures and should not start these antibiotics until 6-8 weeks after your treatment: Quinolones such as Ciprofloxacin, Enrofloxacin, Levoquin etc... have been associated with tendon ruptures and nerve injury.
- Gentamycin, Vancomycin, Tobramycin, should also be discontinued as described above.
- The following antibiotics are okay: Tetracyclines, including Azithromycin, Doxycycline and Erythromycin. Amoxicillin, Augmentin, Ceftriaxone, Penicillin and are also okay.

11. Osteoporosis medications

Bisphosphonates such as alendronate, Fosamax, zoledronic acid, Reclast, Etidronate,
 Didronel, Risedronate, Atlvia, ibandronate, Boniva, must be stopped at least 4 weeks prior to procedures.

12. Alcohol

 Avoid alcohol or limit to 1 glass of red wine or less per night, or no more than 2 other alcoholic beverages per week.

13. Artificial Sweeteners

- Avoid products with Aspartame, Acesulfame K, NutraSweet, Saccharin, Splenda, Sucralose, Sweet'N Low. These can be found in many diet sodas and other diet or zero calorie beverages.
- Products with Stevia or Sugar alcohols such as Erythritol, Sorbitol, Xylitol, etc. are ok.

14. Others:

- Avandia (rosiglitazone anti-diabetic medication)
 Pepto-Bismol (contains salicylates)
- Interferon immune suppressant
- Chemotherapy drugs
- Erythropoetin (EPO)
- Human Chorionic Gonadotropin (HCG)
- Marijuana
- Blood donation: refrain from donating blood for 2 months prior to BMA and for 2 months after last injection.
- If you have titanium implants where wear and tear on the implant is suspected, please discuss with the doctor!

Exceptions for prescription medications:

- You may continue to take thyroid medication and hormone therapy, but should <u>avoid</u> abrupt changes within 1-2 weeks before or after your procedures.
- This includes Male or Female Hormone replacement, including thyroid hormones, estrogen, progesterone, testosterone, and growth hormone like Norditropin.
- This does not include Human Chorionic Gonadotropin (HCG) which should be stopped.

Anti-inflammatory Medication Alternatives

As stated earlier, we generally do not recommend anti-inflammatory medications (NSAIDs): Aleve, Aspirin, Bayer, Cataflam, Cox-2 inhibitors (Celebrex, Voltaren, Feldene, Piroxacam) and Indomethacin, Ibuprofen, Motrin, Naprosyn or Naproxen. We also do not recommend steroids or cortisone.

All of these drugs have many side effects with long term use, including GI upset, kidney problems, increased cardiac risks and they block the body's natural ability to heal. Steroids have an even longer list of potential complications.

As detailed earlier, if you are undergoing a Regenexx procedure you should stop the above for 2-4 weeks prior and 6-8 weeks post procedure. Continue reading for alternatives that do not impair your healing mechanisms.

- Acetaminophen (Tylenol) Take 500mg (1-2 tabs) every 6 hours as needed for pain. No more than 6 tabs or 3000mg in a day. If you have a prescription for Tramadol, take an extra strength Tylenol at the same time to potentiate the effects of either drug alone.
- *Curcumin/Turmeric*: Take 1-2 capsules per day of Regenexx Turmeric Curcumin Complex, which is an all-natural Turmeric extract with BioPerine (black pepper). 95% standardized Curcuminoids extract of 750 mg Turmeric, vegetable capsule. Includes BioPerine 5 mg to increase Turmeric absorption by 2000%. Can be taken with the Regenexx Stem Cell Support Formula.
- *Omega 3s*: Have anti-inflammatory properties and can help with arthritis pain at high doses. Take 3-4grams of a mix of EPA and DHA per day, divided 2-3 time per day. Don't take if it has a rancid odor. Best if taken with mixed isomers of vitamin E or a mixed antioxidant supplement to decrease risk of oxidation.

The best brands are:

- Nature's Bounty: Triple Strength Red Krill Oil
- Dual Spectrum Omega 3s
- Meijer Naturals: Omega 3 high EPA Fish Oil or
- Nature Made: Ultra Omega 3 Fish Oil
- Burpless Fish Oil or
- Finest Nutrition: Cod Liver Oil
- Double Strength Fish Oil or
- Simply Right: Fish Oil or VIt D-3
- Wild Alaskan Salmon Oil
- Sundown Naturals; Plant Based Omega 3
- Pure Alaska Omega 3: 100% Natural Omega Natural Omega Wild Alaskan Salmon Oil;
 and Purelife Naturals
- *Glucosamine*: Building block for cartilage. Helps with mild to moderate arthritis. Take combined with chondroitin +/-MSM. Take 1500mg daily divided in 2-3 doses in a day as it may cause stomach upset if taken all at once. This is in the Regenexx Advanced Stem Cell Support Formula.

