



REGENERATIVE EXPERIMENTAL TREATMENT FOR ISCHEMIC STROKE SURVIVORS

Degenerative Problem: Ischemic Stroke

- One in six people worldwide will have a stroke in their lifetime.
- **→** In the U.S., 87% of strokes are ischemic strokes.
- According to the US National Stroke Association, two out of three stroke survivors will experience minor to severe physical and/or cognitive impairments over the long term.
- ♣ Up to 25% of stroke patients recover their capabilities, but currently, more than 50% have moderate to severe impairments requiring special and long-term care. Of note, there is no therapeutic regenerative treatment available after stroke in the US, including cord blood treatment.

Regenerative Solution: Cord Blood Center Health Ischemic Stroke Treatment

- → CBC Health is offering an experimental, therapeutic solution that is based on infusing ischemic stroke survivors with intravenous cord blood.
- ♣ Recent clinical trials have demonstrated that infusing cord blood can noticeably help ischemic stroke survivors to improve cognitively and physically. View trial here.
- ♣ A medical case report demonstrated long-term, therapeutic effectiveness when cord blood was infused even five years after a stroke event. <u>View medical case report here.</u>
- ◆ CBC Health's Ischemic Stroke Treatment is available in a specially designed day-clinic in Munich, Germany. The German healthcare system is noted for its high standards for efficiency, cleanliness, quality, and innovation.

CBC HEALTH REDEFINES THE REGENERATIVE HEALTH EXPERIENCE FOR STROKE VICTIMS

Call +49 1525 2012 111 to Learn More



Cell Replacement

Boosts restorative effects of progenitor cells



Neurotrophic Influence

Neurotrophins reduce cell death and increase cell growth



Immune Benefits

Immune modulation and paracrine signaling stimulate cell repair



Inflammation Reduction

Promotes cellular healing and cell regeneration

Combining Innovation with 20-Years of Cord Blood Expertise

In Europe, clinical and experimental teams are utilizing some of the methods and technologies being studied in U.S. clinical trials and combining them with CBC Health's experience with cord blood infusion treatments to provide therapeutic solutions for ischemic stroke survivors.

CBC Health offers cord blood infusions for ischemic stroke survivors from around the world. The research-based treatments use cord blood components provided by CBC Health's parent company, Cord Blood Center Group, which is known for providing therapeutic cord blood with aboveaverage quantities of nucleated cells.

CBC Health provides high quality blood typematched allogeneic cord blood that can enhance neuronal recovery and other regenerative modalities via neuroplasticity in the brain that may include:

- + Cell Replacement
- ♣ Neurotrophic Influence
- + Immune Benefits
- ➡ Inflammatory Modulation in the Brain

CBC Health Redefines the Regenerative Health Experience for Stroke Victims

CBC Health uses cord blood that is readily available, tested and stored by Europe's second-largest private cord blood repository, Cord Blood Center Group.

The treatment should take a little over six hours (approx. three hours per day) and includes check-in, medical tests, and a relatively painless cord blood infusion divided up in two days which is followed by routine monitoring by the medical staff.

CBC Health is Patient-Centered

CBC Health's medical program is designed around the individual patient to make the three-day experience as safe and efficient as possible.

- Day 1: Initial Screening & Testing
- Day 2 & 3: Treatment & Routine Monitoring
- Day 4: Final Physical Exam & Release

Your medical concierge will assist you and your family members with travel, accommodations or sightseeing requests during your stay.

FREQUENTLY ASKED QUESTIONS

Click on the questions below for expanded answers.

WHAT IS ISCHEMIC STROKE?

WHAT IS CORD BLOOD?

WHY USE UMBILICAL CORD BLOOD FOR THE TREATMENT OF ISCHEMIC STROKE?

HOW DO UMBILICAL CORD BLOOD STEM CELLS DIFFER FROM OTHER SOURCES OF STEM **CELLS?**

DO PATIENTS NEED TO PROVIDE THEIR OWN BLOOD?

WHAT TYPE OF EXPERIENCE DOES CBC HEALTH HAVE IN REGENERATIVE HEALTH?

HOW DOES THE GERMAN HEALTHCARE SYSTEM COMPARE TO THAT OF THE U.S.?

IS CBC HEALTH'S CORD BLOOD TREATMENT FOR ISCHEMIC STROKE SAFE?

WHAT QUALIFIES A PATIENT FOR CBC HEALTH'S CORD BLOOD TREATMENT FOR ISCHEMIC STROKE?

