Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

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

Protocol summary

Summary

The purpose of this clinical study is to compare the effects of contrast agent (iohexol) Opacuesol produced by Shahid Ghazi pharmaceutics 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.

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

+98 21 8822 0086

Email address

rheshmat@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Shahid Ghazi Pharmaceutics 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

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
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Person responsible for scientific inquiries

Contact
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Person responsible for updating data

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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