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Autologous intra-carotid arterial transfusion of peripheral blood stem cells improves brain ischemia and reperfusion in patients with chronic stroke

Submission date
11/04/2016

Recruitment status
No longer recruiting

Registration date
28/06/2016

Overall study status
Ongoing

Last Edited
06/06/2024

Condition category
Circulatory System

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Stroke is a leading cause of death and disability worldwide, and is the third highest cause of death in Taiwan. About 85% of strokes are ischemic strokes. Ischemic strokes happen when the arteries that supply the brain with oxygen (the carotid arteries) become narrowed (stenosis) or blocked (occluded) by a sticky substance called plaque that builds up on the artery walls (atherosclerosis), causing reduced blood flow (ischemia) to the brain. Atherosclerosis in the carotid arteries is one of the biggest causes of recurrent stroke, and so reducing carotid stenosis is an important part of stroke prevention. There is growing evidence that stem cell therapy using endothelial progenitor cells (EPCs) (stem cells from bone marrow) can help to regenerate the lining of blood vessels. Previous studies have shown that increasing levels of EPCs circulating in the blood is related to improvement in the recovery of those with ischemic stroke. Currently, there is little research looking at the safety and effectiveness of using EPC therapy for treating ischemic stroke. The aim of this study is to find out whether ECP therapy is an effective treatment for patients with brain ischemia following an ischemic stroke.

Who can participate?
Adults aged between 45 and 80 who had an ischaemic stroke at least six months ago.

What does the study involve?
All participants receive eight injections of granulocyte-colony stimulating factor (a protein which stimulates the bone marrow to produce stem cells and release them into the bloodstream) every 12 hours for four days. On the fifth day, patients have a tube placed into the right femoral vein (main vein in the thigh) so that circulating EPCs can be collected. These EPCs are then injected back into the patients into the internal carotid artery (in the neck). Patients are then followed up for five years through a combination of interviews and medical record reviews, in order to find out how effective the treatment has been.

What are the possible benefits and risks of participating?
Participants may benefit from improvement to their disability. There are risks of side effects from the EPC therapy, including deterioration of brain function, recurrent stroke, heart problems, blockage of arteries, bleeding, anemia, deterioration of kidney function, gastrointestinal (gut) complications, electrolyte (minerals in the body) imbalance, sepsis (blood poisoning) and cancer.

Where is the study run from?
Kaohsiung Chang Gung Memorial Hospital (Taiwan)

When is the study starting and how long is it expected to run for?
January 2014 to July 2026

Who is funding the study?
National Science Council (Taiwan)

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
Autologous intra-carotid arterial transfusion of peripheral blood stem cells (PBSC) improves brain ischemia and reperfusion – A safety and tolerability study

Study objectives

Peripheral Blood Stem Cells transplantation for the patients with brain ischemia may be a more effective therapy than traditional drug therapy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Chang Gung Memorial Hospital, 24/11/2015, ref: 104-6798C

Study design
Prospective single-centre non-randomised study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Chronic ischemic stroke

Interventions
All participants receive eight granulocyte-colony stimulating factor (G-CSF) injections of 5 μg/kg sc q12h over a course of four days after admission and endothelial progenitor cell (EPC) collection at day 5 for 3 hours from double lumen sheath inserted from right femoral vein using a machine (COBE Spectra 6.1). The collected EPC will be immediately transfused back to patients themselves with a dose of 3x10(7) EPC once through internal carotid artery of infarct side using a 6F JR catheter through left radial arterial sheath. The participants will be followed up at Neurology and Cardiovascular outpatients clinic for safety and efficacy monitoring for 5 years.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Safety and tolerability of intracarotid artery autologous endothelial progenitor cells injection is measured through patient interviews and reviewing medical records throughout the five years of the study

Key secondary outcome(s))
1. Recurrent stroke or death rate is measured by reviewing medical records at 90 days
2. Disability is measured using the modified Rankin Scale score, Barthel Index WAIS-III and CASI National Institutes of Health Stroke Scale (NIHSS) at 24 hours, 72 hours, 30 days and 90 days
3. Brain reperfusion status is measured using Magnetic resonance imaging (Arterial Spin Labeling (ASL) and Dynamic Contrast Enhancement) at 24-72 hours post-therapy and 90 days
4. Brain perfusion defects are evaluated using radionuclear medicine image (brain Tc-99m scan) 24-72 hours post therapy and 90 days
5. Adverse event rate is measured through patient interviews and reviewing medical records at 5 years

Completion date

31/07/2026

Eligibility

Key inclusion criteria
1. Aged between 45 and 80 years
2. Chronic ischemic stroke (onset more than 6 months ago) over middle cerebral artery territory (NIHSS score 9-16)
3. Not suitable for surgery or carotid artery stenting

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
28

Key exclusion criteria
1. Age less than 45 years old or more than 80 years old
2. Patients received t-PA and anticoagulation
3. Non-middle cerebral artery territory stroke or hemorrhagic stroke
4. Pregnant women
5. Patients with adventitious agents (like HIV virus)
6. Myocardial infarction (MI) within 3 months
7. Severe aortic stenosis or mitral stenosis
8. Congestive heart failure, New York Heart Association functional class (NYHA Fc.)IV
9. Malignancy or other severe disease with life span less than one year
10. Chronic kidney disease with CCr<20ml/min and end stage renal disease
11. Join other clinical trials
12. Patients can not receive regular follow-up
13. Other brain disease (tumor, degenerative disease, infective disease)

Date of first enrolment
01/01/2016

Date of final enrolment
31/12/2019

Locations

Countries of recruitment
Taiwan

Study participating centre
Kaohsiung Chang Gung Memorial Hospital
123, Ta Pei Road Niao Sung District
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Sponsor information

Organisation
National Science Council

ROR
https://ror.org/02kv4zf79

Funder(s)

Funder type
Government

Funder Name
National Science Council

Alternative Name(s)
National Science Council, Taiwan, National Science Council of Taiwan, NSC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Taiwan

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Data sharing statement to be made available at a later date