WHAT DISOUALIFIES A PATIENT FOR CBC HEALTH'S CORD BLOOD TREATMENT FOR ISCHEMIC STROKE?

ARE THERE RISKS OF ADVERSE EFFECTS FROM CBC HEALTH'S CORD BLOOD TREATMENT FOR **ISCHEMIC STROKE?**

IS CBC HEALTH'S CORD BLOOD TREATMENT FOR ISCHEMIC STROKE COVERED **BY INSURANCE?**

HOW IS CBC HEALTH'S CORD BLOOD TREATMENT FOR ISCHEMIC STROKE ADMINISTERED?

WHAT OTHER MEDICATIONS OR SPECIAL CARE IS NEEDED FOR CBC HEALTH'S CORD BLOOD TREATMENT FOR ISCHEMIC STROKE?

HOW LONG WILL IT TAKE FOR STROKE SYMPTOMS TO IMPROVE?

HOW SOON AFTER AN ISCHEMIC STROKE CAN A PATIENT RECEIVE CBC HEALTH'S CORD **BLOOD TREATMENT?**

CAN AN ISCHEMIC STROKE PATIENT UNDERGO CBC HEALTH'S CORD BLOOD TREATMENT **MULTIPLE TIMES?**

WHAT IS ISCHEMIC STROKE?

Ischemic stroke is the most common type of strokes, accounting for about 87% of all strokes. It occurs when the blood supply to part of your brain is interrupted or reduced, depriving brain tissue of oxygen and nutrients. Within minutes, brain cells begin to die, potentially resulting in devastating changes to muscles and nerves of the body with either isolated or complex impairments.

According to the US Centers for Disease Control and Prevention (CDC), stroke is the leading cause of death in the United States, killing nearly 140,000 Americans each year. On average, one American dies from stroke every 4 minutes. The majority of those surviving a stroke will have some form of long-term functional and/or cognitive disability. Stroke costs the United States an estimated \$34 billion each year including the cost of healthcare services, missed days of work, and medicines to treat stroke.

Many people with ischemic strokes are older (60 or more years old), and the risk of stroke increases with age. However, strokes can - and do - occur at any age. Many people at a certain age suffer from certain co-morbidities which put them at higher risk for stroke, such as high blood pressure (hypertension), high cholesterol, heart disease, smoking, and/or diabetes. (1,2)

References:

- 1. Feigin VL, Forouzanfar MH, Krishnamurthi R et al. Global and regional burden of stroke during 1990-2010: Findings from the Global Burden of Disease Study 2010. Lancet 2014;383:245-25.
- Benjamin EJ, Blaha MJ, Chiuve SE, et al. on behalf of the American Heart Association Statistics Committee and Stroke Statistics Subcommittee. Heart disease and stroke statistics-2017 update: a report from the American Heart Association. Circulation. 2017;135:e229-e445.

WHAT IS CORD BLOOD?



Cord blood is the blood that remains in the placenta and umbilical cord after birth. Umbilical cord blood has several unique capabilities, such as being able to create all types of blood cells, stimulate regenerative processes in a brain damaged by an ischemic stroke, and serve as the core building blocks for dozens of regenerative therapies that are reshaping medicine today.

Donated cord blood has been successfully used for 25 years to restore blood production in patients after chemotherapy. In the past decade, cord blood infusions have also shown beneficial therapeutic effects for children diagnosed with cerebral palsy (CP), and for children with cerebral strokes. ⁽³⁾ In a recent clinical trial studying cerebral strokes in adults, patients registered significant therapeutic improvements, safely, when infused in the first ten days after the stroke event. (4)

Cord blood can be collected, cryopreserved, and stored for decades without losing its quality. Cord blood is routinely tested for pathogens and infections using modern blood screening methods. The cord blood stem cells contained in CBC Health's infusions are allogeneic. CBC Health's parent company, Cord Blood Center Group, is a pioneer in cord blood banking. It has more than 20 years of cord blood experience and has successfully processed and stored stem cells for over 170,000 children for later use.