- **Arnica**: Homeopathic medication can be taken orally or topically. It helps with acute traumas, bruises, soreness, and arthritis. Take 2x daily for 1 week. If no improvement after 1 week, stop.
- *Bromelain*: A pineapple extract and a natural anti-inflammatory. As a tablet take 500mg 2-3 times daily. In capsule formulations: 2,000MCU per 1000mg or 1,200 GDU per 1000mg.
- *Capsaicin Cream*: Made from hot peppers and decreases substance P which leads to decreased pain. Helps with pain in superficial joints and muscles. Apply a moderate amount of 0.025% or 0.075% cream up to 3 times daily. We recommend using gloves or washing hands very thoroughly after use because the cream can burn. Do not touch eyes, nose, mouth, or genitals after use, as it can cause irritation and burning.
- **Vitamin D**: hormone made from exposing your skin to sunlight. Most People are chronically deficient which can contribute to chronic pain. We recommend 2-5,000 IU daily. This is in our Regenexx Advanced Stem Cell Support Formula as well.
- *Ginger*: Has been shown to help treat migraines, and menstrual cramps. Take ¼ teaspoon of ground ginger 3x daily at the onset of migraine or cramps.
- *Cherries*: Can reduce incidence of gout flares. Eat ½ cup of fresh or frozen cherries daily or table spoon of cherry juice concentrate 2x daily.

Allow 1-4 weeks to notice a difference in pain for Bromelain, fish oil, Glucosamine and Turmeric. If you take any prescription medications or have any medical conditions, discuss with your physician before taking any of the above products. **AND** If you take blood thinners such as Plavix or Coumadin ensure that you receive authorization from your physician before commencing supplementation with Turmeric or Fish Oil because it may increase the risk of bleeding. Discontinue fish oil at least 2 weeks before any surgeries and at least 1 week before any other procedures/injections. These may be resumed immediately after a Regenexx procedure.

Post Procedure Information and Instructions

Immediately After Your Cell Procedure

Immediately after the procedure, the goal is to allow the stem cells to attach to the targeted area so they can begin the healing process. You may be asked to minimize movement for the first 10-20 minutes after the procedure to allow this to happen.

To allow the bone marrow harvest site areas to heal and reduce the risk of infection, do not take a bath for three days, but a shower 12 hours after the procedure is fine.

The stem cell injection includes producing a micro injury in the joint. As a result, expect the joint to be sore. This can last anywhere from 1 to 3 days. This can be anything from minimally sore to very sore. Your physician may prescribe stronger pain medicines that are safe with the procedure. **Continue to avoid anti- inflammatories**.

Post Procedural General Recommendations:

- Far Infrared heat beginning two days post stem cell injection. Use 2-3 times daily for 30 min max for at least 2 weeks then as needed afterwards. Do not exceed 30 min per session or more than 3x per day. Near infrared or heating pad ok. No ice for 6 weeks.
- **Avoid NSAIDs** (anti-inflammatories) ie: Motrin, Ibuprofen, Aleve, Naproxen, Diclofenac, Voltaren, Meloxicam, Etodolac, Celebrex, Indocin, Indomethacin, Aspirins, steroids such as cortisone injections for at least 6 weeks after the procedure.
- Continue to take the Regenexx™ Advanced Stem Cell Support supplement for at least 6 months post procedure.
- We highly recommend using our physical therapist or another good PT to work on postural restoration and biomechanical corrections.

Activity

These guidelines are a general recommendation on how you should progress through rehabilitation after a Regenexx™ procedure. This is not intended to replace your physician's specific recommendations for you as every patient and situation is different.

Ideally, you should work through rehab with our physical therapist or a good physical therapist convenient for you. In general, we recommend that your progression through the rehabilitation phases and return to activity should be based on your symptoms.

The first 6 weeks we want you to be conservative. For most procedures there is very little down time (1-3 days). Then we want you to balance some activity without overdoing

it. Pain during or after activity is a good indicator you are doing too much. You should start off with light or easy activity then slowly progress to more strenuous activity as tolerated. Start low and go slow. If an exercise or activity causes more than minimal pain 2/10 during or afterwards then you need to back down the duration or intensity of that activity. If you are able to do light activity with no pain then you should progress to slightly harder activity or increase the duration of your lighter activity.

Exercising and using other body areas that were not treated is fine and you have no restrictions on this after the 3rd day as long as it does not affect your treated area(s). Note that every person and situation is different, so some people will progress faster or slower than others. The speed of recovery has no bearing on overall success. Full healing can take up to 3-6 months for platelet procedures and 6-12 months for stem cell procedures.

