Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Aug 2026

Investigating the effectiveness of beta-blockers on hypermetabolic response in adult patients referred to hospital due to acute burns: a single-blind randomized clinical trial

Protocol summary

Study aim

Determining the effect of beta blockers in adults referred to the hospital due to burns

Design

This study is a clinical trial with parallel groups, single-blind, in which people are randomly divided into two groups of 45 people by Random Allocation Software.

Settings and conduct

This study will be conducted in the burn department of Bandar Abbas Shahid Mohammadi Hospital. After explaining the study to the patient and obtaining informed consent, they are randomly assigned to one of the groups and the treatment begins. In this study, participants will be blinded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Burn intensity between 20 and 50% on the entire body surface, obtaining informed consent from the patient or her companion, age between 18 and 65 years, history of acute burns in the last two days at most
Exclusion criteria: Medical conditions against propranolol use, history of cardiopulmonary, endocrine, and peripheral diseases, systolic blood pressure below 90 and heart rate below 60

Intervention groups

Control group: In the first 24 hours of hospitalization, patients receive normal saline solution (Ringer's lactate). From the third day after the burn, they receive a starch tablet (placebo) at a dose of 20 mg every 12 hours (purchased from Merck), which is similar in appearance to propranolol tablets (the same as intervention group).
Intervention group: Patients receive normal saline solution (Ringer's lactate) in the first 24 hours of hospitalization, and oral propranolol at a dose of 20 mg every twelve hours from the third day after the burn (purchased from Hakim Company). Hemodynamic parameters (heart rate, blood pressure) are checked every 3 hours. The intervention period continues until the complete recovery and the patient's discharge from the hospital.

Main outcome variables

Blood pressure, heart rate, blood oxygen, and body temperature

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230301057584N1**
Registration date: **2023-06-04, 1402/03/14**
Registration timing: **registered_while_recruiting**

Last update: **2023-06-04, 1402/03/14**
Update count: **0**

Registration date

2023-06-04, 1402/03/14

Registrant information

Name

MohammadHosein Sheybani-Arani

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-04-21, 1402/02/01

Expected recruitment end date

2024-04-20, 1403/02/01

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigating the effectiveness of beta-blockers on hypermetabolic response in adult patients referred to hospital due to acute burns: a single-blind randomized clinical trial

Public title
Investigating the effectiveness of beta-blocker on hypermetabolic response in adult patients due to acute burns
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Having wounds from 20 to 50% of the total body surface Consent to participate in data collection From the age of 18 to the age of 65 and of both sexes A history of acute burns in the last two days
Exclusion criteria:
Medical conditions against propranolol use Head injury History of cardiopulmonary endocrine and peripheral diseases Systolic blood pressure less than 90 Heart rate less than 60 Inhalation damage History of malignancy History of AIDS Complexes related to AIDS and HIV History of IMI (less than the last 6 weeks), tuberculosis, arthritis, cirrhosis, hyperlipidemia, bone or endocrine diseases, autoimmune diseases Long-term use of corticosteroids or non-steroidal anti-inflammatory drugs Renal failure defined as creatinine greater than 3 Liver disease defined as bilirubin more than 3 Anoxic brain damage Patients with asthma and a history of airway narrowing Respiratory burn History of joint or bone disease Peripheral or central nerve damage Diabetes or taking any medication that affects the autonomic system Any type of plastering Skin wound or skin graft Contraindication to the use of propranolol Hypersensitivity to propranolol A history of hyperthyroidism, unless you are using Synthroid or other thyroid hormones Chronic opioid overdose pre-burn Receiving propranolol in the past 6 months Multiple severe allergic reactions Daily use of methylphenidate or similar stimulants Presence of hypoxic brain injury that is not expected to lead to full recovery History of chronic obstructive pulmonary disease and history of medication use including blocking agents (alpha and beta) or other antiarrhythmic drugs and medical conditions requiring glucocorticoid therapy prior to burn injury.
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant

Sample size
Target sample size: **90**
Randomization (investigator's opinion)
Randomized
Randomization description
The patients will be divided into two groups and the Random Allocation software will be used for simple randomization. concealment will be done using non-transparent envelopes.
Blinding (investigator's opinion)
Single blinded
Blinding description
In this study, blinding will be done for participants. In this way, the medicine and placebo will be placed in the same packages by a person outside the study, which will be labeled with A and B codes. To blind the participants and reduce their bias, it was explained to them only at the beginning of the study that they will receive one of two types of intervention and they will not be told the exact type of treatment.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Hormozgan University of Medical Sciences
Street address
Research and Technology Vice-Chancellor Building, Hormozgan University of Medical Sciences Campus, Imam Hossein Blvd, Bandar Abbas, Iran
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Bandar Abbas
Province
Hormozgan
Postal code
7919693116
Approval date
2023-02-14, 1401/11/25
Ethics committee reference number
IR.HUMS.REC.1401.376

