Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Jul 2026

Investigating the effect of contrast agent reduction and lowering radiation dose on the image quality of pulmonary Computed Tomography (CT) in patients suspected of pulmonary thromboembolism using iterative reconstruction

Protocol summary

Study aim
To determine the effect of the contrast agent and radiation dose reduction, on the image quality of the pulmonary Computed Tomography Angio (CTA) in patients suspected of pulmonary thromboembolism

Design
This study is a randomized clinical trial containing 40 samples. This double-blind study has two parallel groups (control or standard dose and intervention or reduced dose). A table of random numbers will be used to allocate samples to control and intervention groups randomly.

Settings and conduct
In this randomized clinical trial inpatients suspected of pulmonary embolism, at Shahid Faghihi hospital, Shiraz will be allocated into control (standard protocol) and intervention groups. The image quality of pulmonary CTA of both groups will be evaluated by two radiologists blinded to the scanning parameters.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients suspected of thromboembolism on the basis of clinical indications, Abnormal level of plasma D-dimer, laving deep veins thrombosis of lower limb Exclusion criteria: creatinine>1.36 mg/dL, allergy to iodinated contrast, severe pneumonia and atelectasis, Confirmed pregnancy or suspicious of pregnancy, Body Mass Index>30 kg/m2, Critically ill patient or hospitalized in ICU, age<18 years

Intervention groups
Control group: patients will be scanned by a standard protocol containing a 1 ml/kg contrast agent and 120 kVp. Intervention group: patients will be scanned with a 0.5 ml/kg contrast agent and 100kVp. CT images will be reconstructed by Iterative algorithm (IR) in both control and intervention groups.

Main outcome variables
Independent variables: Contrast agent and radiation dose. Dependent variable: image quality of pulmonary CT angiography

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220313054273N1**
Registration date: **2022-08-19, 1401/05/28**
Registration timing: **prospective**

Last update: **2022-08-19, 1401/05/28**
Update count: **0**

Registration date
2022-08-19, 1401/05/28

Registrant information

Name
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Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-08-23, 1401/06/01

Expected recruitment end date
2023-06-21, 1402/03/31

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigating the effect of contrast agent reduction and lowering radiation dose on the image quality of pulmonary Computed Tomography (CT) in patients suspected of pulmonary thromboembolism using iterative reconstruction

Public title
The effect of contrast agent reduction and low dose radiation on image quality in Pulmonary CT angiography
Purpose
Diagnostic
Inclusion/Exclusion criteria
Inclusion criteria:
Patients who are suspicious of pulmonary emboly on the basis of clinical indication Abnormal level of plasma D-dimer Having deep veins thrombosis of lower limb age > 18 years BMI less than 30kg/m2 GFR greater than 60ml/min/1.73m2 Creatinine less than 1.3mg/ml Willingness to participate in the study and sign informed consent Does not have allergy to iodine contrast
Exclusion criteria:
Patient with severe pneumonia and atelectasis Confirmed pregnancy or suspicious of pregnancy Critically ill patient or hospitalized in ICU
Age
From **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
This study will be done by simple randomization. The unit of randomization is individual. The table of random numbers that will be used in this study contains a series of numbers, zero and one, produced by the random method. In this study, the table of random numbers will be used to make the sequence random. Zero and one numbers will be allocated to the control (standard pulmonary CT Angio) and intervention (contrast agent reduction and low dose of radiation) groups, respectively. This process will continue until the end of the sampling process so that finally 20 patients will be assigned to each group.
Blinding (investigator's opinion)
Double blinded
Blinding description
In this study, the investigator (radiologists who evaluate the quality of pulmonary CTA) and patients (ready to take part in this study and signed consent form) are not aware of the scanning protocol. They are blind to the amount of contrast agent and radiation dose. Technologists responsible for scanning patients and the student responsible for performing the study are aware of the scanning protocol.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shiraz University of Medical Sciences
Street address
Research Center, 8th Floor, Mohammad Rasolallah Research Tower, Khalili street
City
Shiraz
Province
Fars
Postal code
7193635899
Approval date
2022-06-21, 1401/03/31
Ethics committee reference number
IR.SUMS.MED.REC.1400.455

