Stem Cell Care India

A GUIDE FOR PATIENTS

STEM CELL TREATMENT

PROTOCOL & PROCEDURE

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STEM CELL TREATMENT PROTOCOL

01. Treatment Goals:-

- Intelligent Aging

Mesenchymal stem cells (MSCs), specifically derived from human umbilical cord tissue, offer significant potential in **slowing aging.**

Their anti-inflammatory properties help reduce systemic inflammation, a key factor in aging.

Moreover, MSCs are adept at repairing and rejuvenating damaged tissues, crucial in countering age-related wear and tear.

Reducing inflammation and promoting tissue repair slows the aging process, **enhancing overall health and longevity.**

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- Degenerative Conditions

Mesenchymal stem cells (MSCs), particularly those derived from human umbilical cord tissue, have shown promise in improving degenerative conditions.

Their potential lies in their ability to **regulate the immune system, thereby reducing chronic inflammation**, a common exacerbator of degenerative diseases.

By modulating immune responses, MSCs help mitigate the progression of such conditions. Additionally, they possess regenerative properties, enabling them to **repair and rejuvenate damaged tissues**.

This combination of immune regulation, anti-inflammatory action, and tissue repair contributes to potentially slowing the progression of degenerative diseases, offering a novel approach to managing these conditions.

02. Protocol Overview:-

- About

Our protocol involves the human umbilical cord tissue-derived adult mesenchymal stem cells (MSCs) / Adipose derive stem cell / Autologous Stem Cells

The infusion takes roughly 2-3 hours, the MSCs are manually infused by a dedicated medical team.

- Method

Our medical team administers the MSCs via different mode of injection. This method helps to promote higher cell viability numbers, leading to greater treatment efficacy. The procedure is non-invasive and there is no pain associated with the injection of cells.

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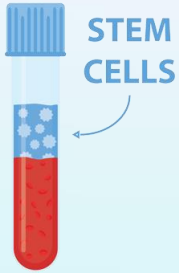
03. Schedule:-

- Day 1-

- Taking a cab to the hospital.
- Interacting with doctors to get a complete run-through of treatment and to clear any doubts.
- Completing Admission Procedure.
- Going through pre-treatment screening and tests.
- Taking some supportive therapies.

- Day 2-

- Getting Stem Cell Treatment
- Taking some supportive therapies.
- Going through Physiotherapy / Occupational Therapy / Diet Consultation



- Day 3-

- Taking Supportive Therapies
- Going through Physiotherapy.
- Completing Discharge Formalities.
- Getting dropped back to the Airport.
- The patient must carry his identity proof during the admission accompanied by reports of past treatments.

04. Cell Product:-

- **First Stage Testing's & Umbilical Cord Collection**

The healthy mothers voluntarily donate the umbilical cord blood post the birth of their children. Each mother when comes to baby delivery is tested for any major diseases. Along with this a detailed medical history is also acquired of the mother and family. There are strict regulations regarding the blood donation which ensures only the best treatment is imparted. There are plenty of rounds of testing which are conducted by the qualified doctors to understand any case of the pathogen. The women who are screened safely and free from any diseases and ill-health are the ones allowed for umbilical cord transplants.

- **Second Round of Testing**

The second step which takes places occurs in the specialized laboratory. The samples once collected are tested negatively for any kind of communicable disease.

The sample is then transferred to the laboratories where it is officially tested and becomes a muse of Biotechnology. The laboratory where the sample goes for testing is wholly responsible for every sample that is processed and provided to the patient. The collected sample is then administered during a second round of testing. The laboratory also carries out testing for various cytomegalovirus, exogenous viruses, micro-organisms like aerobic bacteria, anaerobic bacteria, fungi, etc., survival rate, stem cell and surface markers along with stem cell biological characteristics which help with colony-forming ability, a differential capacity that is a must in each step, since it ensures the highest and the best quality to its cell products.

