

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

A clinical trial to compare the diagnostic quality of CT pulmonary angiogram images between standard and reduced doses of contrast agent in patients with the risk of pulmonary embolism

Protocol summary

Study aim

To compare the diagnostic quality of CT pulmonary angiogram images between standard and reduced doses of contrast agent in patients with the risk of pulmonary embolism

Design

In this research, 50 patients with the risk of pulmonary embolism visiting the Radiology Department of Imam Reza Hospital were chosen randomly and assigned into control and intervention groups. A code was allocated to each of the participants.

Settings and conduct

Patients with the risk of pulmonary embolism presenting to the Radiology Department of Imam Reza Hospital, Mashhad, Iran, are chosen as the participants of the study. In this double-blind study, the participants and radiologist responsible for data collection are unaware of the dosage.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patient with the risk of pulmonary embolism; Weight between 60 and 80 kg. Exclusion criteria: Having acute heart failure; Being CV-line for contrast agent injection.

Intervention groups

The control group: CT pulmonary angiography will be performed with the standard dose of contrast agent (100-120 cc), concentration of 320 mg/ml, and rotation period of 0.75 s for patients with the risk of pulmonary embolism. The intervention group: CT pulmonary angiography will be carried out with the reduced dose of contrast agent (50-60 cc), concentration of 320 mg/ml, and rotation period of 0.75 s for patients with the risk of pulmonary embolism.

Main outcome variables

Evaluation and comparison of the enhancement of the contrast of the aortic arteries, pulmonary truncus, and the right and left main pulmonary arteries based on

Hansfield unit between the intervention and control groups.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180203038595N1**

Registration date: **2018-02-15, 1396/11/26**

Registration timing: **prospective**

Last update: **2018-02-15, 1396/11/26**

Update count: **0**

Registration date

2018-02-15, 1396/11/26

Registrant information

Name

Mansoure Ahrari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3802 2000

Email address

ahraim931@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-10-07, 1397/07/15

Expected recruitment end date

2019-01-20, 1397/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
A clinical trial to compare the diagnostic quality of CT pulmonary angiogram images between standard and reduced doses of contrast agent in patients with the risk of pulmonary embolism

Public title
The diagnostic quality of CT pulmonary angiogram images in patients with the risk of pulmonary embolism

Purpose
Diagnostic

Inclusion/Exclusion criteria
Inclusion criteria:
 Patient with the risk of pulmonary embolism Weight between 60 and 80 kg
Exclusion criteria:
 Having acute heart failure Being CV-line for contrast agent injection

Age
No age limit

Gender
Both

Phase
2

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description
Random number table

Blinding (investigator's opinion)
Double blinded

Blinding description
The participants and radiologist responsible for data collection are unaware of the dosage

Placebo
Not used

Assignment
Other

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
 Ethics Committee of Mashhad University of Medical Sciences
Street address

Vice Chancellor for Research, Mashhad University of Medical Sciences, Ghoreishi building, Daneshgah Street

City
Mashhad

Province
Razavi Khorasan

Postal code
9138813944

Approval date
2017-09-27, 1396/07/05

Ethics committee reference number
IR.MUMS.fm.1396.385

Health conditions studied

1

Description of health condition studied

Pulmonary embolism

ICD-10 code

I26

ICD-10 code description

Pulmonary embolism

Primary outcomes

1

Description

The enhancement of the contrast of the aortic arteries

Timepoint

After taking CT pulmonary angiogram images

Method of measurement

Based on Hansfield unit

2

Description

The enhancement of the pulmonary truncus

Timepoint

After taking CT pulmonary angiogram images

Method of measurement

Based on Hansfield unit

3

Description

The enhancement of the right and left main pulmonary arteries

Timepoint

After taking CT pulmonary angiogram images

Method of measurement

Based on Hansfield unit

Secondary outcomes

empty

Intervention groups

1

Description

Control group: CT pulmonary angiography will be performed with the standard dose of contrast agent (100-120 cc), concentration of 320 mg/ml, and rotation period of 0.75 s for patients with the risk of pulmonary embolism

Category

Diagnosis

2

Description

Intervention group: CT pulmonary angiography will be carried out with the reduced dose of contrast agent (50-60 cc), concentration of 320 mg/ml, and rotation period of 0.75 s for patients with the risk of pulmonary embolism

Category

Diagnosis

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital

Full name of responsible person

Mansoure Ahrari

Street address

Imam Reza Hospital, Ibn Sina Avenue, Imam Reza Square

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ahraim931@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

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Vice Chancellor for Research, Mashhad University of Medical Sciences, Ghoreishi building, Daneshgah Street

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Vcresearch@mums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Mashhad University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mansoure Ahrari

Position

Resident

Latest degree

Specialist

Other areas of specialty/work

Radiology

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

The total data to be included are the primary and secondary effects to be shared

When the data will become available and for how long

6 months after printing results

To whom data/document is available

Our data will only be available to researchers working in science center and university

Under which criteria data/document could be used

Our data will be available for scholars working in science center and university

From where data/document is obtainable

Mansoure Ahrari provides the analysis code to the applicants via email: ahraim931@mums.ac.ir

What processes are involved for a request to access data/document

Data collection was done for 3 months, data were collected one month, statistical analysis of one month, information dissemination as a article six months

Comments**Person responsible for updating data****Contact****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Mansoure Ahrari

Position

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