

**CONSENT DOCUMENT:
Stem Cell Therapy in Osteoarthritis**

Please read the following information carefully and make note of any questions you might have.

Background information:

Platelet-rich plasma is a fraction of your blood which contains a high concentration of platelets. These are known to contain large quantities of growth factors which attract stem cells and stimulate the healing of damaged tissues. Stem cells are in people of all ages. They are the primitive repair cells of the body, and can regenerate many tissues depending on the growth factors to which they are exposed and the location they are placed. Stem cells can easily be harvested from fat and from bone marrow. A sample of each of these can be taken and prepared for injection into an arthritic joint to assist in regenerating healthy tissue. When stem cells are harvested from your own body and prepared for re-injection, they are called “autologous” stem cells, and there is no risk of rejection and no increased risk of cancer.

Clinical work over the last several years has established the safety and usefulness of platelet rich plasma (PRP) for tissue repair and healing in joints with mild to moderate osteoarthritis, resulting in reduced pain and improved function for many who have had this procedure. The combined use of PRP with fat graft and bone marrow has proven to be superior to PRP alone, especially for more advanced arthritis.

Procedures:

Platelet-Rich Plasma will be produced by drawing 60 mL (two ounces) of your own blood and placing it in a machine called a centrifuge. This machine spins the blood at a very high speed causing platelets, growth factors, and white blood cells to be separated from the rest of the blood products. It is this concentration of platelets and growth factors which are then injected into an arthritic joint. Once introduced into the injured site, the platelets then release more growth factors and signaling proteins attracting more stem cells to the area, and direct the tissue repair and healing process. Because this is a gradual repair process, it takes weeks to months to happen.

Additional stem cells will be harvested from fat and bone marrow. To obtain a fat sample, 120 mL of local anesthetic is injected into the flank/buttock region and a sample of approximately 30 mL of fat is then aspirated. It is then centrifuged to concentrate the adipose stem cells.

To obtain a bone marrow sample, local anesthetic is injected over the pelvic bone (posterior iliac crest) in the lower back region and a sample of approximately 10 mL of bone marrow is aspirated. Both additional procedures involve very little discomfort due to the anesthetic. The final products will then be injected in sequence into the arthritic joint. Enough material is harvested to allow injection into two major joints at the same appointment.

Approximately 4 weeks after your initial injection, you will return for a follow-up visit. Another injection of PRP to the same joint will be required, followed by a final injection of PRP another 4 weeks later. These platelet injections allow the stem cells to continue growing and multiplying into cartilage tissue. Stem cells continue to remain active for up to 12 weeks. The repair of the area usually takes 6-9 months but improvement is often apparent within 2-3 months. These PRP follow-up injections may include Human Growth Hormone which provides additional signals for tissue repair and healing.

If you are taking any anti-inflammatory medicine such as Motrin/Advil (ibuprofen), Aleve (naproxen), Celebrex (celecoxib), or Voltaren (diclofenac) please discontinue 2 days prior to treatment and for 7 days after. If you are taking 81mg ASA you may continue with this. If you are on Warfarin (Coumadin) or other blood thinners, be sure to discuss this with Dr. Pagdin before booking your procedure. You may take your other prescription medicine as you normally would. Make sure to drink plenty of water (8-10 glasses) in the 24 hours prior to your treatment. No fasting is required.

After treatment, you will be numb in the areas of the procedures for approximately two hours after the treatment. Due to numbness, please refrain from any strenuous activity. Once the anesthesia wears off, you may resume activities as tolerated. Physical activity will in no way hinder the treatment and may actually benefit the recovery phase. The arthritic joint that was injected will likely experience some pain and soreness for 2-7 days, and aching can persist for up to 14 days. Narcotic pain medicine will usually be prescribed, and Tylenol will also be helpful. You may not resume anti-inflammatory medicine until 7 days after treatment. You may not resume anti-inflammatory medicine until 7 days after treatment. In the first one to two weeks, focus on gentle exercise and range of motion (walking, stationary bike). By week 3-4 you may begin strengthening in the gym and increasing your activities. You may wish to consider having the help of a physiotherapist for your rehab.

DR. G. PAGDIN INC.

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What are the possible side effects?

The risks of these procedures include but are not limited to pain (likely, over 50%), fainting or lightheadedness (less common, 5-10%), bleeding and bruising (rare, less than 1%), infection (very rare, less than 1/50,000), allergic reaction to lidocaine (extremely rare), and possible loss of life or limb (exceedingly rare). Because heparin is used to rinse the instruments required for harvesting bone marrow, there is the very rare possibility of heparin-induced thrombocytopenia which can lead to a blood clotting crisis. Although these possibilities exist, the chance of them happening is generally far less than with a standard surgical operation. It is also possible that the procedure you undergo fails to provide you any improvement. We cannot predict specific benefits from having these procedures.

We recommend a number of nutritional supplements to help support your stem cells including:

- Blueberries
- Green tea
- Dark chocolate (80%)
- Vit D3 6,000-10,000 IU daily
- Immunocal (order through Pagdin Health).

Immunocal is a specially formulated protein derived from whey, containing the building blocks for glutathione which is our body's most powerful antioxidant. This helps reverse oxidative damage, builds and repairs body tissues, and maintains a strong immune system.

For more information on Immunocal, see www.immunotec.com.

For any questions, problems, or concerns regarding your participation, please call Dr. Pagdin's clinic at 250-717-3200, or email info@drgrantpagdin.com.

In case of an emergency after hours please call Dr. Pagdin at 250-808-0516 or go to the nearest hospital emergency department.



Consent

Stem Cell Therapy in Osteoarthritis

I hereby consent to participate in this stem cell therapy which I understand is experimental. I confirm that I have read the information contained in this consent document and have had many opportunities to ask questions, and I have received satisfactory answers. I understand that blood will be drawn from my arm, and then centrifuged to obtain the platelet-rich plasma (PRP) fraction, which will then be injected into the arthritic joint to help with tissue regeneration. In addition, I will have a sample of fat and/or bone marrow extracted which will also be injected into the same arthritic joint. The stem cells used are my own cells.

I have been given no guarantees as to the success of this therapy. I recognize that as with any procedure, there are inherent risks with performing the procedures. These risks include but are not limited to infection, bleeding and bruising, procedure failure, allergic reaction, fainting, heparin-induced thrombocytopenia, and possible loss of life or limb.

I also acknowledge that I am aware there are other surgical and non-surgical options for my treatment, but I have chosen to have stem cell therapy.

I understand that my participation is voluntary and that I am free to withdraw at any time and without giving any reason.

Participant Name (PRINT) Date Signature

Provider Name (PRINT) Date Signature

OPTIONAL: I would like my primary care/specialist physician(s) to be notified of my participation

Name of physician(s) _____