References:

- 3. Feng M, Lu A, Gao H, Qian C, Zhang J, Lin T, Zhao Y. Safety of Allogeneic Umbilical Cord Blood Stem Cells Therapy in Patients with Severe Cerebral Palsy: A Retrospective Study. Stem Cells Int. 2015;2015:325652.
- 4. Laskowitz DT, Bennett ER, Durham RJ, Volpi JJ, Wiese JR, Frankel M, Shpall E, Wilson JM, Troy J, Kurtzberg J. Allogeneic Umbilical Cord Blood Infusion for Adults with Ischemic Stroke: Clinical Outcomes from a Phase 1 Safety Study. Stem Cells Transl Med. 2018 May 12.

WHY USE UMBILICAL CORD BLOOD FOR THE TREATMENT OF ISCHEMIC STROKE?

The only currently available FDA-approved drug for acute ischemic stroke is intravenous tissue plasminogen activator (tPA). While tPA has markedly improved stroke care, it must be administered within a narrow time frame of no more than 4 - 6 hours, limiting its clinical utility. Less than 10% of stroke patients can benefit from such treatments due, in large part, to late referral to the hospital and an inability to meet other eligibility criteria including bleeding risk. ^(5,6)

Consequently, most of the patients are left with physical therapy and antiplatelet drugs such as aspirin in parallel with long-term nursing. All in all, the burden of stroke is felt by patients and their families across the globe.

Thus, while acute therapy exists, there is a distinct need for improved stroke recovery therapy. Numerous clinical trials conducted during the past two decades have tested a variety of pharmacological interventions to reduce tissue injury and improve functional outcomes following acute stroke, but their outcomes have not been as promising as desired. ⁽⁷⁻⁹⁾

In the past few years, promising research has been completed indicating the potential for therapeutic benefits from stem cell-based treatments for stroke victims. So far, more than 100 studies that have been listed by the National Institute of Health (NIH) show that there is a significant improvement in the recovery and rehabilitation processes for stroke victims. Clinical researchers suggest that stem cells can migrate to the injured area of the brain and help to repair and reduce neuronal damage – a major breakthrough in the medical treatment of stroke patients.

In comparison to other stem cell sources, umbilical cord blood stem cells offer improved plasticity and faster growth rates, are more immunologically tolerant, and are readily available without the need for invasive procedures in compromised patients. Moreover compared to other stem cell sources, umbilical cord blood also contains other therapeutic cells and important non-cellular paracrine factors including immunological and anti-inflammatory proteins and growth factors to support the formation of new neural connections ("neuroplasticity").

In June 2014, Duke University School of Medicine has been awarded \$15 million to explore the use of umbilical cord blood to treat stroke and other brain disorders like cerebral palsy and autism. In May 2018, this group published their latest breakthrough findings in a clinical trial showing that the intravenous infusion of non-HLA matched allogeneic, unrelated donor umbilical cord blood administered in adults after acute ischemic stroke is safe, well-tolerated, and feasible. Also, improvements in functional outcomes were observed in all participants by three months post-infusion. (10)

References:

- 5. Allen NB, Kaltenbach L, Goldstein LB, Olson DM, Smith EE, Peterson ED, Schwamm L, Lichtman JH. Regional variation in recommended treatments for ischemic stroke and TIA: Get with the Guidelines-Stroke 2003-2010. Stroke. 2012 Jul; 43(7):1858-64.
- 6. Demaerschalk BM. Alteplase treatment in acute stroke: Incorporating food and drug administration prescribing information into existing acute stroke management guide. Curr Atheroscler Rep 2016;18:53.
- 7. Heather Pagram, Andrew Bivard, Lisa F Lincz, Christopher Levi. Immunity and stroke, the hurdles of stroke research translation. International Journal of Stroke. 2017 Feb: Volume: 12 issue: 2: 123-131.
- 8. Veltkamp R, Gill D. Clinical trials of immunomodulation in ischemic stroke. Neurotherapeutics 2016;13:791-800.
- 9. Kidwell CS, Liebeskind DS, Starkman S et al. Trends in acute ischemic stroke trials through the 20th century. Stroke 2001;32:1349-1359.
- 10. Laskowitz DT, Bennett ER, Durham RJ, Volpi JJ, Wiese JR, Frankel M, Shpall E, Wilson JM, Troy J, Kurtzberg J: Allogeneic Umbilical Cord Blood Infusion for Adults with Ischemic Stroke: Clinical Outcomes from a Phase I Safety Study. Stem Cells Transl Med. 2018 Jul; 7(7): 521-529.

HOW DO UMBILICAL CORD BLOOD STEM CELLS DIFFER FROM OTHER SOURCES OF STEM CELLS?

