Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Study of safety and efficacy of transplantation of platelet extracted mitochondria in heart ischemic stroke, Clinical trial phase 1 and 2

Protocol summary

Study aim
The main aim of this study is investigation of safety and efficacy of platelet- derived mitochondria in heart ischemia

Design
Randomized clinical trial performed on 34 patients with control group, parallel , triple masking in phase I and II clinical trials.

Settings and conduct
This clinical trial study is performed in Heshmat hospital in Rasht.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Participants, their close relatives or lawyers are able to sign a consent form; Patients with recent myocardial ischemia within 24 hours and candidates for interventional treatment; Ejection fraction less than or equal to 41%; The age range is between 45-70 years. Exclusion criteria: Patients with mitochondrial disorders; Patients with diabetes; Patients with renal failure; Pregnant women; patients with cancer.

Intervention groups
Intervention group: In the intervention group, platelet derived mitochondria is transplanted through coronary artery by catheter. Control group: This group receives routine medications and treatments .

Main outcome variables
Cardiac arrhythmia, non-fatal myocardial infarction, fever and shivering, change in vital signs, mortality, re-hospitalization, cardiac enzymes include Cardiac troponin I, Creatin kinase MB.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210920052524N1**
Registration date: **2021-09-22, 1400/06/31**
Registration timing: **prospective**
Last update: **2021-09-22, 1400/06/31**
Update count: **0**

Registration date
2021-09-22, 1400/06/31

Registrant information

Name
Mehryar Habibi Roudkenar

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 13 3336 8540

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-10-23, 1400/08/01

Expected recruitment end date
2023-06-22, 1402/04/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Study of safety and efficacy of transplantation of platelet extracted mitochondria in heart ischemic stroke, Clinical trial phase 1 and 2

Public title
Study of safety and efficacy of transplantation of platelet extracted mitochondria in heart ischemic stroke, Clinical trial phase 1 and 2

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Participants, their close relatives or lawyers are able to sign a consent form; Patients with recent myocardial ischemia within 24 hours Candidate for interventional treatment. Ejection fraction less than or equal to 41% (EF ≤ 41%). The age range is between 45-70 years Both Genders

Exclusion criteria:

Patients with mitochondrial disorders. Patients with diabetes Patients with renal failure. Pregnant women Patients with cancer are not included in the study.

Age

From **45 years** old to **70 years** old

Gender

Both

Phase

1-2

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size

Target sample size: **34**

Randomization (investigator's opinion)

Randomized

Randomization description

In order to assign patients into intervention and control groups, the restricted randomization using block randomization will be used in this study. In order to conceal the last allocated blocks under study, the size of blocks will be consider 4 or 6. To create random numbers, various packages available in R software will be used. Of noted, before the allocation of patients/individuals in the study groups, the allocated group would not be clarified. In order to conceal and confounding factors, allocation concealment will be used. This method will be used for randomization participants in the study. In this study using sealed envelopes in which created randomized sequensces will be recorded on cards, and the cards will be put inside the envelopes respectively. the allocation would be 1:1 ratio.

Blinding (investigator's opinion)

Triple blinded

Blinding description

In this study, the participants (patients) would be blinded by sealed envelopes. It should be noted that each created randomized sequences will be recorded on a card, and the cards will be put inside the envelopes respectively. In order to blind researcher, similar syringes, the same color injection solutions for the control and intervention groups will be used. The analyzer will also be blinded according to coding of envelope and syringes .

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Guilan University of Medical Sciences

Street address

3th floor, Burn and Regenerative Research Medicine Center, Velayat Hospital, Namjo street, Rasht, Guilan

City

Rasht

Province

Guilan

Postal code

4193713194

Approval date

2021-08-31, 1400/06/09

Ethics committee reference number

IR.GUMS.REC.1400.244

Health conditions studied

1

Description of health condition studied

Heart Ischemia

ICD-10 code

I24.9

ICD-10 code description

Acute ischemic heart disease, unspecified

Primary outcomes

1

Description

Cardiac arrhythmia

Timepoint

24 hours and one week after mitochondrial transplantation

Method of measurement

Based on diagnostic tests and physician reports

2

Description

Non-fatal heart ischemia

Timepoint

24 hours and one week after mitochondrial transplantation

Method of measurement

Based on diagnostic tests and physician reports

3

Description

Fever and shivering

Timepoint

24 hours and one week after mitochondrial transplantation

Method of measurement

Thermometer

4

Description

Vital signs change

Timepoint

24 hours and one week after mitochondrial transplantation

Method of measurement

Barometer and diagnostic tests

5

Description

Death

Timepoint

24 hours and one week after mitochondrial transplantation

Method of measurement

Patients records

6

Description

Cardiac enzymes Creatine kinase MB, cardiac troponin I

Timepoint

24 hours and one week after mitochondrial transplantation

Method of measurement

laboratory kits

7

Description

re-hospitalization

Timepoint

24 hours and one week after mitochondrial transplantation

Method of measurement

According to patient file.

Secondary outcomes

1

Description

Left Ventricular Ejection Fraction (LVEF)

Timepoint

3 and 6 months after mitochondrial transplantation

Method of measurement

Echocardiography

2

Description

Left Ventricular End Diastolic Volume Index (LVEDVI)

Timepoint

3 and 6 months after mitochondrial transplantation

Method of measurement

Echocardiography

3

Description

Left Ventricular End Systolic Volume Index (LVESVI)

Timepoint

3 and 6 months after mitochondrial transplantation

Method of measurement

Echocardiography

4

Description

Patient physical activity

Timepoint

3 and 6 months after mitochondrial transplantation

Method of measurement

The Tests such as six-minute walk test and a treadmill test

Intervention groups

1

Description

Intervention group: In the intervention group, platelets derived mitochondrial is transplanted. After preparing the patient, the extracted mitochondria are injected into the coronary artery using a catheter. This group receives all routine interventions similar to control group.

Category

Treatment - Other

2

Description

Control group: This group receives routine medications and treatments such as angioplasty.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Heshmat Hospital

Full name of responsible person

Mehryar Habibi Roudkenar

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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Fax
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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
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Position
Professor
Latest degree
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Other areas of specialty/work
Regenerative Medicine
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Person responsible for updating data

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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, cancer incidence, bleeding and side effects
When the data will become available and for how long
After publishing the results in the article
To whom data/document is available
Universities
Under which criteria data/document could be used
Only for study
From where data/document is obtainable
Dr.Mehryar Habibi Roudkenar Email: roudkenar@gums.ac.ir
What processes are involved for a request to access data/document
The request must be written to the Vice Chancellor for Research of Guilan University of Medical Sciences. The request is sent to the principal investigator and the researcher will send the documents to the deputy. The applicant can receive the documents from the deputy.
Comments