

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 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) $\geq 160/90$ 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)

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+98 13 3336 8540

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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		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.	
Scientific title		Placebo	
Effect of Remote Ischemic Preconditioning on complications and clinical outcome in patients with severe burn, A randomized clinical trial		Not used	
Public title		Assignment	
Effect of Remote Ischemic Preconditioning in treatment of burns		Parallel	
Purpose		Other design features	
Treatment			
Inclusion/Exclusion criteria		Secondary Ids	
Inclusion criteria:		empty	
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		Ethics committees	
Exclusion criteria:		1	
Severe hypertension = BP (Blood pressure) $\geq 160/90$ 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		Ethics committee	
Age		Name of ethics committee	
From 18 years old to 65 years old		Research Ethic Committees of Guilan University of Medical science	
Gender		Street address	
Both		Guilan University of Medical science	
Phase		City	
N/A		Rasht	
Groups that have been masked		Province	
- Participant - Investigator - Outcome assessor		Guilan	
Sample size		Postal code	
Target sample size: 32		4144666949	
Randomization (investigator's opinion)		Approval date	
Randomized		2021-10-13, 1400/07/21	
Randomization description		Ethics committee reference number	
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.		IR.GUMS.REC.1400.330	
Blinding (investigator's opinion)		Health conditions studied	
Triple blinded		1	
Blinding description		Description of health condition studied	
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		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

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Namjoo street

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Province

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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

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Guilan

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4193713191

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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

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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
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Person responsible for updating data

Contact
Name of organization / entity
Rasht University of Medical Sciences
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Position
Medical student
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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