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

Submission date	**Recruitment status**	[_] Prospectively registered
14/06/2019	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
09/07/2019	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
15/07/2020	Circulatory System	[_] 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,
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Case-control study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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 measure
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.

Secondary outcome measures
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)

Overall study start date
03/02/2017

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
97

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
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07601

Sponsor information

Organisation
BHI Therapeutic Sciences

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Sponsor type
Research organisation

Funder(s)

Funder type
Industry

Funder Name
BHI Therapeutic Sciences

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
11/01/2020

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