Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Protective effect of Silymarin on liver during coronary artery bypass surgery

Protocol summary

Study aim
Determination of the protective effect of silymarin on the liver during coronary artery bypass grafting

Design
A randomized, triple-blinding clinical trial, with the parallel groups, Phase 3 on 80 patients

Settings and conduct
In this randomized, triple-blind clinical trial, 80 eligible patients referred to Chamran Hospital in Isfahan will be enrolled and randomly divided into two groups. One week before surgery, patients in the first group will be prescribed silymarin and those in the second group will be prescribed placebo. In this study, the patient, the researcher, and the statistical analyst will not have any knowledge of the type of intervention. Then the inflammatory factors and blood parameters of the patients will be evaluated and compared between the two groups.

Participants/Inclusion and exclusion criteria
The inclusion criteria included patients who were candidates for elective CABG surgery, aged 30 to 70 years, EF greater than 40%, and written consent to participate in the study. The exclusion criteria included having clinical evidence of active inflammatory or immunomodulatory disease, positive HBV and HCV test results, a history of taking anti-inflammatory or antioxidant drugs before surgery, a history of chronic liver disease, chronic alcohol consumption, a candidate for multiple surgeries at the same time, requiring emergency surgery, and having any history of myocardial infarction within the previous 2 months.

Intervention groups
Intervention group: Patients will receive 6 mg/kg of silymarin daily, branded as Livergol, manufactured by Gol Daru Company, each tablet containing 140 mg of silymarin (as 2 mg/kg three times a day), starting one week before surgery. Control group: Patients will receive placebo in the same manner and schedule as the intervention group.

Main outcome variables
Liver enzymes; Bilirubin; Troponin; ESR; CRP; IL-6

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20200825048515N77**
Registration date: **2024-12-15, 1403/09/25**
Registration timing: **prospective**

Last update: **2024-12-15, 1403/09/25**
Update count: **0**

Registration date
2024-12-15, 1403/09/25

Registrant information
Name
Asieh Maghami Mehr
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 31 0000 0000
Email address
asimaghami@yahoo.com

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2025-01-04, 1403/10/15
Expected recruitment end date
2025-07-22, 1404/04/31
Actual recruitment start date
empty
Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Protective effect of Silymarin on liver during coronary artery bypass surgery

Public title
Protective effect of Silymarin on liver during cardiac surgery

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients who are candidates for elective CABG surgery Age between 30 and 70 years EF greater than 40% Written consent to participate in the study

Exclusion criteria:
Clinical evidence of active inflammatory or immunomodulatory disease (such as acute coronary syndromes, malignancy, intermittent infections, renal failure, or autoimmune disease (such as hepatitis)) Positive HBV and HCV test results History of anti-inflammatory or antioxidant drugs before surgery History of chronic liver disease Chronic alcohol consumption Patients who are candidates for multiple surgeries at the same time Patients who require emergency surgery Any history of myocardial infarction within the previous 2 months

Age
From **30 years** old to **70 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, 80 eligible patients are randomly selected. For this, the letter A is written on 40 sheets, and the letter B is written on 40 sheets and each of them is placed in an envelope. Each patient is then asked to choose one of the envelopes. Depending on the selected envelope, the patient is assigned to one of two groups.

Blinding (investigator's opinion)
Triple blinded

Blinding description
In order to achieve the triple-blind study, a placebo drug similar in color, shape, and odor to silymarin will be prepared by the pharmacist before the study begins, and the two drugs will be coded with labels A and B and made available to the researcher. He also prescribes the drugs without knowing the type of medication. In addition, the patient, the person collecting the data, and the statistician will have no knowledge of the type of intervention.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Isfahan University of Medical Sciences

Street address
Street address Isfahan University of Medical Sciences, Hezar Jarib Ave., Azadi Sq

City
Isfahan

Province
Isfehan

Postal code
8179964167

Approval date
2024-11-02, 1403/08/12

Ethics committee reference number
IR.MUI.MED.REC.1403.311

Health conditions studied

1

Description of health condition studied
Coronary artery bypass surgery

ICD-10 code
I25.810

ICD-10 code description
Atherosclerosis of coronary artery bypass graft(s) without angina pectoris

Primary outcomes

1

Description
Alkaline Phosphatase (ALP)

Timepoint
Before the intervention, before surgery, immediately after surgery, 48 hours and one week after surgery

Method of measurement
Blood test

2

Description
Alanine aminotransferase (ALT)
Timepoint
Before the intervention, before surgery, immediately after surgery, 48 hours and one week after surgery
Method of measurement
Blood test

3

Description
Aspartate transaminase (AST)
Timepoint
Before the intervention, before surgery, immediately after surgery, 48 hours and one week after surgery
Method of measurement
Blood test

4

Description
Bilirubin
Timepoint
Before the intervention, before surgery, immediately after surgery, 48 hours and one week after surgery
Method of measurement
Blood test

5

Description
Troponin
Timepoint
Before the intervention, before surgery, immediately after surgery, 48 hours and one week after surgery
Method of measurement
Blood test

6

Description
ESR
Timepoint
Before the intervention, before surgery, immediately after surgery, 48 hours and one week after surgery
Method of measurement
Blood test

7

Description
C-Reactive Protein (CRP)
Timepoint
Before the intervention, before surgery, immediately after surgery, 48 hours and one week after surgery
Method of measurement
Blood test

8

Description
Interleukin-6 (IL-6)
Timepoint
Before the intervention, before surgery, immediately after surgery, 6 hours after surgery
Method of measurement
Blood test

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Patients will receive 6 mg/kg of silymarin daily from one week before surgery with the brand name Livergol, manufactured by Gol Daru Company, each tablet containing 140 mg of silymarin (as 2 mg/kg three times a day).
Category
Treatment - Drugs

2

Description
Control group: Patients will receive placebo daily from one week before surgery.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Chamran Hospital
Full name of responsible person
Mehran Shahzamani
Street address
2nd Moshtagh Street, Isfahan.
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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 for Research, Isfahan University of Medical Sciences and Health Services, Hezar Jarib Street
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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
Mehran Shahzamani
Position
Associate Professor
Latest degree
Subspecialist
Other areas of specialty/work
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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
There is no further 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

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available