

Retrospective chart review study of umbilical cord stem cell therapy for stroke

Submission date 14/06/2019	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 09/07/2019	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 15/07/2020	Condition category Circulatory System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Stroke is a leading cause of adult disability worldwide and the second highest cause of death in the world. To date, there are no clinically effective pharmacotherapies that can promote or facilitate cellular functional recovery after an ischemic stroke. Human umbilical cord blood cell therapy is a promising treatment for ischemic stroke. The current retrospective chart review study is aimed to analyze the impact of human umbilical cord blood mononuclear cell therapy on mobility and muscle strength of upper and lower extremities, and neurological function in subjects with ischemic and hemorrhagic stroke.

Who can participate?

Adult subjects with ischemic and hemorrhagic stroke who were treated with human umbilical cord blood mononuclear cells in the Wuhan Hongqiao Brain Hospital Co., Ltd. (Wuhan, Hubei) between March 2009 and March 2012, were included in the study.

What does the study involve?

Fifty patients with Sequelae of cerebrovascular hemorrhage and CVA (Stroke) Sequelae will be randomly selected from 96 patients treated with hUCBSCs at the Wuhan Hongqiao Brain Hospital Co., Ltd. (Wuhan, Hubei) between March 2009 and March 2012. Another fifty patients with stroke, who received only traditional therapy and no stem cell therapy, will be included as the control group. Data collection will include: base-line characteristics of research subjects, adverse events specification after therapy, physical examination results pre- and post-therapy, including mobility of upper and lower extremities, neurological function, and muscle strength of upper and lower limbs. Data analysis will include analysis of mobility, muscle strength of upper and lower extremities and neurological function pre- and post-therapy in stem cell and conventional therapy group; correlation between initiation of stem cell treatment and effectivity of treatment; correlation between stem cell infusion/injection strategy and effectivity of treatment.

What are the possible benefits and risks of participating?

Possible benefits: improvement of post-stroke symptoms, particularly the improvement of mobility and muscle strength of upper and lower extremities, and neurological function. hUCMNC therapy could ameliorate one's symptoms to a certain extent; however potential

curative effects will differ based on individual characteristics. Some subjects could be totally back to their normal lives.

Possible risks: approximately 1% of subjects experience a low-grade fever, headache or post-transplantation excitation all of which, generally, spontaneously remit in 24 to 48 hours.

Where is the study run from?

1. BHI Therapeutic Sciences (214 State Street, Hackensack, NJ, USA)
2. Wuhan Hongqiao Brain Hospital Co., Ltd (Wuhan, China)

When is the study starting and how long is it expected to run for?

January 2017 - February 2019

Who is funding the study?

BHI Therapeutic Sciences

Who is the main contact?

Dr Marine Manvelyan,
mmanvelyan@bluehorizoninternational.com

Contact information

Type(s)

Scientific

Contact name

Dr Marine Manvelyan

ORCID ID

<https://orcid.org/0000-0002-8202-0341>

Contact details

214 State Street Ste 101
Hackensack
United States of America
07601
2013427662
mmanvelyan@bluehorizoninternational.com

Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

00110

Study information

Scientific Title

Retrospective chart review study of Umbilical Cord Blood Stem Cell (UCBSC) transplantation for sequelae of CVA (Cerebral Vascular Accident, Stroke)

Study objectives

The study aimed to analyze the impact of human umbilical cord blood mononuclear cell therapy on mobility and muscle strength of upper and lower extremities, and neurological function in subjects with ischemic and hemorrhagic stroke

Ethics approval required

Old ethics approval format

Ethics approval(s)

The retrospective chart review study was approved 03/02/2017, Institute of Regenerative and Cellular Medicine Institutional Review Board (1301 20th St., Suite #530, Santa Monica, CA 90404, USA; +1(888) 664-8893; jpfaber@ircm.org), ref: IRCM-2017-135

The study in which the original data was collected was approved 30/06/2009, Ethics Committee of Wuhan Hongqiao Brain Hospital (Jiang'an District, Wuhan Development Avenue No. 387-393, Wuhan, China, 430071; 86-18207143738; bcdcwu@hotmail.com), ref: HQNK-2009-0630

Study design

Case-control retrospective analysis

Primary study design

Observational

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Ischemic and hemorrhagic stroke

Interventions

For the retrospective chart review study, 50 patients with Sequelae of cerebrovascular hemorrhage and CVA (Stroke) Sequelae will be randomly selected from patients treated with hUCBSCs at the Wuhan Hongqiao Brain Hospital Co., Ltd. (Wuhan, Hubei) between March 2009 and March 2012. Another 50 patients with stroke, who received only traditional therapy and no stem cell therapy, will be included as the control group.

