Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Effect of Beta-hydroxy beta-methylbutyrate, Arginine and Glutamine supplementation in patients undergoing cardiac surgery on postoperative outcomes

Protocol summary

Study aim

Compare the mean concentration of immune factors before and after surgery in the intervention and control groups (White Blood Cell, Red Blood Cell, lymphocytes, Neutrophils, Interleukin 6, Interleukin 1, Tumor necrosis factor α) Determine and comparing the mean concentration of inflammatory factors before and after surgery in the intervention and control groups (Erythrocyte sedimentation rat, High-sensitive CRP)

Design

A clinical trial with a control group, in parallel, will be perform on 80 patients

Settings and conduct

Patients will selected by randomized block sampling from Shahid Rajaei Heart Hospital in Tehran will be contacted before surgery until 30 days before surgery and receive sachets containing supplement and placebo. After confirmation, patients are asked to mix and consume 2 sachets containing supplement with beta hydroxy beta-methylbutyrate, arginine and glutamine or placebo with 120 cc of water daily.

Participants/Inclusion and exclusion criteria

Willingness to cooperate and complete the informed consent form by the patient؛ Age 18 to 70 years, Body mass index above 18.5 and below 30

Intervention groups

The intervention group will receive a dietary supplement containing Beta-hydroxy methylbutyrate,Glutamine and Arginine to evaluate its effect on the consequences after heart surgery, and the control group will use packages similar to the same dietary supplement containing maltodextrin.

Main outcome variables

The mean concentration of immune factors before and after surgery did not differ between the intervention and control groups. The mean concentration of inflammatory factors before and after surgery did not differ between the intervention and control groups. The mean concentration of muscle factors before and after surgery is not different between the intervention and control groups.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120913010826N31**
Registration date: **2020-10-13, 1399/07/22**
Registration timing: **registered_while_recruiting**

Last update: **2020-10-13, 1399/07/22**
Update count: **0**

Registration date

2020-10-13, 1399/07/22

Registrant information

Name

Azadeh Nadjarzadeh

Name of organization / entity

Shahid Sadoughi University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 912 202 2817

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-07-26, 1399/05/05

Expected recruitment end date

2020-12-20, 1399/09/30

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

Scientific title
Effect of Beta-hydroxy beta-methylbutyrate, Arginine and Glutamine supplementation in patients undergoing cardiac surgery on postoperative outcomes

Public title
Effect of beta-hydroxy beta-methylbutyrate, arginine and glutamine on complication after cardiac surgery
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Willingness to cooperate and complete the informed consent form by the patient Age 18 to 70 years Body mass index (BMI) above 18.5 and below 30 Do not take supplements or formulas to strengthen the immune system before starting the study No infection and sepsis No need for other entral formulas due to special problems (kidney, lung, liver, etc) Candidate patients for heart surgery
Exclusion criteria:
Drugs that affect metabolism such as steroids and male and female hormonal drugs or corticosteroids Abnormal liver function Metastatic cancer and autoimmune diseases Patients with thyroid, pituitary and hypothalamus dysfunction
Age
From **18 years** old to **70 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
Participants will be randomly assigned to the intervention or placebo, using a computer-generated sequence allocation with permuted blocks, in blocks of 2 with 1:1 allocation ratio to each group . Allocation concealment was via sealed opaque envelopes.
Blinding (investigator's opinion)
Double blinded
Blinding description
Study supplements were identical in appearance . Investigators, patients, and clinicians will be blinded to treatment assignment.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of shahid sadoughi medical science university
Street address
Shahid sadoughi, Yazd
City
Yazd
Province
Yazd
Postal code
2010102748
Approval date
2019-12-31, 1398/10/10
Ethics committee reference number
ir.ssu.sph.rec.1398.122

Health conditions studied

1

Description of health condition studied
cardiac surgery patients
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Biochemical evaluation of interleukin 1 (mean serum interleukin-1 concentration) Biochemical evaluation of interleukin 6 (mean serum interleukin-1 concentration) Biochemical evaluation of TNF-alpha (mean serum TNF-alpha concentration)
Timepoint
Before and after of surgery
Method of measurement
Biochemical experiments

Secondary outcomes

1

Description
Duration of hospitalization in ICU and hospital
Timepoint

After cardiac surgery

Method of measurement

Check the patient file

Intervention groups

1

Description

Intervention group: Intervention group will receive supplement which contains 7 grams of glutamine, 7 grams of arginine and 1.5 grams of hydroxy methylbutyrate. These supplements are given to patients twice a day for 1 month. Patients are given complete training before taking the supplement that mix sachets with 120 cc of cold water and consume.

Category

Treatment - Drugs

2

Description

Control group:Patients in the control group are given sachets containing maltodextrin, which are very similar to Hilagen supplements. These people are also told to consume 2 sachets daily with 120 cc of cold water.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Rajaee Hospital

Full name of responsible person

Mona Norouzi

Street address

Vali-e-Asr St, Shahid Rajaee hospital

City

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Province

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2010102748

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Dr Azadeh Nadjarzadeh

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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

Yazd 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

Yazd University of Medical Sciences

Full name of responsible person

Dr Azadeh Nadjarzadeh

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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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)
Yes - There is 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
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
Not applicable

Title and more details about the data/document
Information about the main outcomes and variables will be shared and personal information is confidential

When the data will become available and for how long
Access starts about 3 months after the results are published.

To whom data/document is available
Students and graduates of this field

Under which criteria data/document could be used
For use in similar research work

From where data/document is obtainable
Dr Azadeh Najarzadeh: azadehnajarzadeh@gmail.com
Mona Norouzi : mona.noruzi@yahooo.com

What processes are involved for a request to access data/document
The file and data will be sent to you two weeks after the review.

Comments