Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 Jun 2026

Effect of Remote Ischemic Preconditioning on complications and clinical outcome in patients with severe burn, A randomized clinical trial

Protocol summary

Study aim
Effect of Remote Ischemic Preconditioning on complications and clinical outcome in patients with severe burn

Design
This study is a parallel triple-blind clinical trial on 32 patients with intervention and control group (16 patients in each group). Restricted randomization method in the form of block randomization will be used to allocate patients into intervention and control groups. The researcher has no information about the selection sequence of samples and the type of procedure performed which are done by the nurses and trained individuals.

Settings and conduct
Location: Velayat Hospital (Rasht, Iran). The patient, researcher, and evaluator are blinded and samples are randomly selected.

Participants/Inclusion and exclusion criteria
Inclusion criteria: 1. Age between 18 to 65 years; 2. Acute burn injury within 24 hours; 3. 20 to 50 percent TBSA (total body surface area); 4. Patient classified as class 1 ASA (American Society of Anesthesiologists) : Normal healthy person; 5. Signed informed consent. Non inclusion criteria: 1.Severe hypertension = BP (Blood pressure) ≥160/90 mmHg; 2. Ischemic changes in ECG (Electrocardiogram); 3. Pregnant women; 4. Peripheral vascular diseases; 5. Inhalation injury; 6. Burn shock: decreased CO (Cardiac output), increased systemic vascular resistance, hypovolemia and hypoperfusion induced by severe burn injury; 7. Patients with burn injury in both upper limbs in which the procedure couldn't be performed.

Intervention groups
Group A (intervention group: patients undergoing procedure); Group B (control group: patients undergoing RIPC-like procedure as described in method).

Main outcome variables
1. Graft percent to TBSA percent ratio; 2. Total fluid requirement; 3. Hospital stay; 4. Final clinical outcome.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210524051384N5**
Registration date: **2021-11-09, 1400/08/18**
Registration timing: **prospective**

Last update: **2021-11-09, 1400/08/18**
Update count: **0**

Registration date
2021-11-09, 1400/08/18

Registrant information

Name
mohammadreza mobayen

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 13 3336 8540

Email address
maziar.mobayen@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-12-06, 1400/09/15

Expected recruitment end date
2022-06-05, 1401/03/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Effect of Remote Ischemic Preconditioning on complications and clinical outcome in patients with severe burn, A randomized clinical trial

Public title
Effect of Remote Ischemic Preconditioning in treatment of burns

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age between 18 to 65 years Acute burn injury within 24 hours 20 to 50 percent TBSA (total body surface area) Patient classified as class 1 ASA (American Society of Anesthesiologists) : Normal healthy person Signed informed consent

Exclusion criteria:
Severe hypertension = BP (Blood pressure) ≥160/90 mmHg Ischemic changes in ECG (Electrocardiogram) Pregnant women Peripheral vascular diseases Inhalation injury Burn shock: decreased CO (Cardiac output), increased systemic vascular resistance, hypovolemia and hypoperfusion induced by severe burn injury Patients with burn injury in both upper limbs in which the procedure couldn't be performed

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

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: **32**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, restricted randomization method in the form of block randomization will be used to allocate patients into intervention and control groups. For this purpose, four blocks with a ratio of 1: 1 will be considered. Sequences are marked in sealed envelopes with the letters A (intervention group) and B (control group). We will consider the size of the blocks randomly with a size of 4 or 6 to prevent the latest allocation from being detected. In the randomization process, random allocation sequences are identified by a statistician, and two student collaborators in the project will register participants and allocate them to interventions.

Blinding (investigator's opinion)
Triple blinded

Blinding description
In order to blind the subjects (patients) in the control group, a RIPC-like protocol with lower pressure will be performed in which the applied pressure is incapable of causing ischemia. In order to blind the researcher (physician who monitors the treatment process of patients in terms of studied variables such as wound examination, systemic complications, length of hospital stay, and others), allocators determine the groups without prior information using the allocation concealment method. The project will be performed based on patients groups by nurses or trained individuals. Final evaluation will be done by evaluators and physicians. In this study, restricted randomization method in the form of block randomization will be used to allocate patients into intervention and control groups.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethic Committees of Guilan University of Medical science

Street address
Guilan University of Medical science

City
Rasht

Province
Guilan

Postal code
4144666949

Approval date
2021-10-13, 1400/07/21

Ethics committee reference number
IR.GUMS.REC.1400.330

Health conditions studied

1

Description of health condition studied
Burn

ICD-10 code
T20

ICD-10 code description
Burn and corrosion of head, face, and neck

Primary outcomes

1

Description
Graft to TBSA (total body surface area) percent ratio

Timepoint
At the admission

Method of measurement
Measurements based on Wallace criteria

2

Description
Total fluid requirement
Timepoint
At discharge
Method of measurement
Based on patients' files

3

Description
Hospital stay
Timepoint
At discharge
Method of measurement
Based on patients' files

4

Description
Final clinical outcome
Timepoint
At discharge
Method of measurement
Based on patients' files

