

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 University of Medical Sciences

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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 nephropathy

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: having chronic stable angina; indication of coronary angiography; 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; taking 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

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Isfahan University of Medical Sciences

Full name of responsible person

Vice Chancellor of Research

Street address

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

Contact

Name of organization / entity

Isfahan University of Medical Sciences

Full name of responsible person

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Resident of Cardiology

Other areas of specialty/work

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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