

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jul 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)

Phone

+98 13 3336 8540

Email address

roudkenar@gums.ac.ir

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 $\leq$ 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 sequences 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
Street address
3 floor, Burn and Regenerative Medicine Research Center, Velayat hospital, Namjo street, Rasht, Guilan
City
Rasht
Province
Guilan
Postal code
4193713194

Phone
+98 13 3336 8540
Fax
+98 13 3336 8540
Email
Roudkenar@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
Mehryar Habibi Roudkenar
Position
Professor
Latest degree

Ph.D.

Other areas of specialty/work

Regenerative Medicine

Street address

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

City

Rasht

Province

Guilan

Postal code

4193713194

Phone

+98 13 3336 8540

Fax

+98 13 3336 8540

Email

Roudkenar@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
Regenerative Medicine
Street address
3th floor, Burn and Regenerative Research Medicine
Center, Velayat Hospital, Namjo street, Rasht, Guilan
City
Rasht
Province
Guilan
Postal code
4193713194
Phone
+98 13 3336 8540
Fax
+98 13 3336 8540
Email
Roudkenar@gums.ac.ir

Person responsible for updating data

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
Regenerative Medicine

Street address

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

City

Rasht

Province

Guilan

Postal code

4193713194

Phone

+98 13 3336 8540

Fax

+98 13 3336 8540

Email

roudkenar@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, 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