Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Jun 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≥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≥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 is 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 centers

1

Recruitment center
Name of recruitment center
Velayat 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
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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
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Postal code
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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
Mehryar Habibi Roudkenar
Position
Professor
Latest degree
Ph.D.
Other areas of specialty/work
Regenerative Medicine
Street address
3th floor, Burn and Regenerative Medicine Research Center, Velayat Hospital, Namjo street, Rasht, Guilan
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Person responsible for scientific inquiries

Contact
Name of organization / entity
Rasht University of Medical Sciences
Full name of responsible person
Mehryar Habibi Roudkenar
Position
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Latest degree
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Other areas of specialty/work
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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
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Ph.D.
Other areas of specialty/work
Regenerative Medicine
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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