Health conditions studied

1

Description of health condition studied
Acute Burn
ICD-10 code
T20.00
ICD-10 code description

Burn of unspecified degree of head, face, and neck, unspecified site

2

Description of health condition studied
Acute Burn
ICD-10 code
T21.00
ICD-10 code description
Burn of unspecified degree of trunk, unspecified site

3

Description of health condition studied
Acute Burn
ICD-10 code
T22.00
ICD-10 code description
Burn of unspecified degree of shoulder and upper limb, except wrist and hand, unspecified site

4

Description of health condition studied
Acute Burn
ICD-10 code
T23.00
ICD-10 code description
Burn of unspecified degree of hand, unspecified site

5

Description of health condition studied
Acute Burn
ICD-10 code
T24.00
ICD-10 code description
Burn of unspecified degree of unspecified site of lower limb, except ankle and foot

6

Description of health condition studied
Acute Burn
ICD-10 code
T25.0
ICD-10 code description
Burn of unspecified degree of ankle and foot

Primary outcomes

1

Description
Blood pressure
Timepoint
At the beginning of the intervention and during the intervention every 3 hours until the end of discharge from the hospital
Method of measurement
Barometer

2

Description
Heart rate
Timepoint
At the beginning of the intervention and during the intervention every 3 hours until the end of discharge from the hospital
Method of measurement
patient vital signs monitoring system

3

Description
Body temperature
Timepoint
At the beginning of the intervention and during the intervention every 3 hours until the end of discharge from the hospital
Method of measurement
Thermometer

4

Description
Blood oxygen
Timepoint
At the beginning of the intervention and during the intervention every 3 hours until the end of discharge from the hospital
Method of measurement
Pulse Oximeter

Secondary outcomes

1

Description
Hospitalization in ICU
Timepoint
Before starting the intervention and After completing the intervention
Method of measurement
Count by number of days

2

Description
The duration of the patient's recovery during the intervention period
Timepoint
Before starting the intervention and After completing the intervention
Method of measurement
check list

3

Description
mortality
Timepoint
Before starting the intervention and After completing the intervention

Method of measurement
Check list

4

Description
TNF-alpha
Timepoint
Before starting the intervention and After completing the intervention
Method of measurement
Examination of cytokine TNF-alpha using ELISA kit

Intervention groups

1

Description
Control group: In the first 24 hours of admission, patients receive normal saline solution (Ringer's lactate) and the patient's dose is calculated with the help of the Parkland formula. For patients under the standard treatment of the Ministry of Health and from the third day after the burn, they receive starch tablets (placebo) with a dose of 20 mg (every twelve hours), which is similar in appearance to propranolol tablets (the same as intervention group). Placebos will be purchased from Merck Pharmaceutical Company. Hemodynamic parameters (heart rate, blood pressure) are checked every 3 hours. The period of consumption continues until the patient's hospitalization and complete recovery and discharge from the hospital.
Category
Placebo

2

Description
Intervention group: Patients receive normal saline solution (ringer lactate) in the first 24 hours of admission, and the patient's dose is calculated with the help of Parkland's formula. For patients, the standard treatment of the Ministry of Health begins and from the third day after the burn, patients receive oral propranolol at a dose of 20 mg (every twelve hours). This drug is prepared from Hakim Pharmaceutical Company. Hemodynamic parameters (heart rate, blood pressure) are checked every 3 hours. If a 20% reduction is maintained with a dose lower than this amount, the patient's dose will be reduced to that amount. If bradycardia occurs, propranolol is stopped and half of the mentioned dose is prescribed 16 hours later. Within 48 hours, the patient's dose will return to a fixed amount. If the patient's blood pressure falls below 65 milliliters of mercury (mmHg), the patient's dose is reduced or stopped until the patient's blood pressure returns to normal. If the parameters do not change, the next received dose will be 40 mg, and after reaching the goal, the dose will be changed to 20 mg. The period of propranolol consumption continues until the patient is hospitalized and fully recovered and discharged from the hospital.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
The Great Prophet Research and Educational Complex Research Center
Full name of responsible person
Dr Sadegh Ahmadi Rashti
Street address
The Great Prophet Research and Educational Complex Research Center, Shahid Mohammadi Hospital, Jomhory Blvd, Old Airport, Bandar Abbas, Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Bandare-abbas University of Medical Sciences
Full name of responsible person
Dr Vali Alipor
Street address
Vice Chancellor Deputy of research and technology , Campus of University of Medical Sciences behind the Central Library, Nabout Town, in front of Kargaran Sports Club, at the beginning of Imam Hossein Boulevard, Bandar Abbas, Iran
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research@hums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Bandare-abbas 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
Bandare-abbas University of Medical Sciences
Full name of responsible person
Dr Sadegh Ahmadi Rashti
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is no further information
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