Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Jun 2026

Evaluation of safety of mitochondrial transplantation extracted from platelets in brain ischemic stroke: Clinical trial Phase I

Protocol summary

Study aim

Evaluation of mitochondrial transplantation on mortality in patients with cerebral ischemia after transplantation Evaluation of mitochondrial transplantation on the incidence of cerebral hemorrhage after transplantation Evaluation of mitochondrial transplantation on the incidence of post-transplant brain cancer Evaluation of mitochondrial transplantation on systemic complications such as heart disease, seizures, worsening of the patient and increase in NIHSS index after mitochondrial transplantation

Design

Randomized with control, parallel and blinded study on 10 patients. Clinical trial I

Settings and conduct

This clinical trial will be performed on 10 brain stroke patients in Poursina Hospital in Rasht. The study is blinded.

Participants/Inclusion and exclusion criteria

-Patients who have recently had a stroke and have not had a stroke for more than 24 hours are selected. - Patients from both sexes and over 40 years are selected. -Patients who able to fill the informed consent of the research project. Exclusion criteria - Patients with mitochondrial disorders. -Patients who are in a coma and have score 1 or 2 according to the NIHSS criteria to assess the level of consciousness. -Aphasis -Inability or unwillingness of the individual or legal guardian / representative to provide informed written consent Patients who do not participate/collaborate to follow up

Intervention groups

In this study, patients are divided into control groups and mitochondrial groups. The control group will receive only respiratory buffer solution that does not contain mitochondria. Treatment group will receive the mitochondria extracted from mitochondria.

Main outcome variables

Mortality rate Bleeding rate adverse side effects The incidence of cancer

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210212050334N1**
Registration date: **2021-02-16, 1399/11/28**
Registration timing: **prospective**

Last update: **2021-02-16, 1399/11/28**
Update count: **0**

Registration date

2021-02-16, 1399/11/28

Registrant information

Name

Amaneh Mohammadi Roushandeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 13 3333 1520

Email address

mohammadi_roushandeh@gums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-04-03, 1400/01/14

Expected recruitment end date

2021-12-20, 1400/09/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of safety of mitochondrial transplantation extracted from platelets in brain ischemic stroke: Clinical trial Phase I

Public title

Evaluation of safety of mitochondrial transplantation extracted from platelets in brain ischemic stroke: Clinical trial Phase I

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

-Patients who have recently had a stroke and have not had a stroke for more than 24 hours are selected . .- Patients from both sexes and over 40 years are selected. -Patients who able to fill the informed consent of the research project. The text of the consent form with full explanation of the nature and purpose of this study must be signed by the patient or their supervisor or legal representative. For example, if a patient fails to sign a consent form in case of confusion or loss of consciousness, it is the responsibility of a close relative Negative pregnancy test for women who are at reproductive age. -- Clinical diagnosis of stroke in patients using computed tomography (CT) or magnetic resonance imaging Brain MRI + DWI (MRI) show acute ischemia in the right middle cerebral artery. - Patients are evaluated and scored according to the National Stroke Institute (NIHSS) scale. Accordingly, patients who get a score of 8 to 20 on this scale will be selected.

Exclusion criteria:

- Patients with mitochondrial disorders. -Patients who are in a coma and have score 1 or 2 according to the NIHSS criteria to assess the level of consciousness. -Aphasia - Imaging of patients' brain using CT scan and MRI that may show signs of tumor, cerebral edema, increased intraventricular pressure, intracerebral hemorrhage, or cerebral infarction. -Patients who currently have and/ or had a history of drug or alcohol abuse are excluded from the study. -Patients with active infectious diseases, including HIV, hepatitis B and C, are excluded from the study. -Patients with dementia. -Patients participating in another clinical trial. Any specific clinical conditions or health conditions, such as decreased life expectancy, or multiple illnesses at the same time, or other conditions that prevent proper diagnosis, treatment, or follow up of the disease in the testing process, are excluded from the study. -Inability or unwillingness of the individual or legal guardian / representative to provide informed written consent Patients who do not able to collaborate for follow up

Age

From **41 years** old

Gender

Both

Phase

1

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **10**

Randomization (investigator's opinion)

Randomized

Randomization description

Blocked randomization is used for randomization. The Quadruple blocks are used and the ratio is 1: 1. Blocking is not done through software and is done manually. Sequences are marked in closed envelopes with the letters A and B in which the letter A is allocated for intervention group and letter B is allocated for control group. In this randomization, blindness is also determined and only the person who is responsible for the extraction of mitochondria will be responsible for doing the work.

