

We would like to give you an overview of what to expect when using our services and guide you through what your Stem Cell procedure at Cellular Hope Institute will entail.

Our objective is to enhance your body's ability to regenerate itself by using the latest regenerative medicine technology to reverse diseases and repair tissues, all while avoiding invasive surgical techniques and harmful medications.



### **HOW WE CAN HELP YOU**

Our treatment plan is based on three advantages exhibited by regenerative cells, also known as Mesenchymal stem cells. Firstly, they release anti-inflammatory proteins over an extended period. Secondly, they have an immunomodulatory effect, meaning they can help control and regulate the immune system. Thirdly, they exhibit a paracrine effect, which means they secrete substances like exosomes to alter cell behavior and communicate with cells to attract them to areas of damaged tissue. These three aspects of Mesenchymal stem cells play a significant role in treating patients and achieving results, especially in autoimmune disorders and chronic degenerative diseases.





# WHY UNDERTAKE A TREATMENT OUTSIDE OF THE UNITED STATES?

Highly-manipulated cellular therapies are those that utilize a laboratory to culture and grow cells within the cell population. Through this process, cell samples are grown to contain larger quantities of Mesenchymal Stem Cells, resulting in improved patient outcomes. In cases of complex conditions, such as chronic degenerative or neurodegenerative conditions, the best results are obtained through the infusion of a larger quantity of cells directly into the diseased area. That is why many patients are choosing to seek the best results at top facilities abroad, as current regulations in the United States prevent practices from treating their patients in this manner.

## CAN STEM CELL THERAPY CURE MY MEDICAL CONDITION?

When treating a medical condition, we aim to manage the condition rather than cure it. Neither fresh cells nor cultured cells can cure every disease, but they can do great things like alleviate symptoms and halt the progression of the condition. Normally, in many chronic degenerative or neurological conditions, several treatments are necessary because the effects of cellular therapies are not permanent. Our unique approach involves a multi-dose treatment plan, administering the cells once and following up at three, six, and twelve-month intervals. If symptoms reappear, additional rounds of treatment may be necessary.





## WHEN WILL I SEE RESULTS?

After the first dose, results can already begin to make themselves apparent, but this depends largely on the type of disease/condition the patient is afflicted with, as well as its severity and current phase of progression. Once the stem cell treatment begins, the body needs a minimum of four weeks to recognize the initial regenerative effects, which become more apparent at the six-month mark. Regenerative medicine is considered a multi-dose treatment, and reinforcements are usually required every six to twelve months. However, depending on a patient's condition, they could be needed up to twenty-four months after the initial procedure. This emphasizes the importance of cryogenically banking and storing stem cells.

## WHAT ARE THE DIFFERENT CELLULAR THERAPIES AVAILABLE FOR YOU?

Our comprehensive stem cell treatment protocols employ well-targeted combinations of Exosomes, Allogeneic Human Mesenchymal Cells, and Autologous Bone Marrow and Adipose derived Stem Cells to treat different diseases and conditions. Our treatment plans are mostly focused on a systemic or whole-body approach, ensuring that patients receive the highest quality and quantity of cellular products during their time in our hospital

Among the various types of cellular products available for treatment, two primary sources can be utilized to address the conditions previously discussed.





## **AUTOLOGOUS**

Autologous procedures involve using the patient's own cells for cellular therapy treatment. In these procedures, a doctor typically takes a sample, often from bone marrow or adipose tissue, and extracts the cells from it before administering them locally to the diseased or damaged area.

## **ALLOGENEIC**

Allogeneic procedures involve the patient receiving cells from a donor other than themselves. These samples typically come from neonatal tissue, such as umbilical cord blood, and undergo extensive screening to ensure the quality and health of the cells.

The type of treatment utilized depends on various factors, including medical history and age. At the Cellular Hope Institute, we strive to provide each patient with a personalized, case-by-case treatment plan, ensuring that the ultimate outcome is nothing short of positive.

## WHICH ARE THE DIFFERENT ADMINISTRATION METHODS THAT WE USE AT CELLULAR HOPE INSTITUTE?

After you've been selected as a candidate, you will meet with our highly-trained team of medical professionals to devise a treatment plan tailored specifically to achieve the best results possible given your current condition. Below, we will outline the different methods of administering cellular therapies used in our medical facilities:

#### Intrathecal-intraarterial

This form of implantation is ideal for neurological conditions because the stem cells are injected past the blood-brain barrier and directly into the spinal fluid, which enables them to reach the spinal cord and brain.

During the procedure, an experienced anesthesiologist inject stem cells into the spinal canal through the lower vertebrae under local anesthesia. TAll procedures are performed in a positive airflow room under sterile conditions, and the procedure usually takes about thirty minutes.

#### Intravenous IV

The safest and simplest method for delivering the stem cells throughout the body. Anesthesia is not required. We may use Lidocaine topical spray to needle prick area beforehand. IV administration usually takes about 20 – 30 minutes.