Worldwide, allogeneic umbilical cord blood is being increasingly used as an alternative source of stem cells for cell therapy for malignant and non-malignant diseases. Especially in the past few years, it has proven great potential in regenerative medicine because it possesses many advantages in contrast to other sources of human stem cells like bone marrow and adipose fat.

Umbilical cord blood is readily available with very low potential for graft-versus-host disease (GVHD) and tumorigenicity as well as infectious complications. Therefore, only blood type must be matched comparable to normal blood transfusions, and definitely, no immunosuppression is required.

Moreover, umbilical cord blood is rich in diverse types of stem cells, mainly blood-forming stem cells, also known as "hematopoietic" stem cells (HSC), as well as mesenchymal stem cells (MSC). In addition, cord blood cells release high amounts of e.g. regenerative proteins and miRNA that signal the body and its affected cells to heal itself (paracrine effect).(11-14)

Over the past few years, infusions of umbilical cord blood have been intensively used around the world as therapy for infants with cerebral palsy and /or perinatal stroke. Published studies have shown that umbilical cord blood stem cells benefit young children with neurologic injury and with almost no adverse effects.

In the United States, umbilical cord blood cells have been used in clinical trials for adults with stroke, and more trials are planned for spinal cord injury, and degenerative diseases such as multiple sclerosis, autism, rheumatoid arthritis, inflammatory bowel disease, and metabolic diseases like diabetes. (12-13)

References:

- 11. Kurtzberg J. 2014; Presentation at ISCT meeting; https://parentsguidecordblood.org/en/faqs/how-are-cordblood-stem-cells-different-other-sources-stem-cells.
- 12. Reddi AS1, Kuppasani K, Ende N.; Human umbilical cord blood as an emerging stem cell therapy for diabetes mellitus. Curr Stem Cell Res Ther. 2010 Dec;5(4):356-61.
- 13. Sun JM, Grant GA, McLaughlin C, Allison J, Fitzgerald A, Waters-Pick B, Kurtzberg J.; Repeated autologous umbilical cord blood infusions are feasible and had no acute safety issues in young babies with congenital hydrocephalus. Pediatr Res. 2015 Dec;78(6):712-6.
- 14. Park SJ, et al.; Tumorigenicity Evaluation of Umbilical Cord Blood derived Mesenchymal Stem Cells. Toxicol Res. 2016 Jul;32(3):251-8.

DO PATIENTS NEED TO PROVIDE THEIR OWN BLOOD?

One of the primary benefits of CBC Health's process is that the patient does not need to provide autologous (self-derived) stem cells. Instead, patients have access to cord blood sourced from one of Europe's most reputable cord blood providers, Cord Blood Center Group.

Perhaps Joanne Kurtzberg, MD of Duke University says it best: "I predict that the use of cord blood cells, in both autologous and allogeneic settings, as cellular therapies in the emerging field of regenerative medicine...will emerge as one of the major great advances in novel therapeutics in medicine over the next decade." (15)

Reference:

15. "A History of Cord Blood Banking and Transplantation." Stem Cells Translational Medicine, 3/29/17.

WHAT TYPE OF EXPERIENCE DOES CBC HEALTH HAVE IN REGENERATIVE HEALTH?

For more than twenty years, our founding company, Cord Blood Center Group (CBCG) has recorded many firsts in regenerative health. In 1997, CBCG was among the first in Europe to process and prepare cord blood for regenerative transplants. CBCG was one of the first companies in Europe to collect, process and store cord blood, cord tissue and placenta tissue with over 170,000 clients. These individuals may benefit from the regenerative effect of their cord blood in the future. Slovak placental stem cell registry, a CBCG company, was among the first in Europe to establish a registry and repository for storing personal cord blood and a repository for donated cord blood which can be used for regenerative treatments for the general population.

CBC Health directly benefits from CBCG's knowledge base. CBCG is leading the way as a regenerative health company with a solid foundation of licensed laboratories and storage facilities. The company has active branches in Switzerland, Austria, Slovakia, Italy, Romania, Hungary, Czech Republic and is expanding into new markets. Slovak placental stem cell registry is a member of the international bone marrow and cord blood donors database. It is connected to the EMDIS, the international exchange network, and it is an associate member of other prestigious international organizations that set quality standards for cord blood products, such as The World Marrow Donor Association (WMDA).

