

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Aug 2026

Double-blinde, randomized clinical trial on efficacy and safety of Dixopaque (Shahid Ghazi) contrast media and Visipaque in coronary angiography

Protocol summary

Summary

The purpose of this clinical study is to compare the effects of contrast agent (iodinol) Dixopaque produced by Shahid Ghazi pharmaceuticals and Visipaque (Commercial Brand). This is a phase 3, double-blind clinical trial with random allocation method. The primary outcome will be image quality which be assessed by interventional caradiologist. Probable adverse events and renal toxicity will be secondary outcomes of this trial. A total of 50 referred patients for peripheral coronary angiography with contrast in both male and female genders, aged between 45 and 65 years old will be eligible for recruitment in this study. Patients suffering from kidney disfunction and history of allergy to contrasts will be excluded.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201607254920N8**

Registration date: **2016-12-25, 1395/10/05**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2016-12-25, 1395/10/05

Registrant information

Name

Ramin Heshmat

Name of organization / entity

Chronic Diseases Research Center

Country

Iran (Islamic Republic of)

Phone

+98 21 8822 0086

Email address

rheshmat@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Shahid Ghazi Pharmaceuticals Company

Expected recruitment start date

2017-01-01, 1395/10/12

Expected recruitment end date

2017-05-02, 1396/02/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Double-blinde, randomized clinical trial on efficacy and safety of Dixopaque (Shahid Ghazi) contrast media and Visipaque in coronary angiography

Public title

Comparison of contrast media Dixopaque (Shahid Ghazi) and Visipaque

Purpose

Diagnostic

Inclusion/Exclusion criteria

Inclusion criteria: patients aged between 45 to 65 years old; referred subjects for coronary angiography by contrast media; provided signed and dated informed consent subjects. Exclusion criteria: patients with contrast administration in the past 7 days; subjects have known contra-indication and allergy to contrast administration; renal insufficiency as defined by GFR < 50; lactation; pregnancy; bronchial asthma; clinical unstable condition (hemodynamic, respiratory,

neurologic); emergency cases; hyperthyroidism; end-stage patients.

Age

From **45 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tehran University of Medical Sciences

Street address

6th fl., TUMS Central Office, Qods St., Keshavarz Ave.,

City

Tehran

Postal code

Approval date

2016-11-19, 1395/08/29

Ethics committee reference number

IR.TUMS.VCR.REC.1395.1047

Health conditions studied

1

Description of health condition studied

Patients candidated for coronary angiography by contrast media

ICD-10 code

120-125

ICD-10 code description

Ischemic Heart Diseases

Primary outcomes

1

Description

Image Quality

Timepoint

After coronary angiography

Method of measurement

Scoring by investigator from 1 to 10

Secondary outcomes

1

Description

Adverse events of contrast media

Timepoint

During injection and 24 after injection

Method of measurement

Interview, Physical exam, Lab test

2

Description

Renal toxicity

Timepoint

Before and 24 hours after injection

Method of measurement

Serum creatinine examination

Intervention groups

1

Description

Intervention: patients in this group based on randomization will receive Dixopaque of Shahid Ghazi with a single dose of 320 mg intravenously.

Category

Diagnosis

2

Description

Control:patients in this group based of randomization will receive Visipaque with a single dose of 320 mg intravenously.

Category

Diagnosis

Recruitment centers

1

Recruitment center

Name of recruitment center

Department of Cardiology, Dr. Shariati Hospital

Full name of responsible person

Dr. Abbass Mohagheghi

Street address

Shariati Hospital, North Kargar Ave., Tehran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Ghazi Pharmaceutical Company

Full name of responsible person

Dr. Ramin Radmanesh

Street address

No 22, Eghbal Ave, Reshadat Ave, Saadat abad

City

Tehran

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Shahid Ghazi Pharmaceutical Company

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**

Chronic Diseases Research Center

Full name of responsible person

Dr. Ramin Heshmat

Position

Epidemiologist

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Person responsible for scientific inquiries

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Full name of responsible person

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Position

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Person responsible for updating data

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Maryam Sanaei

Position

MSc of Microbiology

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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