- **Separation**

After the cord blood serum is obtained and the stem cells are prepared For the process of culturing is accomplished by dividing the desired components that are attained from the cord blood. The blood cells require removal which must be done from the blood serum and the stem cells since it is required that no interference takes place with future injections. A centrifuge is then utilized to separate and differentiate the serum and the stem cells from that of the red cells and platelets. This is a highly refined, cultured, and specialized process of separation. Post the separation process is completed, the stem cells are then taken away and removed for culture.

- **Culturing Process**

The stem cells which are carefully derived from every umbilical cord are then seeded into a flask that is filled well to the brim with a culture medium

The medium is the one that does not contain any animal products, this involves fetal calf serum as well, but it is escalated in functionality with various cell growth factors. The flasks are then placed in a sterilized, temperature and the humidity is controlled of the incubator. The stem cells are then well expanded in the culture medium. Once the culturing is comprehensively complete, the culture medium is withered or washed away and is then harvested.

Storage

The cell products are stored at a consistent -196 degree Celsius, they are cryo-preserved with an automatic supplement of liquid nitrogen which is done using the highly advanced system of BioArchive. This technology allows for the integrated control of freezing temperature rate which totally avoids the sudden drop and dips in the temperature. The cryo-preservation storage equipment is the one which is well-equipped with a 24-hour real-time control system and in case of power failure or any other emergency, it is a redundant fail-safe system which ensures that the normal operation is carried out well. The vacuum protection system can maintain a proper temperature for about 20 days with no outside supplement of liquid nitrogen.

Packing and Transport

All the batches of stem cells are administered to undergo the final testing. During the process, they are checked well for quantity and quality. Once the stem cells are checked well for safety, every unit is placed well into a sterile vial or a sterile IV bag which can be used for future transplantation. All the products are well cataloged individually and then tracked while transit. The cell transplants may take place anywhere around two to three days a week.

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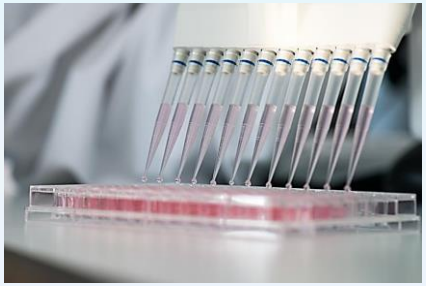
05. Validation:-

- Viability Testing



Viability testing refers to assays that determine whether cells are alive or dead. It assesses the health, integrity, and functionality of cells. Our partner lab's minimum benchmark for viability is 90% - but we commonly achieve a higher rate of about 95%.

Ensuring high cell viability is a part of our commitment to offering quality treatments. This not only meets cGMP standards and regulations, but it also ensures that low viability or improper handling does not hamper the therapeutic efficacy of our treatments.

Our automated cell counters enable us to quantify and assess MSCs rapidly, consistently, and reproducibly. With these advanced tools, we can determine live versus dead cells, total and viable cell concentrations, and even verify counts through integrated imaging.

- Immune Privileged

Human umbilical cord tissue-derived mesenchymal stem cells (hUC-MSCs) exhibit immune-evasive properties that make them suitable for allogeneic transplantation without invoking a negative immune reaction.

These properties are mainly due to their low expression of major histocompatibility complex (MHC) class I molecules and the absence of MHC class II molecules on their surface. This allows MSCs to avoid recognition by CD4+ T lymphocytes and prevents T cell activation

MSCs do not transfer or propagate their own DNA in patients receiving MSC therapy. The transient survival of infused MSCs, lack of genomic integration of engineered transgenes, and paracrine mechanisms of action suggest horizontal DNA transfer does not occur.

STEM CELL TREATMENT PROCEDURE

- **How and where is the therapy done?**

You have taken the right decision of getting treatment done at StemCellCareIndia and so you will be informed about the time and date on which you have to meet our representative. Our representative will take you to the expert at the hospital for a thorough consultation after which you might undergo radiology and/or pathology tests if mandatory

Once the test outcomes are back, the specialist will discuss your treatment modalities in depth. You are cheered to ask as many queries as you want to; feel entirely confident not just about the treatment but also about the surgeon and the hospital. All the treatments will be done under the medical investigation of the most amazing healthcare specialists such as neurologists, anaesthetists, neurosurgeons, cardiologists, orthopaedic doctor, radiologists and paediatricians. The hospitals are of topmost standards and a devoted team of exceedingly skilled physicians, patient counsellors and nurses looks after the patients. Furthermore, we offer other facilities for our outstation patients like travel help, hotel booking, transport, visa support etc.