#### Intramuscular IM

The stem cells are injected directly into the muscle. Intramuscular implantation is very safe and does not require anesthesia.



## **UNDERSTANDING YOUR TREATMENT IN CANCÚN**

Your journey will begin as you depart from your hometown for beautiful Cancún, México. In Cancún you will be greeted at the International Airport by our patient coordinator, then transferred to your accommodations. Once settled in, the patient coordinator will provide you a welcome package.



### **ARRIVAL DAY**

Your journey will begin as you depart your hometown for beautiful Cancún, México. In Cancún, you will be greeted at the International airport by our patient coordinator. From the airport you will be transported to your hotel aand checked into your accommodations for the duration of your procedure.



## TREATMENT DAY

The morning of the procedure:

- Eat a light breakfast.
- Take your regular prescription medications.
- Wear comfortable, loose-fitting clothing that does not have to be pulled over your head.

You will be picked up from your hotel one hour before the procedure. Once at the clinic, you will sign the informed consent form and your vital signs will be checked.



#### **POST-OPERATIVE CARE**

- During the first 72 hours, you may experience pain and inflammation at the puncture sites and joints that have been treated. If so, we recommend applying local cold packs, resting, and taking paracetamol 1 g every 12 hours. If the symptoms do not gradually subside, please consult your referring physician.
- If you experience fever, nausea, vomiting, or general discomfort, please consult your attending physician or medical coordinator.
- You will be prescribed an antibiotic based on your medical condition. Please inform us of any known drug allergies.
- Do not consume alcohol during the next 72 hours.
- There are no post-treatment dietary restrictions.
- Your physician will contact you by phone within the first week for follow-up, then future follow-up visits will be scheduled through your patient coordinator. If you need assistance, please do not hesitate to contact us.

### **DEPARTURE DAY**

Your patient coordinator will pick you up at your hotel and take you to the hospital for a post-procedure consultation with your physician. The doctor will make sure everything is okay before allowing you to return home. You will be dropped off at the airport at least two hours prior to your flight departure.



## SERVICES INCLUDED IN YOUR TREATMENT

- · Medical general assessment.
- · Critical care evaluation.
- · Specialist doctor evaluation.
- · Anesthesiology evaluation.
- · Perioperative care.
- · Pharmacy and Supplies.
- · Operating room.
- · Anesthesia Services.
- · Diagnostic/therapeutic imaging.

- · Autologous stem cell acquisition.
- · Pathology services.
- · Hemodynamics suite.
- · Patient coordination fee.
- · Catheterization procedure.
- · Mannitol injection.
- · Med Surg Supplies sterile.
- · Spinal tap procedure.
- · Recovery.

- · Laboratory fee.
- · Culture/Expansion autologous BM derived stem cells.
- Med Surg room.
- · IV infusion.
- · Follow up and recommendations.
- Pick up / Drop off from airport to accommodation and vice versa.
- $\cdot$  Pick up/Drop Off the day of the procedure to and from hospital.



## WHAT TYPES OF CONDITIONS ARE WE SPECIALIZED IN PROVIDING CELLULAR THERAPIES?

#### **AUTISM**

Autism is a spectrum of disorders characterized by marked abnormalities in communication and social interactions. Two common consistent findings associated with children diagnosed with this disorder are diminished oxygenation in specific areas of the brain and a chronic immunologically mediated inflammatory condition in the gut.

The rationale behind treating autism with Mesenchymal stem cells is that the disorder and its severity have been significantly correlated with inflammatory and neuro-inflammatory cytokines, including macrophage-derived chemokine (MDC) and thymus and activation-regulated chemokine (TARC). Multiple clinical trials have demonstrated that intravenous administration of umbilical cord MSCs can decrease inflammation. By reducing inflammation in autistic patients, it is believed that symptoms of autism may be alleviated

Through administration of mesenchymal stem cells, we have observed improvement in patients treated at our facilities.





#### **MULTIPLE SCLEROSIS**

Multiple Sclerosis (MS) is caused by an immune mediated attack targeting components of the myelin sheath. The myelin sheath is known to act as an "insulator" for neurons so that they can communicate properly with each other.

At present, there are no FDA-approved treatments that specifically target the abnormal immune responses in MS. Current approaches, such as interferon, copaxone, or immuno-suppressants all act in a nonspecific manner blocking immune responses against the myelin sheath. While these approaches are useful for reducing the severity of disease, they do not repair the damage to nervous system tissue that has already occurred and therefore they cannot cure multiple sclerosis. Mesenchymal stem cells (MSCs), have immune regulatory properties which may stop the immune system from attacking the myelin sheath.

#### **AUTOIMMUNE DISEASES**

Autoimmune diseases are conditions in which the patient's immune system generates cellular and antibody responses to substances and tissues normally present in the body. This might be restricted to one organ or involve a particular tissue in different places. As a result of this immune response, damage to different organs occurs. Examples of autoimmune diseases that have responded to stem cell therapy either in animals or humans include rheumatoid arthritis, multiple sclerosis, and lupus.

