

Information for patients

Erectile Dysfunction Treatment with Stem Cells from your own **Bone Marrow** / **Adipose Tissue**





Erectile Dysfunction

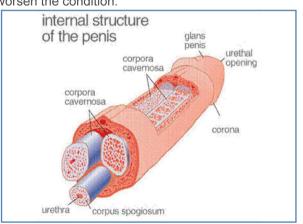
Erectile Dysfunction is a commonly occurring sexual dysfunction above the age 40; however the lower age limit for this disability has been significantly descended to 30 years as per the latest poll.

It may be described as the disability associated with difficulty in lengthening the penile erection to have an effective round of copulation. Up to 30% of the men are affected by this particular inability may be because of the lifestyle changes, alcoholism, smoking, etc. ED is shown to have compelling impact on the self esteem and intimate relationships. Additionally, as backed by the new research it is considered as a sentinel marker for many fatal diseases such as cardiovascular disorders. Even though you may feel awkward to speak to your family physicians, you have to undergo clinical evaluation for the symptoms.

To epitomize the mechanism underlying ED; we need to understand that erection is the phase wherein the blood is suffused in the arteries of the two chambers of the penis known as *corpora cavernosa*. The entire process is networked by the brain through passing signals to penile nerves; the process is also regulated by secondary sexual hormones such as testosterone. But with the severe blockage in the process of signal transmission or decreased production of testosterone, the disability is hit in the person.

What Causes Erectile Dysfunction?

Many causes are listed which are responsible for developing ED, such as loss of testosterone, surgical damage to penile nerves, medication, other chronic illness etc; the most trivial of all may be vasculopathy or clogging of the delicate penile blood vessels. Apart from these; heart diseases, diabetes, obesity, neurological disorders, tobacco consumption, alcoholism, surgeries and treatments such as enlarged prostate can also give rise to ED. Since the brain is the key player in setting off a series of signalling reaction such as feeling of sexual excitements; many factors like stress, anxiety, depression can interfere with the desire and may worsen the condition.



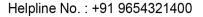
What is the prognosis?

Since vascular disease is often the leading cause of ED, the risk factors associated with heart attack and stroke are also responsible for ED such as obesity, smoking, alcoholism, stress. They are the prime agents in narrowing the artery and thus obstructing the blood flow. Prevention of the diseased condition requires lifelong attention and control of high blood pressure, diabetes and cholesterol. Other therapeutic measure such as cessation of smoking, weight control, regular exercise also has to be incorporated into daily lifestyle.

Is there any treatment?

The mainstay, customary treatment of ED employs oral medications such as Viagra, Levitra or Cialis and/or surgical alternatives such as implantation of hydraulic penile prostheses. The mentioned treatments cannot alter the pathology of the disease as such and are also co-associated with many psychological side effects. Recently developed and popularized stem cell treatment can be an apt solution for this problem.

Stem cells with a peculiar characteristic of getting differentiated into any or all cells of the body can be used for the structural regeneration of damaged blood vessels, nerves or signalling pattern to regain the fully functional organ.



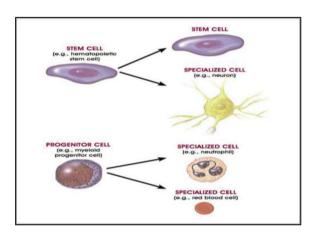


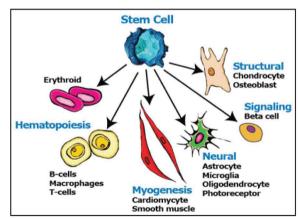
About Stem Cells

Stem cells are basically the "Master Cells" of the human body. These unspecialized cells lie dormant throughout the life and get activated when signals elicit from the site of injury. Upon enlivening they get navigated to the site of injury with the help of strong immune response stimulated by the body. At the site with the help of a programmed cell division they get differentiated into the specialized tissue specific cells. These newly formed daughter cells will be replaced for the damaged one, thus ceasing further progression of the diseased cells.

