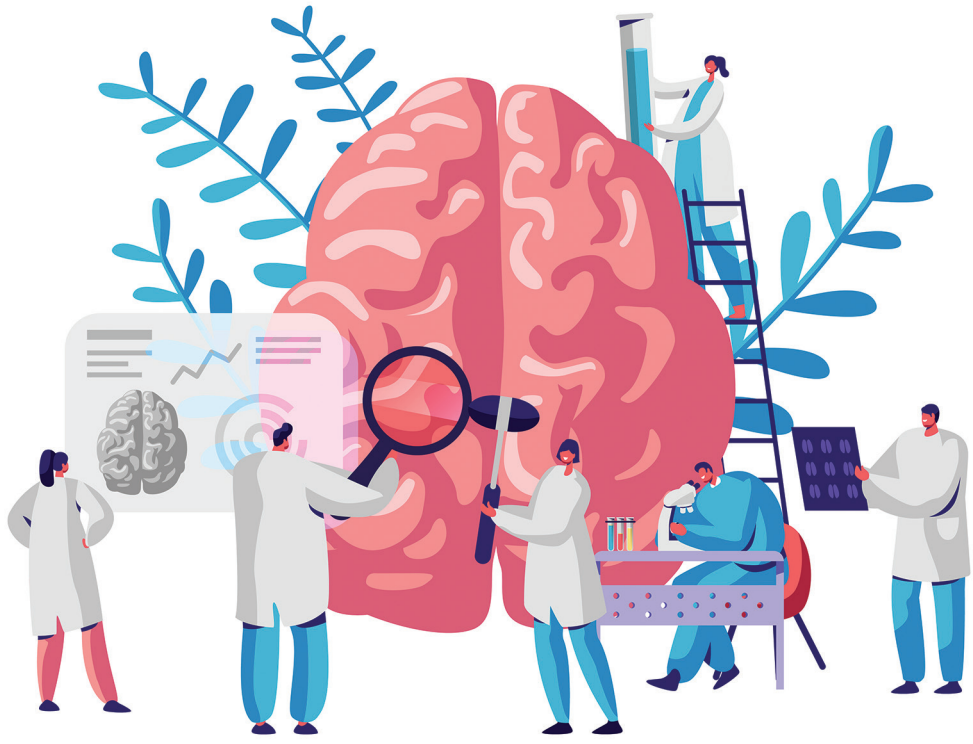

NEW HOPE FOR ISCHEMIC STROKE SURVIVORS

Modern science has produced numerous exciting advances in medicine. The use of nanotechnology for heart failure treatment and immunotherapies to combat cancer are examples of medical breakthroughs that have occurred in recent years. Yet despite scientific advancements, there's no cure, at least for now, for numerous diseases.

Stroke, the second leading cause of death for people above age 60 and a leading cause of disabilities, is one such condition. Desperate to help themselves or a loved one, many of those affected turn to alternative treatments for answers, such as stem cell therapy.

Stroke is a brain disease caused by a blocked blood vessel or intracranial bleeding. During a stroke, not only can brain cells die from a lack of oxygen, but neurotrophic factors, responsible for generating new cells, differentiating cells, and promoting cell survival, may also cease activity. A stroke can create damaged areas of the brain that may become susceptible to infectious pathogens. A growing number of doctors now believe that cord blood applied to stroke patients, which comes from donated umbilical cord blood after a child is born, can aid in cell replacement, heal damaged cells by restarting the neurotrophic effect, provide immune support, and significantly reduce inflammation.

Science shows that cord blood possesses unique capabilities to play a major role in regenerative therapy by encouraging brain healing. Stem cells come from the body and work as "master cells." They can divide to become new cells or specialized cells. According to the Mayo Clinic, no other cell in the body has the natural ability to generate new cell types. The hope is that scientists may one day generate healthy cells to replace diseased cells and cure illnesses.

Scientists have found a way to turn adult stem cells found in cord blood into pluripotent stem cells. This means that they can possibly produce new cells for any organ or tissue. Cord blood stem cell therapies have shown great promise to help heal people with diverse brain injuries. Unlike the unethical use of embryonic cells, the use of cord blood is not controversial.

Differing from other treatments, cord blood IV therapy is unique as it is not surgically invasive. The process is somewhat like a blood transfusion,

in which a patient receives blood intravenously, but the blood comes from donated umbilical cord blood that contain stem cells. This therapy is currently being used in countries including Germany to treat cerebral palsy, stroke, and other conditions. It is a promising alternative treatment for strokes. However, there is growing but still limited data currently available on its use to treat strokes. Cord blood IV transfusions can present risks if the patient is subjected to improper applications, unsanitary conditions, or dangerous products. Though considered rare, allergic reactions may also occur.

