

The Procedure. First I would like to get our terms correct.

Stem Cell Therapy does NOT involve chemotherapy. The current or recent protocol for treating scleroderma so highly touted in the US as a “major” advance has involved first wiping out the immune system with chemicals or radiation, and then following with stem cells. This is **Chemotherapy/Stem Cell Therapy**, or Radiation therapy, not Stem Cell Therapy. Sometimes, though rarely, this treatment is correctly referred to as “**myeloablative**” therapy. The FDA has sent a warning letter to Dr. Burt at the Northwestern University Feinberg School of Medicine that he is under reporting patient deaths from the treatment and must disclose this better. This myeloablative treatment is very rough on a patient.

True **Stem Cell Therapy** has no side effects and never makes the patient ill or feel bad. And you never have to worry “if am a candidate”. Anyone can have stem cell therapy at any time and at any point in their illness.

What are the Stem Cell Therapy Protocols That You Can Get Right Now

The Primary Protocols

Please keep these rough estimates in mind, gleaned from many papers:

Number of Stem Cells in Peripheral Blood: 14,000/ml. Usually 25 ml is collected (some collect 50 ml), which gives you a range of total stem cells of 350,000-700,000, a very small number considering most practitioners agree that a minimum of 1-2 million cells are needed for therapeutic effect.

Number of Stem Cells in Bone Marrow aspirate. Typically the consensus is that only the first ml of bone marrow is satisfactory, and that the yields have a wide range of 3 million -30 million stem cells depending on patient and success of procedure. This number is considered sufficient for a therapeutic effect. **However, only a portion of these stem cells are the very important mesenchymal stem cells.** Some clinics will culture the bone marrow cells in order to multiply the numbers of mesenchymal stem cells (MSC's).

Number of Stem Cells in Abdominal Lipo-aspirate: In my own study, we typically used 15-30 million stem cells for IV transfer and these are primarily the preferred mesenchymal stem cells. This compares favorably with the Regenerative Stem Cell Institute (Chicago) who report they typically harvest 10-40 million cells from 60 ml adipose tissue: <https://stemcelldr.com/the-svf-procedure/>

Therefore, fatty tissue lyposate is the best and richest source of mesenchymal stem cells, and the preferred source for stem cell therapy.

There are only 3 stem cell treatment procedures in regular use worldwide, and including a small number of clinics in the US, and most are completed in 30-90 minutes in a Physician's office or clinic outpatient setting

(A) Preparation of **Platelet Rich Plasma (PRP)**. 25-50 ml of patient's blood is withdrawn, centrifugations are done, and the PRP is collected for injection. This fraction does not contain any stem cells, but contains a lot of growth factors and stimulatory factors. Many times, this fraction is combined with stem cells to supercharge them. PRP is used primarily for pain management in orthopedic conditions and, lacking any stem cells is not applicable for IV stem cell therapy.

(B) Preparation of **Stromal Vascular Fraction (SVF)** from mini-lyposuction of abdominal belly fat. This stem cell fraction, full of mesenchymal stem cells **and endothelial cells** which boost stem cell activity, is the main stem cell fraction being used worldwide. The lyposate is processed which takes an hour or so, then the cells are re-injected IV into the patient. This procedure is so simple yet powerful, it is being used now in all sorts of debilitating diseases, including all the auto-immune diseases including scleroderma.

SVF is referred to as “Liquid Gold”. This “soup” of material isolated from fatty tissue includes many cytokines and growth factors useful in therapy. We know that endothelial cells have been shown to work in harmony with stem cells to help grow them in large numbers. Endothelial cells are included. We know that cytokines and unknown growth factors help in therapy, which, in other types of treatment centers, is why a soup of fetal tissue is so effective in therapy. Cytokines and growth factors are included. Many other beneficial cells are also included:

Vascular Fraction Cellular Composition:

- Adult autologous stem cells (Mesenchymal)
- Endothelial Cells
- Fibroblasts
- Growth Factors
- Pericytes Preadipocytes cells
- Smooth muscle cells
- Blood Cells from the capillaries supply including:
 - B&T cells
 - Erythrocytes
 - Hematopoietic stem cells
 - Endothelial progenitor cells
 - Macrophages
 - Mast Cells
 - Monocytes
 - Natural killer (NK) cells

As you can see, you get way more goodies with the SVF than you would ever receive from stem cells purchased from a stem cell bank that are not your own.