Thus, stem cells are known to be vital to the body for its normal wear and tear due to their exclusive characteristics such as

- 1. Undifferentiated cells capable of giving rise to any tissue specific cells.
- Capability of prolonged self renewal having an unlimited life span and thus maintaining their number intact.
- 3. The ability to trigger the secretion of certain hormones and grow factors at the site of injury to facilitate damage repair.





Types of Stem Cells

With respect to their origin these Stem cells are broadly classified into two main naturally occurring cell types such as Embryonic stem cells and Adult stem cells. The third one is reprogrammed in the lab to satisfy ethical as well as scientific demands; they are named as Induced Pluripotent stem cells

Embryonic Stem Cell

These cells are the most preliminary cells isolated from the inner cell mass of the blastocyst of preimplantation stage embryos. With their unlimited expansion capacity and ability to differentiate into almost all cell types of the body; earlier they were considered as the potential sources of the regenerative medicines. But the increasing burden of ethical speculations and animal studies showing abnormal occurrence of tumor ex vivo rendered them ineffective for the therapeutic application.

Adult Stem Cells

These cells are settled in adult body organs. They are less controversial due to their ease of isolation



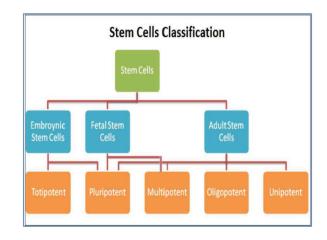
and their production does not require any destruction of embryo. These cells pose a very low or no risk of immune rejection when applied as therapeutic.

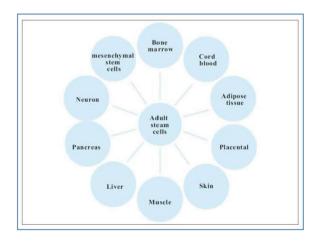
Since they are present in an adult fully grown organ, they are capable of differentiating cell of their lineage only contrary to the embryonic stem cells giving rise to all lineages. Apparently these cells can be directed to become specific cells with the addition of specific growth factors. These properties make them attractive candidates for the therapeutic application in the contemporary field of regenerative medicine.

Induced Pluripotent Stem Cells (iPSCs)

These are adult somatic cells genetically reprogrammed in vitro to an embryonic stem cell like state by being forced to express gene such as OCT-4; important for maintaining Pluripotent property of embryonic stem cells. Although the technology is still in a juvenile state; additional research is needed to use them in transplantation medicine.

Out of the different types mentioned above Adult Autologous Stem cells are known as the most potent and versatile. They are thus the most opted cell sources due to easy isolation, demonstrative plasticity and minimum ethical barricades.





Examples of Autologous stem cell sources are Bone Marrow, Adipose Tissue etc. and we have achieved ultimate expertise over it.

The Advancells Erectile Dysfunction

Advancells uses very comprehensive and individualized treatment pattern, by obtaining stem cell from two sources adipose-derived stem cells (ASCs) and bone marrow-derived stem cells (BMSCs). Through our multidisciplinary team of specialists; we are giving the best treatment possible to improve recovery.

The entire procedure consists of following phases:

Pre Treatment Assessments, Stem Cell Procedure, Stem cell Implantation and Rehabilitation.

Objectives of the Treatment

The Objectives of the treatment are to explore patient specific regimen for the effective prognosis and successful treatment outcome for ED patients.

Type of Treatment

The procedure exploits the use of Autologous Stem Cells isolated from your own body.

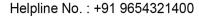


Being an Autologous they are not rejected by the body and hence are completely safe and risk free. At present we are isolating stem cells from two sources such as "Bone Marrow" and "Adipose Tissue". Both these sources are available in abundance from where stem cells can be easily isolated without many manipulations.

Once you are enrolled with us for the treatment, we will intimate you regarding the date and time of the treatment. The entire treatment plan will be divided into three parts;

- Inductive Support: Complete assistance will be given to the patient in all pre treatment procedures such as consultation, hospitalisation (If required), Assessments.
- 2. Stem Cell Procedure: Generally the entire procedure takes around 7-8 hrs including 1-2 hrs of source aspiration, 2-3 hrs of stem cell isolation and injection of the isolated stem cells back in the body. The processing of sample is done in a state of the art class 10000 clean room facility wherein we strictly adhere to maintain quality of standards. Wherein the extracted sources undergo minimum manipulation such as been spun in a centrifuge to cull out a stem cells.

