Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Evaluation of the effectiveness of trehalose on inflammatory factors, cardiac biomarkers and clinical outcomes after coronary artery bypass graft (CABG) surgery: A double-blind randomized controlled clinical trial

Protocol summary

Study aim
Determination of the effectiveness trehalose on inflammatory factors, cardiac biomarkers, atrial fibrillation and clinical outcomes after coronary artery bypass surgery (CABG)

Design
The clinical trial study will have a control group, with 2 parallel groups, double-blind, randomized, phase 3 on 90 patients. Randomization will be done by the permuted block randomization method, with a block size equal to 4, using the site www.sealedenvelope.com.

Settings and conduct
This clinical trial will be performed in Chamran hospital in Isfahan. Trehalose and placebo will be administered in exactly the same packages to the patient. Patients and researchers will not be aware of the type of intervention.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Non-emergency Coronary artery bypass surgery (CABG), Completion of a consent form, age 30 to 80 years, gastrointestinal tract with normal function, ejection fraction above 30%, arrest time 30 to 90 minutes. Exclusion criteria: Herbal supplementation consumption during 3 months before surgery, need for pump balloon, addition of other surgery, uncontrolled diabetes or need to insulin, pregnancy and lactation.

Intervention groups
Intervention group: Patients who receive three sachets of trehalose for 5 days, each sachet containing 10 grams of trehalose (in total 30 g of trehalose per day). Control group: Patients who receive three sachets of maltodextrin for 5 days, each sachet containing 10 grams of maltodextrin (in total 30 g of maltodextrin per day).

Main outcome variables
Inflammatory factors including C-reactive protein, interleukin-6 and lactate dehydrogenase, cardiac biomarkers including Creatine Kinase-MB and atrial fibrillation.

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20201129049534N11**
Registration date: **2025-06-26, 1404/04/05**
Registration timing: **prospective**

Last update: **2025-06-26, 1404/04/05**
Update count: **0**

Registration date
2025-06-26, 1404/04/05

Registrant information
Name
Mohammad bagherniya
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 31 3792 3183
Email address
bagherniya@nutr.mui.ac.ir

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2025-08-06, 1404/05/15
Expected recruitment end date
2025-12-06, 1404/09/15
Actual recruitment start date
empty
Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of the effectiveness of trehalose on inflammatory factors, cardiac biomarkers and clinical outcomes after coronary artery bypass graft (CABG) surgery: A double-blind randomized controlled clinical trial

Public title
The effects of trehalose on CABG patient

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Non-emergency coronary artery bypass surgery Age 30-80 years Gastrointestinal normal function and with intestinal or oral nutrition criteria Ejection fraction (EF) above 30% Arrest Time (cardiac resuscitation) 30 to 90 minutes Willingness to participate in the study and complete the consent form before surgery

Exclusion criteria:
Taking herbal supplements (as a supplement) during 3 months before the operation Requires balloon pump Adding another operation in addition to coronary artery bypass surgery(CABG), like simultaneous valve operation Patients with a history of underlying disease such as congenital and immune disorders and pancreatitis Diabetic patients who require insulin injections to control blood sugar or have uncontrolled diabetes. Pregnancy and lactation

Age
From **30 years** old to **80 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
Randomized

Randomization description
Participants will be divided into two groups, intervention and control, using a stratified block randomization. The following reliable site will be used to allocate the intervention in the above-mentioned manner. https://www.sealedenvelope.com/simple-randomiser/v1/lists In this way, individuals will be randomly divided into two groups, intervention and control, using blocks of four and based on age and gender.

Blinding (investigator's opinion)
Double blinded

Blinding description
In order to conduct this research in a double-blind manner, before the start of the study, all the relevant sachets are coded as A and B by someone other than the researcher so that the researcher does not know the type of sachets received by both groups. The trehalose sachets are purchased from Shaanxi Fruiterco Biotechnology Co., Ltd. China . The trehalose and placebo sachets are completely identical in terms of type, color, shape and size.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethics Committees of School of Medicine - Isfahan University of Medical Sciences

Street address
School of Medicine, Isfahan University of Medical Sciences, Hezar-jerib Avenue

City
Isfahan

Province
Isfehan

Postal code
8174673477

Approval date
2025-03-10, 1403/12/20

Ethics committee reference number
IR.MUI.MED.REC.1403.504

Health conditions studied

1

Description of health condition studied
Cardiovascular disease

ICD-10 code
Z95.1

ICD-10 code description
Presence of aortocoronary bypass graft

Primary outcomes

1

Description
C reactive Protein (CRP)

Timepoint
At baseline (before the start of the intervention) and on the fifth day (end of the intervention).