CBC Health will always be at the forefront of regenerative health science. Our founding partner CBCG is directly involved in pushing the envelope for regenerative health by supporting regenerative clinical research. It has managed clinical regenerative health studies in the European Union that focus on the use of a child's own cord blood to treat cerebral palsy. View Studies Here.

Since 2012, CBCG has conducted and /or participated in research projects and clinical trials aimed to help people find therapies for diseases that have no cure today, like the treatment of cerebral palsy and ischemic stroke. CBCG has also participated in clinical studies at leading medical institutions like Duke University Hospital in the USA. CBCG is building a better future for all as it strives to be a best-in-class company for regenerative health. CBC Health plans to follow in CBCG's footsteps, one satisfied patient at a time.

HOW DOES THE GERMAN HEALTHCARE SYSTEM COMPARE TO THAT OF THE U.S.?

German hospitals and medical clinics receive high ratings for efficiency and quality of care. According to the 2017 Legatum Prosperity Index, the German health care system was ranked No. 11 in the world. The United States was ranked No. 30.

Germany's Health Care Index (HCI) rating of 74.88 places it at No. 14 among all nations. The U.S. is No. 32. The HCI rating includes a wide range of categories including the reach of healthcare infrastructure, efficiency, quality, outcomes, and innovation.

CBC Health's day-clinic in Munich, Germany is a world-class facility designed to meet or exceed Germany's high standards of safety, cleanliness, and efficiency.

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IS CBC HEALTH'S CORD BLOOD TREATMENT FOR ISCHEMIC STROKE SAFE?

In May 2018, a phase I open-label safety study at Duke University in North Carolina presented the latest breakthrough findings by showing that simple intravenous infusion of non-HLA matched allogeneic, unrelated donor umbilical cord blood in adults after acute ischemic stroke is safe, well tolerated, and feasible.

Patients were observed more than 12 months after receiving the umbilical cord blood infusion, and no signs of Severe Adverse Events (SAE) related to the infusion were detected, especially no signs for graft-versus-host disease (GVHD). The only related symptoms which have been noted were moderate pruritus right after infusion. These adverse events generally disappear in a short period of time.

Even more, in another retrospective safety study in 2015 on young patients with severe cerebral palsy, the allogeneic umbilical cord blood treatment caused no adverse event related to the intravenous application modus. All in all, umbilical cord blood treatment is easily available with a very low potential for graftversus-host disease and tumorigenicity as well as infectious complications. Therefore, only blood type must be matched as in normal blood transfusions, and no immunosuppression is required. (16,77)

However, in the general medical literature, the following rare adverse events have been related to the umbilical cord blood infusion:

- **+** Constipation
- **+** Diarrhea
- Pruritus
- + Urticaria
- + Headache
- **+** Dizziness
- + Allergic reactions
- + Hypertension
- **+** Varied tastes
- **+** Mild upper respiratory tract infection
- **+** Hypotension

Many of these reactions are only short-term and mostly related to DMSO (Dimethylsulfoxide), a cryoprotective agent that is dissolved rapidly in your body. Therefore, the pre-medication before the umbilical cord blood treatment reduces the frequency as well as the intensity of these symptoms.

The risk of bacterial and/or viral infections (HIV, hepatitis B/C, CMV, syphilis, vCJD, etc.) transferred via umbilical cord blood by the donor is extremely low and comparable to the rates of common blood products.

References:

- 16. Feng M, Lu A, Gao H, Qian C, Zhang J, Lin T, Zhao Y. Safety of Allogeneic Umbilical Cord Blood Stem Cells Therapy in Patients with Severe Cerebral Palsy: A Retrospective Study. Stem Cells Int. 2015;2015:325652.
- 17. Laskowitz DT, Bennett ER, Durham RJ, Volpi JJ, Wiese JR, Frankel M, Shpall E, Wilson JM, Troy J, Kurtzberg J: Allogeneic Umbilical Cord Blood Infusion for Adults with Ischemic Stroke: Clinical Outcomes from a Phase I Safety Study. Stem Cells Transl Med. 2018 Jul; 7(7): 521-529.

WHAT QUALIFIES A PATIENT FOR CBC HEALTH'S CORD BLOOD TREATMENT FOR ISCHEMIC STROKE?