The FDA, which operates within the US Department of Health and Human Services, has the challenging role of guarding against the use of illegal and potentially harmful supplies, treatments, and devices in the US. The agency has approved limited stem cell-based treatments, some strictly as clinical trials, largely due to issues of safety and efficacy. For this reason, they place regulations and restrictions on the use of human cells, tissues, and cellular and tissue-based products. When stem cell products are used in unapproved manners, the FDA may take judicial actions.

In the aftermath of a stroke where patient improvement is markedly slow and frustration grows over the lack of available medical options, some families consider treatments which some find controversial to help speed recovery of their loved one. This has paved the way for medical tourism, where sick people travel to other countries for so-called "cutting-edge" medical procedures they cannot get at home. Regarding stroke treatment, it is not uncommon for people to travel to Europe to seek out health clinics boasting of revolutionary treatments that use donated cord blood cells to directly target damaged areas of the brain.

The FDA cautions people of the dangers of traveling outside the US for medical procedures, especially to countries who fall behind the America in medical technology, and to those with poor safety regulations. There are always medical risks inherent in travel and in the medical procedure itself no matter where you go. There is also the potential to lose a lot of money betting on a "miracle" cure. Once a person pays for a treatment out of the country, there is little chance of getting money back. If you or your loved one is injured, there is also likely no recourse.

Although researchers remain optimistic that stem cells may one day cure people of numerous diseases, it's important to understand that there are no present guarantees that stem cell therapies will work. If you or a loved one is considering stem cell IV therapy in another country, be aware of the risks and benefits. Before deciding, make sure you understand the procedure, safety factors, and costs. Thoroughly research the science behind the medicine, the doctor, and facility, and be sure to consult with a physician or specialist in the US.

At present, there are limited clinical studies being performed in the United States using newer stem cell technologies. Let's hope that reliable treatments will soon be available to the public so that cord blood infusions, and other such medical science advancements, can be safely administered here at home to save lives.

This informational article is not a substitute for medical advice.

Further Insight: An Interview with Dr. Thoennissen

With more than 20 years of experience in evidence-based medicine and over 14 years clinical experience in hemotherapy, including blood transfusions and stem cell transplantation, Nils H. Thoennissen, MD is an international specialist in cancer, chronic degenerative diseases, and regenerative medicine, with a doctoral thesis in neurological research, having graduated summa cum laude.

AMAC

Which diseases are best treated using cord blood stem cells and why?

Dr. Thoennissen

Umbilical cord blood (UCB) is being used in a growing number of clinical trials to successfully treat a variety of chronic degenerative conditions, particularly stroke and cerebral palsy.

UCB is collected after birth with no harm to mother or baby and contains a variety of very potent substances with a high potential to regenerate tissues, including neural, heart, and others. In less than 25 years, cord blood has become one of the biggest real success stories in regenerative medicine. It is estimated that up to 128 million individuals, or almost 1 in 3 individuals, in the US might benefit from regenerative medicine therapy (Harris DT et al. 2007).

AMAC

How are cord blood stem cells different from other types of adult stem cells?

Dr. Thoennissen

Compared to other sources of stem cells, UCB contains not only multiple (!) populations of pluripotent stem cells but also non-stem cell components, including mononuclear cells,

Nils H. Thoennissen, MD

platelets, regenerative proteins, and other anti-inflammatory substances, such as exosomes. Consequently, UCB is capable of giving rise to hematopoietic, epithelial, endothelial, and neural tissues. Because of the unique immunological properties of both the stem cell and non-stem cell components of cord blood, it is possible to utilize allogeneic cells for regenerative applications without needing to influence or compromise the recipient immune system. In the last three decades, UCB therapy has proven to be feasible and well tolerated in patients.

AMAC

Can you describe some of the success stories regarding the patients you have treated?

Dr. Thoennissen

In parallel with the growing number of clinical trials, we see significant improvement in brain connectivity and functional status including gross and fine motor skills, cognition, speech, as well as activities of daily living and social/personal behavior in a substantial number of our stroke patients treated with UCB. Just recently, Kurtzberg and colleagues from Duke University in North Carolina showed in a phase I clinical trial that infusion with UCB is very safe and feasible in adults with ischemic stroke (Kurtzberg J. et al., 2018). Moreover, in several randomized, placebo-controlled, double-blinded clinical trials on cerebral palsy with perinatal stroke as the most common cause, treatment with umbilical cord impressively led to significant improvements of brain connectivity, systemic immune reactions, cognition and motor functions (e.g. Kang M. et al., 2015; Sun JM. et al., 2017; Rah WJ. et al., 2017; Huang L. et al., 2018).

