Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 May 2026

Effect of co-administration of zinc and vitamin E supplements on plasma concentrations cytokines secreted by T-helper1, 2, and 17 in cardiac surgery patients: Randomized controlled trial

Protocol summary

Study aim

Comparison of the post surgery length of hospital stay in each group and between the two groups Comparison of the plasma concentration of the interferon gamma (Th1 cells cytokine) at the beginning and end of the study Comparison of the plasma concentration of the interleukin 4 (Th2 cells cytokine) at the beginning and end of the study Comparison of the plasma concentration of the interleukin 17 (Th 17 cells cytokine) at the beginning and end of the study

Design

Two arm, parallel, randomized trial with blinded outcome assessment. The sequence of assigning individuals to the study groups is done using Random Allocation Software.

Settings and conduct

Patient assignment is done by stratified permuted Block Randomization sampling method (stratification by history of diabetes) to two study groups. After surgery, from the second day after admission to the intensive care unit to 3 weeks after surgery, patients of the Intervention group will receive 200 units per day of vitamin E supplement + 40 mg zinc supplement (5 days per week) and the control group will receive the placebo capsules.

Participants/Inclusion and exclusion criteria

Inclusion criteria: -Patients who are candidates for open heart surgery Exclusion criteria: -Frequent use of zinc, vitamin E, multivitamin, and omega-3 supplements during the past month -Chronic rheumatic disease, active cancer treatment, severe infection (WBC>12000 mm3) before surgery, ESRD, liver cirrhosis -Regular use of corticosteroids before heart surgery or continuous use of NSAID drugs during two weeks before admission (except A.S.A.) -Off-pump surgery -Need for re-surgery

Intervention groups

Placebo group: Patients will take two placebo tablets daily Zinc+Vitamin E group (Vitamin E in a daily dose of 200 units of alpha tocopherol and zinc in the form of zinc gluconate in a dose of 40 mg, five times a week)

Main outcome variables

IL-17; IFN gamma concentration

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160702028742N12**
Registration date: **2022-09-03, 1401/06/12**
Registration timing: **registered_while_recruiting**

Last update: **2022-09-03, 1401/06/12**
Update count: **0**

Registration date

2022-09-03, 1401/06/12

Registrant information

Name
Javad Nasrollahzadeh
Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 21 2236 0656
Email address
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-08-27, 1401/06/05

Expected recruitment end date

2023-01-20, 1401/10/30

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effect of co-administration of zinc and vitamin E supplements on plasma concentrations cytokines secreted by T-helper1, 2, and 17 in cardiac surgery patients: Randomized controlled trial

Public title
Effect of zinc and vitamin E supplements on immune system cytokines
Purpose
Basic scienece
Inclusion/Exclusion criteria
Inclusion criteria:
Patients who are candidates for open heart surgery
Exclusion criteria:
Off-pump heart surgery
Age
From **40 years** old to **80 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant

Sample size
Target sample size: **62**
Randomization (investigator's opinion)
Randomized
Randomization description
Participants will be randomized to receive vitamin supplement or the placebo. To ensure that the study participants were balanced in two groups, stratified block randomization will be used. Stratification will be based on having/not having diabetes. In each stratum, randomization will be in blocks of four. The sequence of each block will be determined using random assignment software (RAS) with a 1:1 ratio between the two groups in the block. The allocation sequence is placed in an opaque envelope and they are numbered, and during the study they are opened sequentially and people are assigned to groups based on it.
Blinding (investigator's opinion)
Single blinded
Blinding description
The researcher is aware of the type of supplements used, but due to similar shape and color, they cannot be distinguished by the patient. Also, those responsible for data collection and outcome assessment are blinded to the type of supplement used by the patient.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
کمیته اخلاق انستیتو تحقیقات تغذیه و صنایع غذایی کشور
Street address
No. 7, West Arghavan Ave., Farahzadi Blvd., Qods Town
City
Tehran
Province
Tehran
Postal code
1981619573
Approval date
2021-11-09, 1400/08/18
Ethics committee reference number
IR.SBMU.NNFTRI.REC.1400.069

Health conditions studied

1

Description of health condition studied
Coronary heart disease
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Interleukin 17 interferon gamma concentration
Timepoint
Measurement of cytokine concentration at the beginning of the study (before surgery) and 21 days after surgery
Method of measurement
ELISA

Secondary outcomes

1

Description
post surgery length of hospitalization
Timepoint
After open heart surgery
Method of measurement
Medical record

Intervention groups

1

Description
Control group: Placebo capsules produced by the pharmaceutical company producing the study supplements (Dana Pharmaceutical Company) and contain all the ingredients used in the supplement except the active ingredient (vitamin E or zinc) from the second day after surgery until the end of the study (3 weeks after surgery)
Category
Placebo

2

Description
Intervention group: Zinc and vitamin E capsules (Vitamin E in 200 international units of alpha-tocopherol and zinc in the form of zinc gluconate in a dose of 40 mg, 5 days a week) from the second day after surgery until the end of the study (3 weeks after surgery).
Category
Lifestyle

Recruitment centers

1

Recruitment center
Name of recruitment center
Shafa Hospital - Kerman University of Medical Sciences
Full name of responsible person
Elham Makiabadi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Azita Hekmatdoost
Street address
No. 7, West Arghavan Ave., Farahzadi Blvd., Qods Town
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nnftri_food@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Elham Makiabadi
Position
PhD. candidate
Latest degree
Master
Other areas of specialty/work
Nutrition
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Person responsible for scientific inquiries

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Position

Associate professor

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Other areas of specialty/work

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Person responsible for updating data

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Position

Associate professor

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Other areas of specialty/work

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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