Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Jul 2026

Effect of add-on therapy with Ranolazine on reducing tissue ischemia and improvement of clinical outcome in patients with severe burn: A clinical trial

Protocol summary

Study aim

Effect of add-on therapy with Ranolazine on reducing tissue ischemia and improvement of clinical outcome in patients with severe burn

Design

This study is a parallel single blind clinical trial on 78 patients with intervention and control group (39 patients in each group). Patients in the intervention group will be treated with ranolazine 500 mg for 5 days. Restricted randomization method in the form of block randomization will be used to allocate patients into intervention and control groups.

Settings and conduct

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

Participants/Inclusion and exclusion criteria

* Inclusion criteria: Age range from 18 to 65 years/ Acute burn in less than 6 hours/ TBSA between 20 - 50%/ patients of ASA class I (a normal healthy person)/ Fill out the informed consent. * Non-inclusion: Having severe hypertension BP ≥ 160/90 mmHg or systolic pressure below 100 mm Hg; ischemic changes in ECG; Heart rate less than 70 beats per minute; Pregnant women; Peripheral vascular disease; Presence of inhalation injury; Presence of burn shock (including decreased cardiac output, increased vascular resistance, hypovolemia and hypoperfusion following severe burns); Electrical and chemical burns; Kidney or liver failure caused by burns (according to the kidney and liver metabolism of the drug); Presence of drug interactions with the patient's previous medications.

Intervention groups

intervention group (patients receiving ranolazine along with standard burn treatment) and control group (patients receiving standard burn treatment)

Main outcome variables

1) Graft to TBSA ratio; 2) Mortality

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210524051384N10**
Registration date: **2023-06-20, 1402/03/30**
Registration timing: **prospective**

Last update: **2023-06-20, 1402/03/30**
Update count: **0**

Registration date

2023-06-20, 1402/03/30

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

2023-06-22, 1402/04/01

Expected recruitment end date

2024-02-20, 1402/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Effect of add-on therapy with Ranolazine on reducing tissue ischemia and improvement of clinical outcome in patients with severe burn: A clinical trial

Public title
Effect of add-on therapy with Ranolazine on reducing tissue ischemia and improvement of clinical outcome in patients with severe burn

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age range from 18 to 65 years Acute burn in less than 6 hours Total body surface area (TBSA) between 20 - 50% patients of American Society of Anesthesiologists (ASA) class I (a normal healthy person) Fill out the informed consent

Exclusion criteria:
Having severe hypertension blood pressure (BP) ≥ 160/90 mmHg or systolic pressure below 100 mmHg Ischemic changes in electrocardiogram (ECG) Heart rate less than 70 beats per minute Pregnant women Peripheral vascular disease Presence of inhalation injury Presence of burn shock (including decreased cardiac output, increased vascular resistance, hypovolemia and hypoperfusion following severe burns) Electrical and chemical burns Kidney or liver failure caused by burns (according to the kidney and liver metabolism of the drug) Presence of drug interactions with the patient's previous medications

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

Gender
Both

Phase
N/A

Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **78**

Randomization (investigator's opinion)
Randomized

Randomization description
In this research, in order to assign patients to the intervention and control groups, the limited randomization approach will be used in the block randomization method. In order to prevent revealing the last allocation in the blocks, we will consider the size of the blocks randomly with sizes 4 and 6. The sequences inside each block are randomly determined so that half of the members of each block are assigned to the control group and the other half to the intervention group. For this purpose, the "Sealed envelope" online software is used to determine the blocks, so that the random blocks and sequences of each one are specified, and then the patients are assigned to the intervention and control groups based on the specified sequence.

Blinding (investigator's opinion)
Single blinded

Blinding description
Blinding in this study will be done in such a way that the patients were assigned to the intervention and control groups by the statistician, and the student colleagues will be responsible for conducting the interventions. Evaluation and completion of the checklists on specific determined times was the responsibility of the surgeon and project manager, who was not aware of the grouping of the patients.

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
Guilan University of Medical Sciences

City
Rasht

Province
Guilan

Postal code
4144666949

Approval date
2023-05-17, 1402/02/27

Ethics committee reference number
IR.GUMS.REC.1402.101

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 discharge

Method of measurement

Measurements based on Wallace criteria

2

Description
Mortality
Timepoint
At discharge
Method of measurement
Based on the clinical outcome recorded in the patients' files

Secondary outcomes

1

Description
Length of hospital stay
Timepoint
At discharge
Method of measurement
Based on patient's file

2

Description
SIRS (Systemic inflammatory response syndrome)
Timepoint
On the 1st, 3rd and 7th days of hospitalization
Method of measurement
Based on criteria including temperature, heart rate, respiratory rate, and WBC (white blood cell) count

3

Description
Infection
Timepoint
On the 1st, 3rd and 7th days of hospitalization
Method of measurement
Based on clinical decision of doctor

Intervention groups

1

Description
Intervention group: The treatment with oral ranolazine 500 mg tablets for patients in the intervention group will be started in the emergency room in such a way that the maximum time interval between the occurrence of the accident and the start of treatment is 6 hours. It should be noted that patients in the intervention group will take the prescribed pill with water. The medicine will continue to be taken every 12 hours until the fifth day after the injury. It should be mentioned that the patients received standard burn treatment during the entire hospitalization. These measures include: Resuscitation with fluids based on the Parkland formula and modification based on urinary output, monitoring vital signs and laboratory findings, regular washing and wound debridement and dressing using local antibiotics and surgical debridement and grafting based on the patient's need. Additionally, if any complication caused by the drug was observed in the study group, the patient was immediately excluded from the study and all necessary measures were taken to eliminate the complication and recover the patient as quickly as possible.
Category
Treatment - Drugs

2

Description
Control group: Patients in the control group receive standard burn treatments since the admission to emergency room. These measures include: Resuscitation with fluids based on the Parkland formula and modification based on urinary output, monitoring vital signs and laboratory findings, regular washing and wound debridement and dressing using local antibiotics and surgical debridement and grafting based on the patient's need. During the hospitalization, the required information will be collected from the patients. This information includes demographic data, vital signs, renal factors, local symptoms such as infection and itching, graft size, clinical outcome and length of hospitalization.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Velayat hospital
Full name of responsible person
Dr. Mohammadreza Mobayen
Street address
Namjoo st.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Rasht University of Medical Sciences
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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
Dr. Mohammad Reza Mobayen

Position
Associate professor

Latest degree
Subspecialist

Other areas of specialty/work
General Surgery

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Person responsible for updating data

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General Practitioner

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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