(C) Preparation of stem cells from **Bone Marrow**. This is another source for stem cells and is used depending on patient status. Sometimes these cells are taken from the patient and multiplied by tissue culture to boost the number of cells to be re-injected back into the patient. The procedure is well worked out, there is likely some discomfort, and again, takes about an hour, unless multiplication of the cells is done, which can take 4-6 weeks. Then patient must return for injection.

All the best places are using the SVF fraction collected from abdominal belly fat.

In order to be sure you have a complete picture of what is going on, there are a couple of other things being done ONLY in the US, because no one outside the US would consider these ideas, mostly because of the feeling that fresh is best, and that banked cells are bare of other essentials and will not yield as good a therapeutic result.

So you may come across some clinics doing stem cell therapy using stem cells purchased from stem cell “banks”. These are not your own cells, they are bare cells with no associated growth factors, endothelial cells, and activator molecules. Many times these are cells cultured from

placental tissue that are cryopreserved, that is frozen then thawed before use. There is no evidence in any paper that I know of that banked stem cells have any therapeutic effect.

The one exception to the preferred use of SVF is the **Panama Stem Cell Clinic** of Neil Riordan: <https://www.cellmedicine.com/stem-cell-therapy-for-autoimmune-diseases/>

Dr. Riordan is a master clinician who has published recent papers on the cure for autism using stem cells obtained from placental tissue of newborns, which tissue, the afterbirth, is often discarded. His center is among the finest treatment centers in the world. However, his cost for a single treatment is about \$23,000.

Specific treatments and where. Where can you go, and what is the cost.

(1) The Stem Cell Institute of Panama [<https://www.cellmedicine.com/>], founded and operated by Neil Riordan maybe 10 years ago, is the finest treatment center in the world and is treating scleroderma. They specialize in treating patients with stem cells harvested from placental tissue of newborns, which is generally discarded, and so he has a ready source. Dr. Riordan was first to observe that umbilical cord stem cells are immune-privileged, and could be transplanted to any patient with no immune consequences. He also found these stem cells to be far more energetic in repair functions than the sometimes less active stem cells found in aged patients. Knowing this was going to be an avenue for curing debilitating auto-immune diseases. and recognizing that the US was not favoring any non-drug therapy for anything, he promptly moved overseas. Dr. Riordan, has even discovered a dietary supplement derived from lactobacillus that increases circulating stem cells by 2x.

Because the source of stem cells is not from the patient, but rather harvested from placental tissue (or cell cultured placental tissue), the cost of treatment is higher. The cost of a treatment is about \$23,000 which includes (for auto-immune diseases):

Transplantation of stem cells given intravenously (IV) over the course of a few days.

Treatment duration: 4 days and 5 nights

Physical examination and blood testing

3 IV injections of expanded allogeneic (low-passage) mesenchymal stem cells

Stem-kine supplement for 1 month (only after medical evaluation in Panama)

*Includes Hilton hotel room with breakfast, WIFI, transportation from and to the airport with VIP airport gate service and expedited customs clearance upon arrival.

If money were no object, that is a good place to go.

As Dr. Neil Riordan observed 12 years ago **when discussing stem cell therapy of scleroderma**: “Mesenchymal stem cells do not need myeloablation for efficacy”. **He discusses the Northwestern myeloblative treatments here:**

“Therefore, certainly with autologous (in which the donor and recipient are the same person) adult stem cell therapy, there is no risk of immune rejection **so there is no need to destroy the immune system with chemotherapy**; but even with many types of allogeneic (in which the donor and recipient are not the same person) adult stem cell therapy, such as with "immune privileged" "universal donor" stem cells, there is also no need to destroy the immune system with chemotherapy.