Currently, autoimmune conditions are treated with immunosuppressive agents such as steroids, methothrexate, cyclosporine, gold, and more recently infliximab (Remicade). Despite inducing temporary improvement, these approaches possess the possibility of long-term adverse effects, as well as need for life-long treatment.

Stem cell therapy has been demonstrated to induce profound healing activity in animals with various forms of autoimmune disorders. Besides healing damaged tissues, stem cells have the unique ability to modulate the immune system so as to shut off pathological responses while preserving its ability to fight off disease. Stem cells and specifically, mesenchymal stem cells hone to inflamed tissue and start producing anti-inflammatory agents. These mediators act locally and do not suppress the immune response of the patient's whole body. Additionally, mesenchymal stem cells induce the production of T regulatory cells, a type of immune cell whose function is to protect the body against immunological self-attack.







#### SPINAL CORD INJURY

Spinal cord injury (SCI) occurs when the spinal cord becomes damaged, most commonly, when motor vehicle accidents, falls, acts of violence, or sporting accidents that fracture vertebrae and crush or transect the spinal cord.

Damage to the spinal cord usually results in impairments or loss of muscle movement, muscle control, sensation and body system control. Presently, post-accident care for spinal cord injury patients focuses on extensive physical therapy, occupational therapy, and other rehabilitation therapies; teaching the injured person how to cope with their disability.

A number of published papers and case studies support the feasibility of treating spinal cord injury with allogeneic human umbilical cord tissue-derived stem cells and autologous bone marrow-derived stem cells. Through administration of umbilical cord tissue-derived mesenchymal stem cells, we have observed improvements in spinal cord injury patients treated at our facilities.

#### **NEURODEGENERATIVE DISEASES**

(NDs), such as Alzheimer's disease, Huntington's disease, and Parkinson's disease are characterized clinically by their subtle onset but chronic progression and involve the degeneration of defined neuronal phenotypes in the central nervous system (CNS).

In recent years, numerous studies have shown that stem cell transplantation elicits neurogenesis and angiogenesis by releasing neuroprotective factors brain- derived neurotrophic factor (BDNF) and nerve growth factor (NGF). Results have provided proof of principle that cell replacement can work in humans with Parkinson's disease, however there are still many obstacles to the use of stem cells as a cure for neurodegenerative disease, especially due to our incomplete understanding of the true mechanisms of these diseases and clinical data is still scarce.

Despite substantial research and the development of a number of neuroprotective drugs to treat NDs and to improve patient survival, no effective therapy for these diseases is currently available.

A concentrated human stem cell product, derived from donated cord blood, undergoes processing to remove excess plasma, red blood cells, vascular material and tissue solids, leaving behind stem cells and other cellular components, which are then concentrated and banked through a validated process. Therapeutic approaches involving the transplantation of stem cells primarily focus on replacing lost neurons and restoring neural tissue structure. Umbilical cord blood (UCB) cell-induced neuroprotection involves anti-inflammatory and immunomodulatory effects, while neurotrophic factors act through paracrine and/or autocrine interactions between transplanted UCB-derived cells and the neural microenvironment.





#### CHRONIC OBSTRUCTIVE PULMONARY DISEASE

COPD is caused by a combination of small airway disease (obstructive bronchiolitis) and parenchymal destruction (emphysema). The pathophysiology of COPD is mediated primarily by a pathogenic triad: inflammation, oxidative stress, and protease-antiprotease imbalance. The inflammatory process in the lungs of COPD patients involves concentration of macrophages, neutrophils, CD8+ cytotoxic lymphocytes in the small airways and the subsequent release of humoral factors cytokines, chemokines, and elastolytic enzymes.

To address these complexities, it is essential to provide the patient with a treatment that regenerates lung structure, induces lung functional recovery through the reduction of inflammation, and induces immunomodulation.

### SAFETY AND EFFICACY

All of our procedures follow the strict cGTP guidelines that regulate the methods, facilities, and controls used for the manufacture of HCT/Ps (defined as: articles containing or consisting of human cells or tissues that are intended for implantation, transplantation, infusion, or transfer into a human recipient)-these guidelines are there to ensure patient safety and that all procedures prevent the introduction, transmission, or spread of communicable diseases by HCT/Ps (§1271.150(a)).



# ADVANTAGES OF CELLULAR HOPE INSTITUTE TREATMENT

- Extremely low risk of rejection.
- · Alternative treatment for degenerative diseases, which do not have effective traditional therapies.
- They offer treatments with high possibility of recovery and improvement of hope and quality of life.
- · Can reverse or slow the progression of disease.
- · MSCs of adipose and bone marrow tissues are obtained through ambulatory, low-risk procedures under local anesthesia.
- · Wharton jelly mscs of umbilical cord are available at all times in the incubators of the cellular hope institute cell bank.
- · No extraction surgery.
- · Can be used for rejuvenation and anti-aging treatments.