The following criteria make you eligible for our umbilical cord blood treatment and should be individually discussed with our medical doctors and/or your doctor of trust:

- **★** 18-90 years old
- + Recent, acute, cortical, hemispheric, ischemic stroke without a clinically significant midline shift as detected by latest MRI
- ◆ Patient must be transportable to Munich, Germany after medical assessment
- ♣ Blood count: platelet count >100,000/µL, hemoglobin >10mg/dL, and WBC >2,500/µL
- + Patients who received tPA or underwent endovascular reperfusion are in general eligible, too
- + Patient must be able to provide consent to treatment
- + Patient has no disease or therapy that compromises current immune functions
- + CBC Health reserves the right to make the final decision of umbilical cord blood treatment by our experienced medical doctors after their thorough evaluation

WHAT DISQUALIFIES A PATIENT FOR CBC HEALTH'S CORD BLOOD TREATMENT FOR ISCHEMIC STROKE?

The following criteria exclude you from our umbilical cord blood treatment:

- + A severe pre-existing deficit
- + A severe psychiatric impairment
- + Evidence of significant midline shift as assessed by CT or MRI
- + Significant ongoing hemorrhage associated with stroke
- + The requirement of mechanical ventilation or craniotomy
- ◆ Not transportable to Munich, Germany after medical assessment
- + Active systemic infection
- + Acute organ failure (e.g. liver, kidney, heart, lung)
- + History of or currently active autoimmune disease
- + Recipient of bone marrow or organ transplant
- + History of severe transfusion reaction
- + Pregnancy or lactating woman
- ♣ Concurrent illness or condition that in the opinion of the Investigator might interfere with treatment or evaluation of safety

ARE THERE RISKS OF ADVERSE EFFECTS FROM CBC HEALTH'S CORD BLOOD TREATMENT FOR ISCHEMIC STROKE?

Over the past 25 years, more than 35,000 cord blood infusions have been administered worldwide. As with any medical treatment, there is always a risk of a reaction, but the odds are extremely low.

Through clinical advancements in infusion blood screening, technology has reduced the chance of infection from donated blood to almost negligible levels. Furthermore, thanks to the placental barrier, cord blood is so pristine that it is 300,000 times less likely to be contaminated than blood infused from adult donors.

The umbilical cord blood units are selected from the CBCG, Europe's second largest private cord blood bank with almost 20 years of experience. Selection is based on blood type and race, provided they satisfy the following criteria:

- ♣ A targeted cell dose of more than 5.0 x 10^7 per kg of body weight. Viability of \geq 95 %
- **★** Sterility cultures that were negative for growth
- ◆ Negative testing of maternal blood for hepatitis B (HBsAg, anti-HBc), hepatitis C antibody, human immunodeficiency virus (HIV)-I and HIV-2 antibodies, human T cell lymphotropic virus (HTLV-1 and HTLV-2) antibodies, and syphilis
- ◆ Mothers who may have been exposed to vCJD aren't eligible for umbilical cord blood donation

The umbilical cord blood units and its containing cells are wider and more deeply screened for bacteria and viruses in comparison to common blood products such as red blood cells and/or platelets.

RISK OF INFECTIONS VIA COMMON BLOOD TRANSFUSIONS

In the following, we provide the risk of infections via common blood transfusion according to the National Heart, Lung and Blood Institute (NHLBI), Bethesda, MD, USA (18)

- + HIV. Your risk of getting HIV from a blood transfusion is lower than your risk of getting killed by lightning. Only about 1 in 2 million donations might carry HIV and transmit HIV if given to a patient
- ♣ Hepatitis B and C. The risk of having a donation that carries hepatitis B is about 1 in 205,000. The risk for hepatitis C is 1 in 2 million
- + Variant Creutzfeldt-Jakob disease (vCJD). This disease is the human version of Mad Cow Disease. It's a very rare, yet fatal brain disorder. There is a possible risk of getting vCJD from a blood transfusion, although the risk is very low. Because of this, people who may have been exposed to vCJD aren't eligible umbilical cord blood donors

Reference:

18. https://www.nhlbi.nih.gov/health-topics/blood-transfusion.

IS CBC HEALTH'S CORD BLOOD TREATMENT FOR **ISCHEMIC STROKE COVERED BY INSURANCE?**

So far, for most insurance plans, umbilical cord blood treatment or stem cell treatment aren't covered services for the treatment of stroke patients.

The future intention of CBC Health is to make umbilical cord blood treatment accessible for all U.S. based health insurance plans.

HOW IS CBC HEALTH'S CORD BLOOD TREATMENT FOR ISCHEMIC STROKE ADMINISTERED?

