Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of short-term effect of adding Silymarin versus placebo to standard treatment, in prevention of contrast induced nephropathy in patient undergoing coronary angiography

Protocol summary

Summary

The aim of this study is to evaluate the efficacy of Silymarin in preventing contrast nephropathy. Patients with chronic stable angina who need to coronary angiography will be included. Patients with diabetes, kidney disease, acute infarction, or unstable angina will not be included. Study sample will be consisting of 200 patients referring for angiography to the Khorshid Hospital in Isfahan, Iran. Patients will receive either a single dose of silymarin tablet (280 mg) or placebo tablet 2 hours before administration of the contrast material. All patients will be hydrated with 0.9% sodium chloride (1 mL/kg/h) for 12 hours, started 6 hours before operation and continued to 6 hours after the procedure. In all cases, a non-ionic contrast media with low osmolality will be used. Primary outcome is occurrence of the contrast nephropathy which is defined as an increase in serum creatinine of equal or more than 0.5 mg/dL or equal or more than 25% of the baseline creatinine after 48 hours of contrast material injection.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014051117648N1**
Registration date: **2015-04-13, 1394/01/24**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2015-04-13, 1394/01/24

Registrant information

Name

Zohreh Sedighifard

Name of organization / entity

Esfahan Univercity of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical Sciences

Expected recruitment start date

2015-01-10, 1393/10/20

Expected recruitment end date

2015-03-31, 1394/01/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of short-term effect of adding Silymarin versus placebo to standard treatment, in prevention of contrast induced nephropathy in patient undergoing coronary angiography

Public title

Effect of Silymarin in prevention of contrast nephropaty

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: having chronic stable angina; indication of coronary angiograghy; willingness to participate. Exclusion criteria: FBS >=100; eGFR < 60 cc/1.73m2; history of diabetes or kidney disease; having

myocardial infarction, unstable angina, or cardiogenic shock; tacking contrast agent during one month before study.

Age
No age limit

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **200**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Isfahan University of Medical Sciences

Street address
Hezar Jerib Ave.

City
Isfahan

Postal code

Approval date
2015-01-10, 1393/10/20

Ethics committee reference number
393752

Health conditions studied

1

Description of health condition studied
Nephropathy

ICD-10 code
N14

ICD-10 code description
Nephropathy induced by other drugs, medicaments and biological substances

Primary outcomes

1

Description
Contrast induced nephropathy

Timepoint
48 hours after angiography

Method of measurement
Measuring serum creatinine level

Secondary outcomes

1

Description
-

Timepoint
-

Method of measurement
-

Intervention groups

1

Description
Patients in the intervention group will receive a single dose of silymarin tablet (280 mg) 2 hours before administration of the contrast material.

Category
Prevention

2

Description
Patients in the placebo group will receive placebo tablet 2 hours before administration of the contrast material.

Category
Placebo

3

Description
All patients will be hydrated with 0.9% sodium chloride (1 mL/kg/h) for 12 hours, started 6 hours before operation and continued to 6 hours after the procedure.

Category
Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Khorshid Hospital

Full name of responsible person
Zohreh Sedighifard

Street address
Ostandari St., Khorshid Hospital

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Isfahan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Isfahan University of Medical Sciences
Full name of responsible person
Vice Chancellor of Research
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Vice Chancellor of Research, Isfahan University of Medical Sciences, Hezar Jerib Ave.
City
Isfahan
Grant name
Grant code / Reference number
393752
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Isfahan University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty