Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Jul 2026

Assessment of the β-alanine effect on postoperative clinical outcomes in patients with acute lower and upper extremity ischemia

Protocol summary

Study aim
Assessment of the β-alanine effect on postoperative clinical outcomes in patients with acute lower and upper extremity ischemia

Design
This randomized-controlled parallel, double-blind clinical trial study, phase 3 will be conducted on 40 patients. The randomization will be done with a stratified block randomization method using Random Allocation Software.

Settings and conduct
In this double-blind clinical trial study, patients with acute lower and upper extremity ischemia undergoing surgery in Urmia Imam Khomeini hospital will be enrolled. The patients will be divided randomly into intervention or placebo groups. Patients in the intervention group will be received 4 gr of oral β-alanine before surgery and 4 hours after surgery. Patients in the placebo group will be received 4 gr of placebo in addition to routine treatment.

Participants/Inclusion and exclusion criteria
In this study, the patients with acute lower and upper extremity ischemia who have surgical indication and the possibility of limb preservation will be enrolled. The exclusion criteria will be including gangrene of the limbs, motlelling of the limbs, Indication of amputation, and renal failure diseases.

Intervention groups
Patients in the intervention group will be received 4 gr of oral β-alanine before surgery and 4 hours after surgery. Patients in the placebo group will be received 4 gr of placebo in addition to routine treatment.

Main outcome variables
Frequency and vastness of limbs loss

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210919052515N5**
Registration date: **2022-05-04, 1401/02/14**
Registration timing: **prospective**

Last update: **2022-05-04, 1401/02/14**
Update count: **0**

Registration date
2022-05-04, 1401/02/14

Registrant information
Name
Naser Masoudi
Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 44 3337 9924
Email address
masoudi.n@umsu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-05-22, 1401/03/01

Expected recruitment end date
2022-09-22, 1401/06/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Assessment of the β-alanine effect on postoperative clinical outcomes in patients with acute lower and upper extremity ischemia

Public title
Assessment of the β-alanine effect in acute lower and upper extremity ischemia
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Acute extremity ischemia patients Having surgical indications and the possibility of limb preservation
Exclusion criteria:
Gangrene of the limbs Motlelling of the limbs Amputation Indication Renal failure diseases
Age
No age limit
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients will be divided into intervention and placebo groups using stratified block randomization based on generated numbers by random allocation software. Firstly, patients will be stratified according to the duration of thrombectomy or embolectomy into 1-2, 4-2, and 6-4 and more than 6 hours groups, and then block randomization will be performed in each stratum. So that, in this software, the number of groups (two groups including intervention or placebo) and the sample size in each stratum (for example in 1-2 stratum of the duration of thrombectomy or embolectomy) will be entered, and then in the block section, the block randomization method will be implemented. In each stratum, patients will be allocated to intervention or placebo groups based on generated numbers. Random Allocation Software version 1.0.0 has been developed by Mr.Saghaei, MD. department of anesthesia, Isfahan University of Medical Sciences, Isfahan, Iran.
Blinding (investigator's opinion)
Double blinded
Blinding description
The study will be conducted as a double-blind clinical trial. The patient and the researcher who will be evaluating the outcomes will be blinded to the intervention or placebo groups. Beta-alanine and placebo will be given to the patient by another surgeon (other than the researcher) and the placebo tablets will be similar to the Beta-alanine tablets in shape and size. Group names will be encoded with the letters A and B.
Placebo
Used
Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Imam Khomeini University hospital- Urmia University of Medical Sciences
Street address
Imam Khomeini hospital., Ershad Ave., Modarres Blvd., Urmia., Iran.
City
Urmia
Province
West Azarbaijan
Postal code
57157-89397
Approval date
2022-01-23, 1400/11/03
Ethics committee reference number
IR.UMSU.HIMAM.REC.1400.015

Health conditions studied

1

Description of health condition studied
acute extremity ischemia
ICD-10 code
BD30.2
ICD-10 code description
Acute lower limb arterial occlusion

Primary outcomes

1

Description
Loss of limbs
Timepoint
After the intervention at hospitalization
Method of measurement
Clinical examination

Secondary outcomes

1

Description
Complications
Timepoint
After the intervention at hospitalization
Method of measurement
Clinical examination

2

Description
Mortality
Timepoint
After the intervention at hospitalization
Method of measurement
Yes/no

Intervention groups

1

Description
Intervention group: Patients in the intervention group will be received 4 gr of oral β-alanine before surgery and 4 hours after surgery. The routine treatment of patients is receiving an anticoagulant (heparin or enoxaparin) before or after surgery.
Category
Treatment - Other

2

Description
Control group: Patients in the placebo group will receive 4 gr of placebo before surgery and 4 hours after surgery in addition to routine treatment. The routine treatment of patients is receiving an anticoagulant (heparin or enoxaparin) before or after surgery.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini hospital
Full name of responsible person
Dr. Naser Masoudi
Street address
Imam Khomeini hospital., Ershad Ave., Modarres Blvd., Urmia., Iran.
City
Urmia
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57157-89397
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Oroumia University of Medical Sciences
Full name of responsible person
Dr.Saber Gholizadeh
Street address
Urmia University of Medical Sciences, Resalat street, Jahad Blvd., Urmia, Iran.
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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
Oroumia 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
Oroumia University of Medical Sciences
Full name of responsible person
Dr. Naser Masoudi
Position
Assistant professor
Latest degree
Subspecialist
Other areas of specialty/work
General Surgery
Street address
Imam Khomeini hospital., Ershad Ave., Modarres Blvd., Urmia., Iran.
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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

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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
Confidentiality of patient information

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
The results of the study will be published as an article.

When the data will become available and for how long
After publishing the article

To whom data/document is available
Researchers

Under which criteria data/document could be used
The results will be published as an article and the data will not be published.

From where data/document is obtainable
corresponding author

What processes are involved for a request to access data/document
By email address of the corresponding author: masoudi.n@umsu.ac.ir

Comments