Blinding (investigator's opinion)

Triple blinded

Blinding description

Patients know that they are going to be involve in a project. Participants who completed the informed consent are two groups of control and intervention who are blinded to with mitochondria or buffer. The principal investigator and the treating physician and all those who interact with the patient in some way are blinded like the nurses. Those who analyze the data are also blinded. The Data Safety and Monitoring Committee and those who analyze the outcome are also blinded. The only person who is not blinded is the one who extracts the mitochondria. The draft article will be written after the completion of the project as well as obtaining all the results and data. The author of the draft article is the main researcher who has been blinded from the beginning.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic committee of Guilan University of Medical Sciences

Street address

Anatomical Sciences Department, Medicine faculty, Guilan University of Medical Sciences, Rasht, Guilan

City

Rasht

Province

Guilan

Postal code

4144666949

Approval date

2021-02-07, 1399/11/19

Ethics committee reference number

IR.GUMS.REC.1399.587

Health conditions studied

1

Description of health condition studied

Brain ischemia

ICD-10 code

I63

ICD-10 code description

Cerebral infarction

Primary outcomes

1

Description

Mortality rate

Timepoint

24hour, one week, six months, one year

Method of measurement

The death rate is indicated by a number.

2

Description

- Systemic and adverse Side effects after 24, one week and six months and one year

Timepoint

24hour, one week, six months, one year

Method of measurement

Barometer, EKG, NIHSS

3

Description

Brain Bleeding

Timepoint

24hour, one week, six months, one year

Method of measurement

National Institutes of Health stroke scale score, MRI

4

Description

cancer incidence

Timepoint

Six months , one year

Method of measurement

MRI

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The product that is going to be transplanted is mitochondria. Patients will receive approximately 500,000 platelet-derived mitochondria intravenously three times at one-hour intervals.

Category

Treatment - Other

2

Description

Control group: In this group only the respiration buffer is injected.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Poursina hospital

Full name of responsible person

Amaneh Mohammadi Roushandeh

Street address

Poursina hospital-Parastar street, Rasht, Guilan

City

Rasht

Province

Guilan

Postal code

4144666949

Phone

+98 13 3333 5820

Fax

+98 13 3333 6395

Email

mohammadi_roushandeh@gums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

Mohammad Reza Naghipour

Street address

Deputy of research and technology, shahid siadati street, Namjoo street, Rasht, Guilan

City

Rasht

Province

Guilan

Postal code

4144666949

Phone
+98 13 3333 5820
Fax
+98 13 3333 6395
Email
research@gums.ac.ir
Web page address
https://www.gums.ac.ir/research

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Rasht University of Medical Sciences

Proportion provided by this source
100

Public or private sector
Public

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Rasht University of Medical Sciences
Full name of responsible person
Amaneh Mohammadi Roushandeh
Position
Professor
Latest degree
Ph.D.
Other areas of specialty/work
Anatomy
Street address
Anatomical Sciences department, Medicine faculty, Guilan University of Medical Sciences, rasht, Guilan
City
Rasht
Province
Guilan
Postal code
4144666949
Phone
+98 13 3333 5820
Email
mohammadi_roushandeh@gums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Rasht University of Medical Sciences
Full name of responsible person
Mehryar Habibi Roudkenar
Position
Professor
Latest degree
Ph.D.
Other areas of specialty/work
Medical Biotechnology
Street address
Burn and regenerative medicine research center, Velayat hospital, Rasht, Guilan
City
Rasht
Province
Guilan
Postal code
4144666949
Phone
+98 13 3333 5820
Email
mhr376@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Rasht University of Medical Sciences
Full name of responsible person
Amaneh Mohammadi Roushandeh
Position
Professor
Latest degree
Ph.D.
Other areas of specialty/work
Anatomy
Street address
Anatomical Sciences Department, Medicine Faculty, Guilan University of Medical Sciences, Rasht, Guilan
City
Rasht
Province
Guilan
Postal code
4144666949
Phone
+98 13 3333 5820
Email
mohammadi_roushandeh@gums.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Age, sex, mortality rate, cancer incidence, bleeding and side effects

When the data will become available and for how long

After publishing of the results in the journal

To whom data/document is available

Universities

Under which criteria data/document could be used

Only for studying not for analysis

From where data/document is obtainable

Amaneh Mohammadi Roushandeh dinachal@yahoo.com

What processes are involved for a request to access data/document

The application must be written to the Deputy of Research and technology of Guilan University of Medical Sciences. From there, the request is sent to the principle investigator and the researcher sends the documents to the deputy. The applicant can receive the documents from the deputy.

Comments