Method of measurement
ELISA test

2

Description
Lactate Dehydrogenase (LDH)
Timepoint
At baseline (before the start of the intervention) and on the fifth day (end of the intervention).
Method of measurement
ELISA test

3

Description
Interleukin 6 (int-6)
Timepoint
At baseline (before the start of the intervention) and on the fifth day (end of the intervention).
Method of measurement
ELISA test

4

Description
Creatine Kinase-MB
Timepoint
At baseline (before the start of the intervention) and on the fifth day (end of the intervention).
Method of measurement
ELISA test

5

Description
Atrial fibrillation
Timepoint
On the fifth day (end of the intervention)
Method of measurement
Electrocardiogram (ECG or EKG)

Secondary outcomes

1

Description
28-days mortality rate
Timepoint
28 days after coronary artery bypass surgery
Method of measurement
Mathematically dividing the number of dead people by the total number of people using hospital records or telephone follow-up

2

Description
Fasting Blood Sugar
Timepoint
At baseline (before the start of the intervention) and on the fifth day (end of the intervention).
Method of measurement
Photometric

3

Description
Cell Blood Count
Timepoint
At baseline (before the start of the intervention) and on the fifth day (end of the intervention).
Method of measurement
Auto hematology analyzers

Intervention groups

1

Description
Intervention group: Patients who receive three sachets daily, each containing 10 grams of trehalose purchased from Shaanxi Fruiterco Biotechnology Co., Ltd. China, for 5 days (total of 30 grams of trehalose per day). In the groups, one sachet is given to the patient at 6 am, one sachet at 2 pm, and one sachet at 10 pm, along with gavage (if enteral nutrition is used) or half an hour after the main meal (if oral nutrition is used). In order to comply with ethical principles, no intervention is performed in the field of drug therapy of the patients.
Category
Treatment - Drugs

2

Description
Control group: Control group: Patients who receive three sachets daily, each containing 10 grams of maltodextrin purchased from Espinas Shimi Co. Iran, (total 30 grams of maltodextrin daily) for 5 days. In the groups, one sachet is given to the patient at 6 am, one sachet at 2 pm, and one sachet at 10 pm, along with gavage (if enteral nutrition is used) or half an hour after the main meal (if oral nutrition is used). In order to comply with ethical principles, no intervention is made in the field of drug therapy of the patients.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Chamran heart hospital
Full name of responsible person
Maedeh Banaei Pour
Street address
Salman Farsi St., after Shahrestan Bridge, 3rd Mushtaq St., Bozorgmehr Sq., Isfahan
City
Isfahan
Province
Isfehan
Postal code
8166173414

Phone
+98 31 3260 0961
Email
chamran@mui.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Gholamreza Askari
Street address
Vice-Chancellor in Research Affairs -Medical University of Isfahan, Hezar-jerib Avenue
City
Isfahan
Province
Isfehan
Postal code
8174673461
Phone
+98 21 8145 5618
Email
ethics@behdasht.gov.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Isfahan 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
Esfahan University of Medical Sciences
Full name of responsible person
Mohammad Bagherniya
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Nutrition
Street address
Chamran Hospital, Salman Farsi Street
City
Isfahan
Province
Isfehan
Postal code
8166173414
Phone
+98 31 3260 0961
Email
heart@med.mui.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Mohammad Bagherniya
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Nutrition
Street address
Chamran Hospital, Salman Farsi Street
City
isfahan
Province
Isfehan
Postal code
8166173414
Phone
+98 31 3260 0961
Email
heart@med.mui.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Mohammad Bagherniya
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Nutrition
Street address
Isfahan University of Medical Sciences, Hezar-jerib Ave.
City
Isfahan
Province
Isfehan
Postal code
8174673461
Phone
+98 31 3972 3138
Email

bagherniya@nutr.mui.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is 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
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Study information will be published after the individuals are unidentified and after the project is completed.
When the data will become available and for how long
Access period starts six months after the results are published
To whom data/document is available
Researchers working in academic and scientific institutions
Under which criteria data/document could be used
For further analysis
From where data/document is obtainable
Dr. Mohammad Baghernia bagherniya@nutr.mui.ac.ir
What processes are involved for a request to access data/document
After reviewing the request and making it fully clear about the purposes of using the data, the data will be provided.
Comments