97 subjects with ischemic and hemorrhagic stroke, treated with human umbilical cord blood mononuclear cells in the Wuhan Hongqiao Brain Hospital Co., Ltd. (Wuhan, Hubei) between March 2009 and March 2012. Subjects received three administrations of 5 ml human umbilical cord blood mononuclear cells (3×10^8) isolated from human umbilical cord blood of three different donors. Treatment was conducted in three sessions that included intrathecal (IT), intravenous (IV) and the combination of IT plus IV (IT+IV) administrations. Different treatment modalities were applied to subjects: one IV and two IT+IV administrations; two IV and one IT+IV administration; three IV administrations; three IT+IV administrations. The interval between

administrations was 7-14 days. Selection of the treatment modality was based on the ability of the subject to tolerate IT injection. Subjects, unable to tolerate IT injection, received three IV or one IT+IV plus two IV administrations.

Chart records are located at the Wuhan Hongqiao Brain Hospital Co., Ltd. (Wuhan, Hubei) and BHI Therapeutic Sciences (214 State Street, Hackensack, NJ 07601). Charts were reviewed, and information regarding subjects' demographics, cell therapy modality and stroke assessment scales results (baseline and 12 weeks post-therapy) were collected in the data collection forms.

Intervention Type

Biological/Vaccine

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Human umbilical cord blood mononuclear cells (hUCBMNCs)

Primary outcome(s)

The incidence of adverse events (AEs), including vital signs and physical examination findings (baseline to 12 weeks post first intravenous/intrathecal administration) as assessed by adverse events questionnaires.

Key secondary outcome(s)

Changes in stroke assessment scales developed by Wuhan Hongqiao Brain Hospital (baseline to 12 weeks post first intravenous/intrathecal administration):

1. Upper extremity mobility 3/0 scale (3 = able to make a fist, eat independently, carry heavy weights and realize normal activities; 0 = high muscle tension, not able to bend independently, eat and realize other normal activities)
2. Lower extremity mobility 3/0 scale (3 = able to walk with or without help; 0 = high muscle tension, not able to move independently, stay and walk)
3. Neurological function (ability to speak) was graded on a 5/0 scale (5 = conscious, able to speak clearly; 0 = deep coma/mild coma/light coma-like/unconscious, unable to open eyes and speak)
4. Upper and lower extremity muscle strength 5/0 scale (5 = normal motor function; 0 = total paralysis)
5. Neurological function (urination) 1/0 scale (1 = urinates via a catheter; 0 = urine incontinence)
6. Neurological function (bowel function) 1/0 scale (1 = normal bowel function; 0 = stool incontinence)

Completion date

12/12/2020

Eligibility

Key inclusion criteria

1. >18 years old
2. Diagnosis of ischemic stroke
3. Admitted to Wuhan Hongqiao Brain Hospital Co., Ltd between March 2009 and March 2012

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Total final enrolment

97

Key exclusion criteria

1. Incomplete records of subjects' follow-up evaluation

Date of first enrolment

06/02/2017

Date of final enrolment

01/12/2018

Locations

Countries of recruitment

China

United States of America

Study participating centre

Wuhan Hongqiao Brain Hospital Co., Ltd

Jiang'an District

Wuhan Development Avenue

No. 387-393

Wuhan

China

430071

Study participating centre

Mehling Orthopedics

214 State Street

Hackensack
United States of America
07601

Sponsor information

Organisation

BHI Therapeutic Sciences

Funder(s)

Funder type

Industry

Funder Name

BHI Therapeutic Sciences

Results and Publications

Individual participant data (IPD) sharing plan

All data generated or analysed during this study will be included in the subsequent results publication.

IPD sharing plan summary

Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file		18/01/2017	11/07/2019	No	No