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

CBC Health physicians will carefully review and assess all pertinent patient data including past medical history, risk factors, date and extent of ischemic stroke, present condition, medications, transportability, etc.

DAY 1 - ARRIVAL AND PERSONAL EVALUATION

On arrival in our CBCHealth MedMunich's day-clinic in Munich, Germany, final clarifications and information is given, followed by thorough clinical evaluation including anamnesis, physical examination, and blood analysis.

DAY 2 & 3 - TREATMENT

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

A peripheral IV is used to administer the allogeneic umbilical cord blood over a period of usually less than three hours per each day under direct physician supervision. We use an intravenous route of administration of the umbilical cord blood, as this is the least invasive and safest. After the infusion has been administered, the patient vitals will be monitored prior to release.

DAY 4 - FINAL PHYSICAL EXAMINATION AND RELEASE

The day after the umbilical cord blood infusions the doctors will perform a final physical evaluation prior to being released. Follow-up information will be provided to the patient, along with medical documentation.

WHAT OTHER MEDICATIONS OR SPECIAL CARE IS NEEDED FOR CBC HEALTH'S CORD BLOOD TREATMENT FOR ISCHEMIC STROKE?

To reduce the risk of an allergic reaction, patients are routinely pre-medicated about 30 minutes before the umbilical cord blood infusion, e.g. with:

- + Diphenhydramine
- + Hydrocortisone
- + Acetaminophen

Antihypertensive medication is available at the patient's bedside because of the potential risk that hydrocortisone and residual dimethyl sulfoxide (DMSO) in the cell product would elevate blood pressure. Also, the patient receives IV hydration of normal saline for approx. I hour after the umbilical cord blood infusion.

THE DAY OF TREATMENT

The day of treatment, urine output is monitored, and vital signs (heart rate, blood pressure, temperature, respiratory rate, oxygen saturation) are measured shortly before the umbilical cord blood infusion, every 5 minutes during the infusion, every 15 minutes for the first hour, and every 30 minutes for the following 2 hours after infusion.

If necessary, the patient will be closely monitored for up to 24 hours in the day-clinic. A close follow-up examination is routinely performed 24 hours after the application of the umbilical cord blood infusion.

We also recommend a neurological examination at 3, 6, and 12 months to assess functional outcome.

HOW LONG WILL IT TAKE FOR STROKE SYMPTOMS TO IMPROVE?

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In most cases, it can take up to three months before symptoms improve. As with any medical procedure, there is also the risk that a patient will not experience any improvement in his or her symptoms.

Clinical trials with children have shown that therapeutic effects aren't achieved in all children, and those therapeutic improvements are achieved only with a high dose of cells. CBC Health is noted for providing high-quality therapeutic components with above-average quantities of nucleated cells.

In a recent clinical trial on stroke conducted at Duke University, all patients showed improvement when treated with a high dose of cord blood cells. (19)

Reference:

19. Laskowitz DT, Bennett ER, Durham RJ, Volpi JJ, Wiese JR, Frankel M, Shpall E, Wilson JM, Troy J, Kurtzberg J. Allogeneic Umbilical Cord Blood Infusion for Adults with Ischemic Stroke: Clinical Outcomes from a Phase 1 Safety Study. Stem Cells Transl Med. 2018 May 12. doi: 10.1002/sctm.18-0008.

HOW SOON AFTER AN ISCHEMIC STROKE CAN A PATIENT RECEIVE CBC HEALTH'S CORD BLOOD TREATMENT?

Clinical trials indicate that the sooner umbilical cord blood treatments are administered, the better. In a 2018 clinical trial at Duke University Hospital, umbilical cord blood treatments were administered within 3-10 days following an acute ischemic stroke without any adverse effects. (20)

So how long after an ischemic stroke can an umbilical cord blood infusion be effective? More research is needed, but there is the case of a girl whose brain was injured at birth. She had a stroke and presented symptoms of cerebral palsy. At the age of five, her parents requested that she be administered an autologous stem cell infusion. After three months, her cognitive and physical condition had improved dramatically. By the age of eleven, she had become an excellent student, pianist, equestrian, and swimmer. She displayed only minor neurological symptoms on her right side. (21)

References:

- 20. Laskowitz DT, Bennett ER, Durham RJ, Volpi JJ, Wiese JR, Frankel M, Shpall E, Wilson JM, Troy J, Kurtzberg J: Allogeneic Umbilical Cord Blood Infusion for Adults with Ischemic Stroke: Clinical Outcomes from a Phase I Safety Study. Stem Cells Transl Med. 2018 Jul; 7(7): 521-529.
- 21. A. Jensen and E. Hamelmann, "First Autologous Cord Blood Therapy for Pediatric Ischemic Stroke and Cerebral Palsy Caused by Cephalic Molding during Birth: Individual Treatment with Mononuclear Cells," Case Reports in Transplantation, vol. 2016, Article ID 1717426, 9 pages, 2016.