Nevertheless, for clinical trials such as those conducted at Northwestern University, the autologous adult stem cell therapies offer tangible improvement – **at least for those patients who survive the life-threatening destruction of their immune systems from the chemotherapy.** One can only conclude, therefore, as has already been demonstrated by other doctors at other clinics [outside the US], that **patients would exhibit even greater and faster improvement if they did not have to recover from the deliberate destruction of their immune systems prior to receiving the stem cell therapy.** Additionally, other clinical evidence indicates that even greater patient improvement would be seen if the stem cell therapy would utilize the "superior proliferative potential" of the adult stem cells that are found in umbilical cord blood" [Found at: <https://www.cellmedicine.com/scleroderma-northwestern-trial/>] and paper also attached.

(2) US Stem Cell in Florida. [<http://us-stemcell.com/>] I just emailed my friend and colleague in Florida, **Kristin Comella**, who operates one of the best stem cell clinics in the US (was lead author of the safety paper I co-authored). She said they have been treating scleroderma patients with stem cell therapy and have had success, and said, Yes, they could help.

They stated: **"I left a message for you, but also wanted to respond by email. I would be happy to discuss how we treat our Scleroderma patients, and the expectations for healing. We have had tremendous results with patients suffering from this condition."**

After I sent along Julie's brief 1 paragraph summary she recently sent to Jeff (who is a bit mad at me that I breached medical confidentiality), they reported: **"We actually have treated ILD, with benefit. Again, the key is going to be in the repeat dosing. Anything administered IV passes through the heart and lungs first, so this is often where we see the first benefits."**

Their website mentions treatment of scleroderma: <https://usstemcellclinic.com/regenerative-medicine-offers-new-solutions-scleroderma/>

The costs they quoted:

The below costs are for IV (systemic treatment).

Extraction of stem cells from BM and culture expansion - \$5000 (this would be the cost the 1st day)
IV administration (6-8 weeks later) - \$500
Dose of MSC's from the bank - \$500
Annual banking fee after 1st year - \$250

So you are talking about \$6250 to get started. I am happy to meet you there if you should want to try. This treatment is under supervision of Kristin Comella. She has individually entered more clinical trial registrations concerning adult stem cell therapy than any other single researcher and even more than nearly any other institution. Her background and professional accolades are summarized here: <https://panamacollegeofcellscience.org/2019/01/23/kristin-comella-phd-leading-the-way-to-adult-stem-cell-therapy/>

Another add-on they offered for an additional \$2500 (usually \$5000) was to add “exosomes” from placental tissue. This is a very good add-on of cytokines and other activating and growth factors, and I recommend it, especially since they are using bone marrow and not SVF.

While nothing is ever guaranteed, I see no reason why you would not see some improvement. The first injections would just be beginning to repair damaged heart and lung tissue. You would need to get to a second and maybe third shot to get a handle on the disease due to your present condition; but it is a step by step. Some patient's only need one shot, but there is a lot of damage that has to be repaired first before the stem cells can begin modulating your immunity in a positive way, in my opinion.

The only thing is that I am a bit disappointed her clinic is not using SVF from belly fat at this time, even though the SVF fraction was used for patients in our joint paper. And so, this would not be my first choice for you, even though they are my first choice as clinicians.

(3) Dr. Melvin Propis at the South Florida Stem Cell Center

<https://www.southfloridastemcellcenter.com/>

Dr. Propis has been doing very fine work is the Head of the Academy for Regenerative Medicine, a physician's group. He uses the procedure I already summarized for you, harvesting SVF from belly fat: <https://www.southfloridastemcellcenter.com/faq>

We actually teach and feature Dr. Propis' work at the Panama College of Cell Science. I had a nice conversation with him on August 15, he stated that the SVF is useful for all autoimmune diseases including scleroderma, and he agreed that the SVF fraction from adipose tissue is the best mix to use. He further stated that in his opinion, banked stem cells that one can buy to use have never been shown to have any effect and that one really needs to receive all the other growth factors and activators that are present in the SVF including specifically the endothelial cells.