Secondary outcomes

1

Description
Infection
Timepoint
Day 1, 3, 7, 14 and 28 post admission
Method of measurement
Based on examination done by evaluators

2

Description
Itching
Timepoint
Day 1, 3, 7, 14 and 28 post admission
Method of measurement
Asking patients

3

Description
Burning
Timepoint
Day 1, 3, 7, 14 and 28 post admission
Method of measurement
Asking patients

4

Description
Shock index
Timepoint
Hour 1, 6, 12, 24 post admission
Method of measurement
Heartbeat per minute / systolic Blood pressure in mmHg

5

Description
SIRS (Systemic inflammatory response syndrome)
Timepoint
Day 1, 3, 7, 14 and 28 post admission
Method of measurement
Based on body temperature, heart rate, respiratory rate, and WBC (white blood cells) count

6

Description
Cr (creatinine)
Timepoint
Day 1, 3, 7, 14 and 28 post admission
Method of measurement
Based on patients' laboratory results

Intervention groups

1

Description
Intervention group (Patients receiving RIPC procedure): RIPC procedure will be performed on the first day of hospitalization under the following protocol twice with an interval of 12 hours: 20 minutes after using NSAID as analgesic to prevent pain, sphygmomanometer will be attached to the patient's healthy arm and will be remained under the pressure of 200 mmHg for 5 minutes (ischemic phase) , followed by 5 minutes of rest (reperfusion phase). This cycle will be performed 3 times. All patients (both intervention group and control group) will receive the routine treatment in burn management. For all patients, ٪TBSA and Used graft will be calculated using the Wallace scale on admission. Also, demographic characteristics, including age, sex, cause and degree of burn will be recorded. The length of hospital stay is defined as the length of time from the day of admission to the day of discharge. Laboratory parameters including ESR and CRP, renal profile (BUN, creatinine) and liver enzymes (AST, ALT and ALP) will be measured through venous blood samples according to the laboratory protocol of Velayat Medical Center Rasht on days 1,3,7,14 and 28. Additionally, local complications including burning, itching and infection of the wound will be checked during the examination.
Category
Treatment - Other

2

Description
Control group (Patients receiving RIPC-LIKE procedure): RIPC procedure will be performed on the first day of hospitalization under the following protocol twice with an interval of 12 hours: 20 minutes after using NSAID as

analgesic to prevent pain, sphygmomanometer will be attached to the patient's healthy arm and will be remained under the pressure of 60 mmHg for 5 minutes (ischemic phase) , followed by 5 minutes of rest (reperfusion phase). This cycle will be performed 3 times. All patients (both intervention group and control group) will receive the routine treatment in burn management. For all patients, ٪TBSA and Used graft will be calculated using the Wallace scale on admission. Also, demographic characteristics, including age, sex, cause and degree of burn will be recorded. The length of hospital stay is defined as the length of time from the day of admission to the day of discharge. Laboratory parameters including ESR and CRP, renal profile (BUN, creatinine) and liver enzymes (AST, ALT and ALP) will be measured through venous blood samples according to the laboratory protocol of Velayat Medical Center Rasht on days 1,3,7,14 and 28. Additionally, local complications including burning, itching and infection of the wound will be checked during the examination.

Category
Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Velayat hospital

Full name of responsible person
Dr. Mohammad Reza Mobayen

Street address
Namjoo street

City
Rasht

Province
Guilan

Postal code
4193713194

Phone
+98 13 3336 8540

Email
Maziar.mobayen@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Rasht University of Medical Sciences

Full name of responsible person
Dr.Mohammadreza Naghipour

Street address
Deputy of Research and Technology, in front of 17 Shahrivar Hospital, Namjoo St

City
Rasht

Province
Guilan

Postal code
4193713191

Phone
+98 13 3333 6394

Email
research@gums.ac.ir

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
Mohammad Reza Mobayen

Position
Director of the Department of Surgery, Head of the Burn and Plastic Surgery Hospital, Head of the Bu

Latest degree
Subspecialist

Other areas of specialty/work
General Surgery

Street address
Namjoo street

City
Rasht

Province
Guilan

Postal code
4193713194

Phone
+98 13 3336 8540

Email
Maziar.mobayen@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Rasht University of Medical Sciences

Full name of responsible person
Dr. Mohammad Reza Mobayen

Position
Director of the Department of Surgery, Head of the Burn and Plastic Surgery Hospital, Head of the Bu

Latest degree
Subspecialist
Other areas of specialty/work
General Surgery
Street address
Namjoo street
City
Rasht
Province
Guilan
Postal code
4193713194
Phone
+98 13 3336 8540
Email
Maziar.mobayen@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Rasht University of Medical Sciences
Full name of responsible person
Negin Rahimzadeh
Position
Medical student
Latest degree
A Level or less
Other areas of specialty/work
General Practitioner
Street address
Namjoo street
City
Rasht
Province
Guilan
Postal code
4193713194
Phone
+98 13 3336 8540
Email
N.rahimzadeh97@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be 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