

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Study of Safety and Efficacy of mitochondrial transplantation extracted from platelets on grade 3 degree burn; Clinical trial Phase I and II

Protocol summary

Study aim

Study of Safety and Efficacy of mitochondrial transplantation extracted from platelets on grade 3 degree burn Clinical trial Phase 1 and 2

Design

The randomized clinical trial with control and intervention groups, parallel study, double blind, and clinical trial phase I,II is performed on 15 patients in each group (30 patients in total).

Settings and conduct

Location: Rasht Velayat Hospital. The patient and physician have been blinded and samples have been randomly selected.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age range 18 to 65 years, Acute burns in less than 24 hours, 20 to 60% burns, Fill out the informed consent form. Exclusion criteria: Hypertention, (mmHg 90/160 $\geq$ BP), Higher cardiac Troponin, Pregnant Women, Presence of severe underlying diseases (incurable disease, advanced cancer with low life expectancy, renal and hepatic failure, rheumatoid diseases, Peripheral vessels diseases, Inhalation damage, Burn shock (including decreased cardiac output, increased vascular resistance, hypovolemia, and hypoperfusion) following severe burn, Known inflammatory diseases, Off-pump surgery.

Intervention groups

Control : In the control group, the needle is inserted only to a depth of 1 to 2 mm with no injection. Intervention : Transplantation of platelets derived mitochondria is used in intervention group.

Main outcome variables

1. Ratio of Graft percent to percent of burn 2. Total fluid requirement 3. Hospital stay 4. Final clinical outcome.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210920052524N2**

Registration date: **2021-12-01, 1400/09/10**

Registration timing: **registered_while_recruiting**

Last update: **2021-12-01, 1400/09/10**

Update count: **0**

Registration date

2021-12-01, 1400/09/10

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

2021-11-22, 1400/09/01

Expected recruitment end date

2022-11-22, 1401/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study of Safety and Efficacy of mitochondrial transplantation extracted from platelets on grade 3 degree burn; Clinical trial Phase I and II

Public title

Study of Safety and Efficacy of mitochondrial transplantation extracted from platelets on grade 3 degree burn; Clinical trial Phase I and II

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age range should be 18 to 65 years Acute burns should be occurred less than 24 hours Percentage of Burn should be 20 to 60. The patient should be capable to fill out the informed consent.

Exclusion criteria:

The patient should have severe hypertension (90/160 $\geq$ BP mmHg). The Cardiac troponin level should be high. The patient is pregnant. There are severe underlying diseases. The patient has peripheral vascular disease. The patient has an inhalation injury. The patient has Burn shock (including decreased cardiac output, increased vascular resistance, hypovolemia, and hypoperfusion following severe burn). The Patient has Known inflammatory disease. The patient has undergone off-pump surgery.

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

1-2

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, in order to allocate patients to intervention and control groups, the limited randomization approach will be used as a block randomization method. To prevent the clarification of the last allocation in the blocks, the size of blocks will be considered 4 or 6 randomly.

Blinding (investigator's opinion)

Double blinded

Blinding description

The patients are blind in this study. In addition, the doctor that evaluates and collects the outcomes is blind.

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 Medicine Research Center, Velayat Hospital, Namjo street, Rasht, Guilan

City

Rasht

Province

Guilan

Postal code

4193713194

Approval date

2021-10-26, 1400/08/04

Ethics committee reference number

IR.GUMS.REC.1400.357

Health conditions studied

1

Description of health condition studied

burn (3th grade)

ICD-10 code

T20

ICD-10 code description

Burn of unspecified degree of unspecified site of lower limb, except ankle and foot

2

Description of health condition studied

burn (3th grade)

ICD-10 code

T21

ICD-10 code description

Burn and corrosion of trunk

3

Description of health condition studied

burn (3th grade)

ICD-10 code

T22

ICD-10 code description

Burn and corrosion of shoulder and upper limb, except wrist and hand

4

Description of health condition studied

burn (3th grade)

ICD-10 code

T23

ICD-10 code description

Burn and corrosion of wrist and hand

5

Description of health condition studied

burn (3th grade)
ICD-10 code
T24
ICD-10 code description
Burn and corrosion of lower limb, except ankle and foot

6

Description of health condition studied
burn (3th grade)
ICD-10 code
T25
ICD-10 code description
Burn and corrosion of ankle and foot

Primary outcomes

1

Description
Ratio of Graft to burn percentage is detected.
Timepoint
At the admission
Method of measurement
Measurement based on Wallace criteria

2

Description
Total fluid receive
Timepoint
At discharge
Method of measurement
It would be recoded based on patients' files.

3

Description
Hospital stay
Timepoint
At discharge
Method of measurement
It would be recorded based on patients' files.

4

Description
Final clinical outcome
Timepoint
At discharge
Method of measurement
It would be detected based on patients' files.

Secondary outcomes

1

Description
The rate of infection is reduced.
Timepoint
The evaluation is performed on days 1, 3, 7, 14 and 28 post burn.

Method of measurement
Based on evaluators examination

2

Description
Itching
Timepoint
The evaluation is performed on days 1, 3, 7, 14 and 28 post burn.
Method of measurement
By asking patients

3

Description
The patient's burning rate decreases.
Timepoint
The evaluation is performed on days 1, 3, 7, 14 and 28 post burn.
Method of measurement
By asking patients

4

Description
Shock index
Timepoint
The evaluation is performed on 1,6,12 and14 post burn.
Method of measurement
It is measured by heartbeat per minute / systolic Blood pressure in mmHg

5

Description
SIRS (Systemic inflammatory response syndrome) is reduced.
Timepoint
The evaluation is performed on days 1, 3, 7, 14 and 28 post burn.
Method of measurement
It is measured based on body temperature, heart rate, respiratory rate, and WBC number (white blood cells) count

6

Description
Cr (creatinine) level
Timepoint
The evaluation is performed on days 1, 3, 7, 14 and 28 post burn.
Method of measurement
Based on patients' laboratory test results

Intervention groups

1

Description
Control group: In the control group, the needle is inserted only to a depth of 1 to 2 mm with no injection.

Category

Treatment - Other

2**Description**

Intervention group: In the intervention group, transplantation of platelets derived mitochondria is used.

Category

Treatment - Other

Recruitment centers1**Recruitment center****Name of recruitment center**

Velayat Hospital

Full name of responsible person

Mehryar Habibi Roudkenar

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Sponsors / Funding sources1**Sponsor****Name of organization / entity**

Rasht University of Medical Sciences

Full name of responsible person

Mohammad Reza Naghipour

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Deputy of Research and Technology, Shahid Siadati Street, Namjoo Street, Rasht, Guilan

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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

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Rasht University of Medical Sciences

Full name of responsible person

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Other areas of specialty/work

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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

Undecided - It is not yet known if there will be a plan to
make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to
make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to
make this available

Title and more details about the data/document

All data including the primary and secondary outcomes
are shared.

**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**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

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