Health conditions studied

1

Description of health condition studied
Pulmonary thromboembolism
ICD-10 code
I26
ICD-10 code description
Pulmonary embolism

Primary outcomes

1

Description
The objective image quality of pulmonary CT Angio will be determined by radiologists through a scoring system. The quantitative image quality will be determined by quantitative parameters such as Signal-to-Noise Ratio. The quantity of radiation dose to the patient will be measured by the CT system. The related values will be

shown on the Dose Report Page available at the end of the image series.

Timepoint

The CT images will be sent to Picture Archiving and Communication System immediately after the scanning procedure completed. Then the qualitative and quantitative evaluation of the image quality of pulmonary CT Angio will perform. The results of the dose measurement will be available immediately after completing the scan.

Method of measurement

Quantitative pulmonary Computed Tomography Angio (CTA) image quality will be measured by Signal-to-Noise Ratio (SNR). SNR results from the division of the mean CT density of the main pulmonary arteries (left and right) filled with contrast agent by the standard deviation of the background region (without contrast agent for example muscles surrounding the scapula). Qualitative pulmonary CT angiography is measured by the scores which are devoted to each series of images. Qualitative pulmonary CT angiography image quality will be measured by visual assessment. In this method the radiologist will use a scoring system on the basis of 5 scale scores as follow, (1) undiagnosable pulmonary CTA image (2) limited diagnostic value (3) sufficient diagnostic value (4) good image quality (5) excellent diagnostic value. Radiation dose to the patient will be measured by CT dose indices which are available on the page of dose report at the end of the CT image series.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients suspected of pulmonary embolism referred to Shahid Faghihi Hospital (Shiraz) will be scanned by contrast agent reduction and radiation dose reduction protocol. The amount of injected contrast agent to the patients in intervention group will be 0.5 millilitre per each kilogram of body weight. The Pecnograph contains 300mgI/ml (milligram iodine per millilitre) made in Iran is the available contrast agent. This contrast agent will be used to scan patients in intervention group. These patients will be scanned by 128-MDCT Philips Ingenuity system, made in Netherland, at 100kVp. This CT system uses Iterative Reconstruction (IR) algorithm to reconstruct CT images. The pulmonary CT Angio images of patients in intervention group will be reconstructed by iDose level4 (a type of IR reconstruction), made in Netherland by Philips Company.

Category

Diagnosis

2

Description

Control group: Patients suspected of pulmonary embolism referred to Shahid Faghihi Hospital (Shiraz) will be scanned by standard protocol (pulmonary CT Angio). The amount of injected contrast agent to the patients in control group will be 1.0 millilitre per each kilogram of patient's body weight. The Pecnograph contains 300mgI/ml (milligram iodine per millilitre) made in Iran is the available contrast agent. This contrast agent will be used to scan patients in control group. The patients in control group will be scanned by 128-MDCT Philips Ingenuity system, made in Netherland, at 100kVp. This CT system uses Iterative Reconstruction (IR) algorithm to reconstruct CT images. The pulmonary CT Angio images of patients in control group will be reconstructed by iDose level4 (a type of IR reconstruction), made in Netherland by Philips Company.

Category

Diagnosis

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahid Faghihi Hospital

Full name of responsible person
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1

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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shiraz 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
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Position
Assistant professor
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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
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Not applicable
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

Part of the data can be shared after unidentified.

When the data will become available and for how long

3 months after publication

To whom data/document is available

Interested researchers in this field

Under which criteria data/document could be used

using for research work

From where data/document is obtainable

Research and technology deputy

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

Sending an Email to the research and technology deputy
Shiraz University of Medical Sciences

Comments