His cost is \$6500 (I am pretty sure I heard him right) and he invited me to have lunch with him on the day you come in for treatment. If/when interested, they will send out some medical forms to fill, not sure if you have to get blood work or they do it there. He operates at an Outpatient Surgery Clinic and his price includes the facility cost. Only one day is needed.

Dr. Propis would be my first choice for you, based on cost and based on preferred procedure.

(4) Okyanos Center for Regenerative Medicine in the Bahamas: <https://okyanos.com/> offers the cadillac of stem cell therapy in an excellently equipped center. They harvest and use the preferred SVF fraction: <https://okyanos.com/therapy/enzyme-derived-svf/> and specifically note the treatment of scleroderma on their website: <https://okyanos.com/treating-conditions/autoimmune-diseases/>

Unfortunately, their cost is \$28,000. Great treatment, but cost prohibitive.

(5) Stem Cell Therapy Of Las Vegas & Medical Spa: <http://stemlv.com/> Dr. Lambert R.

Abeyatunge MD, a surgeon with 50 years experience, last 5 years practice limited to stem cell therapy. I spoke with Dr. Abey personally and found him to be a nice guy, very enthusiastic about the wonders of stem cells who stated that the therapy should work for scleroderma. Although his website lists SVF and bone marrow sources, he stated to me that he likes to use 30 million stem cells derived from placental tissue, cultured, and purchased from a stem cell bank. Along with this, he adds Whartons Jelly (another cryopreserved product from newborn placentas) as well as exosomes also purchased. He then resuspends the entire mixture in PRP (see above) for injection. It is an interesting mixture. He stated that normally improvement appears by 3 months and felt that most patients see improvement for a year, meaning, he did not really see the need for continued treatments.

His cost is \$8500. I think he tries very hard to do a good job and does present an interesting mixture, that I do not see anywhere else so far, and had not previously come across **Compared to other treatment centers, I would be more comfortable for myself with either Dr. Comella's or Dr. Propis' clinics in Florida, as these are very experienced practitioners who have been in this field for many years.**

(6) Regenerative Medicine Institute of Nevada. <https://www.rminlasvegas.com/> Another clinic you can browse the website. From my brief discussion with their office, they appear to be also using banked stem cells along with peptides. The staff quoted \$3500 for exosomes, but could not quote for stem cells, I have a scheduled phone conference coming up. However, like I said before, the two Florida clinics are much better I believe.

(7) The Regenerative Stem Cell Institute of Chicago. <https://stemcelldr.com/> A very informative website that you maybe can learn from. I did not go any further into pricing.

Who do I Recommend? Tough call for me as both these centers are excellent. I recommend #1 Dr. Propis in Florida; #2 Dr. Comella in Florida. If you could afford it and money were no object (\$23,000), I would have to also consider Dr. Riordan's treatment center in Panama, a very highly regarded center.

I enclose a few research papers that may or may not be helpful, mostly just to show that scleroderma has been subjected to stem cell therapy before, it is not a new idea, and while I did not list them, the disease is treated in most countries using stem cell therapies.

Italian paper 2013: This paper presents the treatment of systemic scleroderma, however, treatment was limited to skin. They report: "All patients showed arrest of local disease progression (100%)".

They also note the beneficial immune modulatory effects of stem cell treatment (which is important in auto-immune diseases):

"Furthermore, it has been recently demonstrated that ASCs show angiogenic properties and **could also exert some immunomodulatory properties**, including a suppressive response on collagen-reactive T-cells and the capacity to restore immune tolerance by inhibiting the inflammatory response in vivo."

Italian paper 2017: Treating scleroderma, believe that PRP should be combined with SVF because patient's inherent growth factors and cytokines may be compromised.

Riordan seminal paper 2007: (from the Panama Stem Cell Center). The paper discusses the immune modulatory function of adult stem cell therapy: "**An important aspect of this cell population is their anti-inflammatory and immunomodulator activity.** For example, they constitutively secrete immune inhibitory cytokines such as IL-10 and TGF- β while maintaining ability to present antigens to T cells, thus suggesting they may act as a tolerogenic antigen presenting cells."