Tissue healing after your procedure progresses through 3 phases: 1) Inflammation, 2) Proliferation and 3) Remodeling. All patients will progress through these same phases of healing in similar time points, however, pain, symptom improvement, and return to function and desired activities will vary greatly between patients. The variability is due to pathology, procedures performed, age, health, genetics, previous activity level, and goals. Here is a general guideline of what to expect at each phase:

- 1. **Inflammation (Days 1 to 7):** During this period other healing cells are being recruited to the area to begin the healing process. During this stage you may have swelling, pain and redness. This initial inflammation is temporary and good for healing so anti-inflammatory medications should be avoided. Supplements with anti-inflammatory properties will have no negative effect. The first 2-3 days is the "down time" when you mostly rest and avoid exercise.
 - For tendon, muscle, and ligament treatments you want to take the joint through normal range of motion but you don't have to worry about stretching. Move the tissue gently but do not stress it out.
 - For joints, you want to protect them and limit weight bearing if a lower extremity joint has been treated. This may be easy to do; as you may have a natural limp or "antalgic" gait (your body does this to reduce pressure on the area to allow healing). If you don't have this, then simply, naturally taking a bit of weight off this area as you walk is a good idea the first 2 days. If an upper extremity joint was treated, limit the stress on this joint. Avoid all contact sports as well as jogging, running, or sports that involve impact on that joint. Wear all recommended braces or boots.
- 2. **Proliferation (Day 4 to week 6):** During this phase new tissue, collagen and the building blocks for the injured tissue are being laid down. The first tissue to form during this stage (first 2 weeks) is delicate and then it progressively gets stronger. During this time, pain may decrease but since the first tissue formed is weak, still be cautious and activity progression should be graded and gradual. Generally, any exercise or activity

that causes greater than 2/10 pain should be avoided as this is a sign the new tissue is being over stressed. You want to continue to move the tissue through its normal range of motion. For lower extremity treatments you can start to walk normally -- if you were set up with a brace or a boot for the procedure, use this during activity. Avoid all contact sports as well as jogging, running, or sports that involve impact on that joint. Bike riding is fine as are stationary bikes, elliptical machines, pool exercises, and swimming. Yoga and Pilates are fine with modifications if needed. For upper extremity treatments, start range of motion exercises and only light activities that do not stress the affected area much. During this phase you should begin structured therapy to work on improving posture, joint alignment, and biomechanics. This is important to treat the biomechanical factors that may have contributed to your problem(s). For the body areas not treated you can exercise them without restriction.

- a. For tendons, muscles, and ligaments:
 - i. Weeks 2-4: You can begin isometric then isotonic exercises for the affect area.
 - ii. Weeks 4-6 progress to concentric exercises for the treated area.
- b. For joints:
 - i. Weeks 2-4: You can begin isometric then isotonic, the concentric strength training exercises for the affect area. Keep load/weight to a minimal.
 - ii. Weeks 4-6: Begin concentric exercises and slowly progress load/weight on the joint.
- 3. Remodeling stage (Week 2 to 3-6 months): During this phase the tissue is constantly improving to become stronger, functional and closer to normal. As you progress through the remodeling process you will gradually feel better and better week to week. There may be some periods where you seem as if you regressed temporarily but that is likely due to either over stress or temporary weakness in the tissue as it breaks itself down in order to rebuild more improved. Continue to work on structured therapy. After week 6, start slowly integrating back all desired activities as tolerated, adding back approximately 10-20% per week. For example, if you were used to running 10 miles a week, you would start at 1-2 miles a week, then the next week add back another 1-2 miles, and so on. Again, let pain be your guide.

Therapeutic Modality Guidelines:

- Ok at any point: TENS units, alpha stim, light therapy, paraffin, massage, low velocity/gentle manipulation, IMS/dry needling, acupuncture.
- Wait until you are at phase 3 of rehab or at least 2 weeks before doing: joint mobilization, chiropractic, muscle activation therapy, active release therapy
- No ultrasound therapy within 2 weeks of the procedure. No ionto- or phonophoresis for 6 weeks and never with NSAIDs or steroids.
- No Accelerated Recovery Performance (ARP) therapy or Extracorporeal Shock Wave Therapy (ECSWT) within 3 months of the procedure.

Infrared Heat Therapy – Blood Flow

Indications for Use:

The thermal effect of the deep-penetrating infrared upon tissues may provide temporary relief of minor aches and pains in muscles, joints, tendons, and tissues. This device helps provide for a temporary improved range and freedom of motion due to muscle relaxation and temporary minor pain relief. It also aids in the relaxation of muscles and provides a temporary increase in local blood circulation, helping to keep your cells viable after they've been injected.

Treatment:

- Begin using two days post stem cell injection
- Begin treatment on the Medium setting
- Use up to 30 minutes twice a day for 6-12 weeks. Please be cautious not to exceed 30 minute intervals! Your pad comes equipped with a built-in 30-minute shut-off timer. Do not use more than 3 times daily.

Bracing

Your doctor may recommend a brace to be worn usually for a 6 week time period when rehabilitating the joint. You will receive further information on the bracing if this is part of your treatment plan identified by your physician. The brace is typically covered by insurance and Medicare.

Thank you for trusting us with your care!