CAN AN ISCHEMIC STROKE PATIENT UNDERGO CBC HEALTH'S CORD BLOOD TREATMENT MULTIPLE TIMES?

The safety and efficacy of umbilical cord blood infusions were studied in children diagnosed with cerebral palsy and associated neurological complications. Patients received up to six intravenous infusions. Multiple intravenous infusions of allogeneic umbilical cord blood may be a safe and effective

4

Cord blood treatments for ischemic stroke will not interfere with your current cognitive or physical rehabilitation therapies. As more treatment data becomes available, some researchers feel that umbilical cord blood treatment could become a complementary procedure. It is the only treatment that provides a structured defense against the injury mechanisms of an ischemic stroke:

+ Cell Regeneration (Neurogenesis)

intervention in most cases.

- ★ Neurotrophism (Neurotrophicity)
- + Immune Protection (Neuroprotection)
- ♣ Anti-Inflammation Protection

CBC HEALTH'S TREATMENT OFFERS NEW HOPE

FOR STROKE SURVIVORS

Call +49 1525 2012 111 to Learn More

STEP BY STEP GUIDE TO ISCHEMIC STROKE RECOVERY



CONTACT US

If you or a loved one are interested in learning more about CBC Health's ischemic stroke recovery options or need more information, our medical team is here to help!

- + Fill out a contact form on our website
- + Call CBC Health at: +49 1525 2012 111
- + Email CBC Health: info@cbchealth.de

SEND US YOUR MEDICAL INFORMATION

For your convenience, you can email us your recent medical evaluations to info@cbchealth.de. All patient information will be stored securely and reviewed by the CBC Health medical team.

MEDICAL REVIEW, COSTS & TREATMENT OPTIONS

CBC Health's medical team will review your medical information and determine if you can benefit from an umbilical cord blood treatment. Additional information or testing may be required before scheduling treatment.



STEP

REVIEW AND SCHEDULE YOUR TREATMENT APPOINTMENT

Once CBC Health's medical team has the necessary information, you will be given customized treatment options, detailed costs, and be assigned a medical concierge staff member who will guide you and your loved ones through the rest of the process.

If you have been qualified to enter the experimental treatment program, your assigned medical concierge will work with you, your family and your local doctor to determine when to begin the treatment process.

You will receive detailed information about the treatment. As your medical concierge discusses the consent form with you, please ask him or her to explain any words or information that you do not clearly understand. Your informed consent is necessary to move ahead with the treatment.

TRAVEL ARRANGEMENTS & PREPARATIONS

Your medical concierge will work with you and your loved ones to help arrange travel and accommodations. CBC Health has a network of hospitality, transportation and tourism partners that are qualified to serve medical patients.

STEP

CORD BLOOD ISCHEMIC STROKE TREATMENT

Once you have been admitted to CBCHealth MedMunich's day-clinic, you will be under the care of our fully qualified doctors and experienced medical staff. If you and anyone accompanying you have informed us in advance of any special needs, our team will seek to meet those needs completely. Here is an overview of the course of treatment:

- Day 1: Initial Screening & Testing
- Day 2 & 3: Treatment & Routine Monitoring
- Day 4: Final Physical Exam & Release



VIABLE CELL COUNTS

Superior collection and screening techniques guarantee sample viability and delivery of the highest number of cells per unit in the industry.

SINGLE SOURCE CONTROL

All cells and tissues are harvested, stored and processed for transfusion under one company - reducing chance of cross contamination and ensuring the highest quality sample is delivered to the patient.

QUALITY ASSURANCE

Every sample undergoes stringent quality control testing to ensure the safety, identity and quality of each sample.

ETHICALLY SOURCED

Each umbilical cord blood sample is harvested voluntarily from informed, willing donors for use in medical treatments and studies.

CLINICAL EXPERTISE

With over 20 years of experience and over 170,000 individual units collected, CBC Health's continues to be pioneer in the umbilical cord blood banking industry.











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