

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jul 2026

Comparison of the efficacy and adverse effects of visipaque and Ultravist in Contrast-enhanced CT Scan

Protocol summary

Summary

120 patients referred for evaluation of abdomen by contrast-enhanced CT Scan were included in this study. Patients were randomly allocated into two groups, group A and group B. Exclusion criteria: severe fatty liver; diabetes, hepatic tumor and portal vein thrombosis. Each group received a different contrast agent through IV route. Group A received 150 cc iodixanol (visipaque)300mg/ml and group B received 150 cc iopromide(Ultravist300mg/ml). CT scan were obtained with Somatom helical CT scanner (Simense, Germany). The contrast agents were injected via a power injector via antecubital vein using a gauge 18 needle. Images were obtained 60 second after injection. Injection pressure after each injection was recorded. Hepatic, portal and aortal enhancements were determined 60 second after injection. Adverse effects in 1 hour after injection and up to 1 week after injection were recorded using two questionnaires.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138904144316N1**

Registration date: **2011-01-08, 1389/10/18**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2011-01-08, 1389/10/18

Registrant information

Name

Farideh Gharekhanloo

Name of organization / entity

Hamedan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 1264 0064

Email address

f_gharekhanloo@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Hamedan University of Medical sciences

Expected recruitment start date

2009-09-23, 1388/07/01

Expected recruitment end date

2010-05-22, 1389/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the efficacy and adverse effects of visipaque and Ultravist in Contrast-enhanced CT Scan

Public title

Comparison of the efficacy and adverse effects of visipaque and Ultravist in Contrast-enhanced CT Scan

Purpose

Diagnostic

Inclusion/Exclusion criteria

Inclusion criteria : patients referred for abdomenoplevic CT
Exclusion criteria : renal disease, Diabetes, known drug reaction

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **120**

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

Hamedan University of Medical sciences Ethics Committee

Street address

Besat Hospital

City

Hamedan

Postal code

6514845411

Approval date

2010-03-09, 1388/12/18

Ethics committee reference number

253/3/54/16/p

Health conditions studied

1

Description of health condition studied

All of patients referred to abdominal and pelvic CT

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Increasing of contrast enhancement

Timepoint

60 seconds after injection

Method of measurement

dansitometry with CTscan apparatus

Secondary outcomes

1

Description

complication post injection

Timepoint

To one week after injection

Method of measurement

registration in questionare

Intervention groups

1

Description

injection contrast ultravist 300mg/ml

Category

Diagnosis

2

Description

injection contrast of visi paque300mg/ml

Category

Diagnosis

Recruitment centers

1

Recruitment center

Name of recruitment center

Department of Radiology, Besat Hospital

Full name of responsible person

Dr Farideh Gharekhanloo

Street address

Besat hospital

City

Hamedan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Hamedan University of Medical Sciences

Full name of responsible person

Dr Ghaleiha

Street address

Besat hospital

City

Hamedan

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice chancellor for research, Hamedan 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

Hamedan University of Medical sciences

Full name of responsible person

Dr Farideh Gharekhanloo

Position

Academic member

Other areas of specialty/work

Street address

Besat hospital

City

Hamedan

Postal code

6514845411

Phone

+98 81 1264 0064

Fax

+98 81 1264 0064

Email

f_gharekhanloo@umsha.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Hamedan University of Medical sciences

Full name of responsible person

Dr Farideh Gharekhanloo

Position

Academic member

Other areas of specialty/work

Street address

Besat hospital

City

Hamedan

Postal code

6514845411

Phone

+98 81 1264 0064

Fax

+98 81 1264 0064

Email

f_gharekhanloo@umsha.ac.ir

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Person responsible for updating data

Contact

Name of organization / entity

Hamedan University of Medical sciences

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Dr Farideh Gharekhanloo

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Street address

Besat hospital

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Fax

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Email

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Web page address

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