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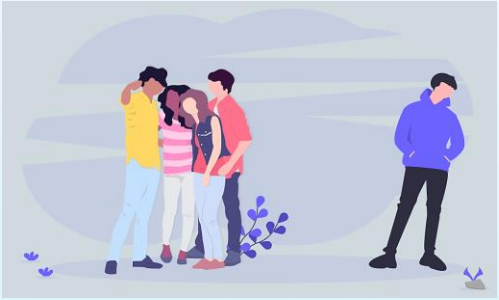
❖ Inclusion Criteria

- 18 years and older; If less than 18, parental sanction is needed
- Patients without chronic ailment
- Patient providing written agreement to receive treatment

❖ Exclusion Criteria

- Haemoglobin below or equal to 10
- Patients with inherited blood disorders
- Denial to offer signed informed agreement
- Patient had medical surgery within six weeks before treatment initialization
- Pregnant or breast-feeding females
- Severe cachexia and malnourishment



- Patients with negotiated immunity
- Positive serology for other communicable ailments.

➢ The whole medical process at SCCI involves 4 steps:

- Gathering of Umbilical Cord Tissue & Maternal Blood
- QC Testing (Infectious ailment screening + Sterility Testing)
- Processing of Mesenchymal Stem Cell – P2 Final Product
- Stem cell implantation
- Post-treatment care

Stem cell therapy is executed consistent with the ideologies of good manufacturing practice together with the most cutting-edge technologies and the finest medical standards that are available. The hazards associated with adult stem cell therapy are almost insignificant

The treatment embraces the use of patient's own cells so the risk of rejection merely does not exist, which might be conceivable in case if a donor is used. Contingent upon the assessment the source of stem cells will be decided. It can either be bone marrow or adipose tissue. In some cases, we can offer stem cells gained from both sources but the treating surgeon will exclusively take the decision.

❖ Quality standards

We run each client a Third-Party Certificate (from a globally accredited lab) for the cell count and feasibility of the cells that we process from the allogeneic mesenchymal stem cell Certificate of Analysis (COA).

❖ Stem cell implantation

Stem cells can be implanted in following ways such as:

- Intravenous Administration
- Intrathecal Administration (Lumbar Puncture)
- Intramuscular Administration
- Intra-arterial Administration via catheter
- Intravitreal Infusion
- Retrobulbar Infusion of cells
- Liberation Angioplasty for Multiple Sclerosis CCSVI
- Intra-Dermal Administration

❖ Postoperative care

The stem cell therapy does not damagingly affect patients in any way. Generally, the patients are permitted to leave after few hours after the completion of the stem cell treatment. A 24-hour patient hotline number is there for any inquiries after their discharge. The concerned physicians or surgeons of the clinic also stay in contact with their corresponding patients through telephone or email. By doing this, they can get precise feedback about their progress and also suggest further recovery if required.

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Say for example, in the case of a diabetic patient, after hearing about the patient's present symptoms, the concerned doctor can recommend the needed dosage of insulin.

❖ Treatment disclaimer

It is an imperative fact to comprehend that stem cell treatment in every prospect has the ability to diminish symptoms of numerous diseases. It also has the aptitude of ceasing several degenerative procedures

But one should also know that this treatment may not work for all kinds of patients. Stem Cell Care India does not have the right of forecasting or warranting the success of this treatment.

In harmony to the current condition of a patient, the medical team of Stem Cell Care India might propose stem cell transplantation or may even withdraw the treatment under abnormal situations. However, in any case, the approval of the patient is a must. Keeping the patient's current health condition and unforeseen health hazards in mind, the medical staff might propose an alternative stem cell transplantation process. In exceptional situations, they may entirely cancel the treatment.