

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Image contrast quality and safety comparison of OPAQUESOL (Shahid Ghazi) and OMNIPAQUE in CT-Scan with contrast

Protocol summary

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Summary

The purpose of this clinical study is to compare the effects of contrast agent (iohexol) Opacuesol produced by Shahid Ghazi pharmaceuticals and Omnipaque (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 radiologist. Probable adverse events and renal toxicity will be secondary outcomes of this trial. A total of 50 referred patients for peripheral CT-Scan 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.

Recruitment status

Recruitment complete

Funding source

Shahid Ghazi Pharmaceuticals Company

Expected recruitment start date

2016-06-01, 1395/03/12

Expected recruitment end date

2016-09-29, 1395/07/08

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201604094920N7**

Registration date: **2016-05-09, 1395/02/20**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2016-05-09, 1395/02/20

Registrant information

Name

Ramin Heshmat

Name of organization / entity

Chronic Diseases Research Center

Country

Iran (Islamic Republic of)

Phone

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Email address

Scientific title

Image contrast quality and safety comparison of OPAQUESOL (Shahid Ghazi) and OMNIPAQUE in CT-Scan with contrast

Public title

Comparison of OPAQUESOL (Shahid Ghazi) and OMNIPAQUE in CT-Scan with contrast

Purpose

Diagnostic

Inclusion/Exclusion criteria

Inclusion criteria: Patients aged between 45 to 65 years old; Referred subjects for CT-Scan by contrast media; Provided signed and dated informed consent subjects. Exclusion criteria: Patient 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 Floor, Ghods St, Keshavarz Blvd.

City

Tehran

Postal code

Approval date

2016-04-10, 1395/01/22

Ethics committee reference number

IR.TUMS.REC.1395-2341

Health conditions studied

1

Description of health condition studied

patients candidat for CT-Scan by contrast media

ICD-10 code

I99

ICD-10 code description

Other and unspecified disorders of circulatory system

Primary outcomes

1

Description

image quality

Timepoint

after CT-Scan

Method of measurement

1 to 10 scoring by investigator

Secondary outcomes

1

Description

Renal Toxicity

Timepoint

Before and 72 hours after injection

Method of measurement

Serum creatinine

2

Description

Adverse events of contrast media

Timepoint

During injection, 4 and 72 hours after injection

Method of measurement

Interviewing with patient

Intervention groups

1

Description

Intervention: Patients in this group based on randomization will receive a single dose Opaquesol of Shahid Ghazi with dosage of 300 mg.

Category

Diagnosis

2

Description

Control: Patients in this group based on randomization will receive a single dose Omnipaque with dosage of 300 mg.

Category

Diagnosis

Recruitment centers

1

Recruitment center

Name of recruitment center

Department of Radiology, Dr. Shariati Hospital

Full name of responsible person

Dr. AmirPejman Hashemi Taheri

Street address

North Kargar Ave., Jalal-e-Al-e-Ahmad

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 3, Norani Blvd, Farahzadi Blvd.

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

Head of Chronic Diseases Research Center

Full name of responsible person

Dr.Ramin Heshmat

Position

Ph.D of Epidemiology

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Head of Radiology Depaetment

Full name of responsible person

Amir Pejman Hashemi Taheri

Position

MD, Radiologist

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Chronic Diseases Research Center

Full name of responsible person

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Position

M.Sc of Microbiology

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