ADVANCELLS STEM CELL TREATMENTS Adipose Tissue Extraction Bone Marrow Extraction C C D D Figure 2: Bone Marrow collection procedure Figure 1: Adipose Tissue collection procedure A. Application of local anesthesia A. Application of tumescent anesthesia B. Bone Marrow collection by needle insertion in the B. Adipose Tissue collection by lipoaspiration C. Isolation of Stem Cells in the clean room C. Isolation of Stem Cells in the clean room D. Intra-arterial catheter based Injection of stem D. Intra-arterial catheter based Injection of stem cells at the targeted site cells at the targeted site





3. **Stem cell Implantation**: - Once isolated, intensified and ready for reinstalling back into the body, we work out different mode of implantation; depending upon patient's health condition.

CLICIDILITY CRITERIA	STEM CELL COLIDCES	INADI ANITATIONI
Pre Treatment Assessments Routine Blood Tests Infectious disease testing Urine Analysis Physical Examination Ultrasound	The source of stem cells can either be Bone Marrow or Adipose Tissue or Both depending upon the assessment. • Bone Marrow:- 100-120 ml of bone marrow is collected from iliac crest	IMPLANTATION Specialists exercise various input options for implanting cells back into the body depending upon physical condition and treatment demand.
Overnight erection test Counselling	with the application of general anaesthesia. • Adipose Tissue (Fat):- 100 cc adipose tissue is collected from the	 Intravenous Injections (IV):- Infusion through vein Intracavernous:- Infusion directly into the artery of
	belly area with application of local anaesthesia.	corpora <u>cavernosa</u> (Penis)

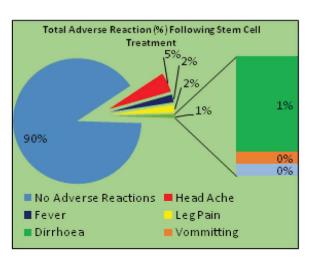
4. **Rehabilitation**: - Post treatment care involves reclamation therapies such as Physiotherapy, Occupational Therapy, Speech Therapy, patient's counselling etc. for accelerated recovery. The follow up schedule will be provided at the time of discharge.

Quality Control Parameters	Post Treatment Care
Cell counting & Viability Assessments • Stem cell isolation and separation from unwanted cells • Number of cells recovered through Trypan Blue Viability Assessments • Percentage of Live cells • Documentation	Rehabilitation Physical exercises Ultrasound Counselling to understand medical problem, quit smoking, healthy diet tips Psychological support for depression, mood swings, anxiety etc. Evaluation and Follow up
Flow Analysis /characterisation of Bone Marrow Mononuclear Cells (BMMSCs) • Total percentage of CD 34+ and CD45+ cells recovered	
Flow Analysis /characterisation of Adipose Tissue (SVF Cells) • Total percentage of CD 73+and CD90+ and CD 105+ cells recovered	



Possible Adverse events from the treatments

Since stem cell therapy in minimally invasive and reasonable safe procedure none of our patients treated so far have observed any major offshoot from the transplant, but complaints are consistent with the expected reaction to routine IV/LP injections such as fever, headache, pain, diarrhoea, vomiting and allergic reactions. Less than 5% of our patients have experienced any of these symptoms.



Follow Up

Once you have returned home, a member of our medical team will monitor your progress in given intervals via telephone and email. For your convenience, a telephone 'hotline' is always at your disposal.

General

No additional charges will be incurred unless you are required to extend your stay at the medical center as a result of complications. Costs do not include additional stem cell treatments. If another treatment is necessary, we will discuss potential options with you. You will receive an invoice one week prior to treatment. This invoice must be paid in-full before treatment can begin.

Note: If your bone marrow/adipose tissue sample is negative or the stem cells cannot be administered due to unforeseen medical circumstances, you will only be required to pay charges incurred to that point. In the case of a negative sample, it might be possible to schedule another collection.







Contact us

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