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Why is cord blood infusion not available in the United States?

Dr. Thoennissen

Cord blood is available but, unfortunately, only within few clinical trials approved by FDA running at Duke University and some other clinics in the US. The FDA regulates cord blood in different ways depending on the source, level of processing, and intended use. Right now, the "hematopoietic stem cell transplantation" procedure remains the only FDA-approved regular cord blood treatment available at this time in the US. It involves the use of umbilical cord blood hematopoietic stem cells to treat individuals with blood cancers such as leukemias and lymphomas, as well as with certain disorders of the blood and immune systems, such as sickle cell disease and Wiskott-Aldrich syndrome.

AMAC

How do cord blood stem cells differ from embryonic stem cells?

Dr. Thoennissen

The relation of embryonic stem cells (ESCs) to human blastocysts always stirs ethical, political, moral, and emotional debate over their use in research and clinical settings. In addition, ESCs have extremely limited availability. Thus, for the reasonably foreseeable future, the march of regenerative medicine to the clinic will depend upon the development of non-ESC therapies. Current sources of non-ESCs easily available in large numbers can be found in the bone marrow, adipose tissue, and UCB. Overall, in comparison to other available sources of stem cells, UCB contains not only high yields of young

and potent stem cells with much greater proliferative activity and a higher life span but also a "chaperoning" neurorestorative secretome with superior immunotolerance, simple availability, and long-term safety. Consequently, UCB can be considered a superior alternative to ESCs on different levels.

AMAC

Describe the umbilical intravenous procedure (infusion of non-HLA-matched unrelated human donor UCB).

Dr. Thoennissen

From the first phone call with the prospective patient or their family member, a purposeful, professional, and rapid evaluation process is initiated, since time is a valuable element in the treatment of strokes.

CBC Health arranges the treatment with well-experienced physicians who will carefully review and assess all pertinent patient data, including past medical history, risk factors, date and extent of the ischemic stroke, present condition, medications, transportability, etc.

Day 1 – Arrival and Personal Evaluation

On arrival to the doctor's clinic in Munich, Germany, final clarifications and information are given, followed by a thorough clinical evaluation that includes anamnesis, a physical examination, and a blood analysis.

Day 2 & 3 – Treatment

A day after the individual and personal evaluation, the required UCB units are available in our clinic and are prepared for immediate infusion. After detailed matching of the ordered units with the patient data, premedication is applied, followed by the UCB infusion.

A peripheral IV line is used to administer the allogeneic UCB, usually divided up into three to four units over a period of three hours under direct physician supervision on days 2 and 3. We use an intravenous route of administration for the UCB, as this is the safest and least invasive method. The patient's vitals are closely monitored throughout the whole procedure.

All in all, you can compare the procedure with a simple blood transfusion which is routinely performed in many clinics throughout the world.

Day 4 – Final Physical Examination and Release

The day after the UCB infusion, the doctors perform a final physical evaluation prior to releasing the patient. Follow-up information is provided to the patient along with medical documentation.

AMAC

Where is cord blood IV infusion available, and what are the average costs for treatment?

Dr. Thoennissen

CBC Health is exclusively arranging highly regenerative treatment in our clinic in Munich, Germany, using biologically matched allogeneic UCB as an effective and readily available therapeutic solution for ischemic stroke survivors. CBC's ischemic stroke treatment is available in a specially designed clinic in Munich, Germany. The German healthcare system is noted for its high standards of efficiency, cleanliness, quality, and innovation.

The average costs for the whole treatment procedure are approximately $45,000.

AMAC

Where do you see the future of cord blood stem cell usage headed?

Dr. Thoennissen

Human UCB is one of the best-known sources for diverse kinds of highly regenerative cells and their potent factors. There are many studies demonstrating the potential clinical use of cord blood in the rapidly growing field of regenerative medicine. Cord blood, which is still considered a biological waste product in some countries, could be used as a non-controversial source of stem cells with unlimited availability and a wide range of therapeutic benefits. All in all, cord blood is amenable to treating a wide variety of diseases, including neurologic, cardiovascular, ophthalmic, orthopedic, and endocrine diseases.★

D.J. Wilson

WANT TO LEARN MORE?

Visit CBC Health's website at ***www.cbchealth.ch*** to learn more about their process, browse frequently asked questions, and even request a call.