Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Jun 2026

Evaluation of contrast agent reduction on the image quality of pulmonary Computed Tomography using a standard reconstruction available in the conventional CT system

Protocol summary

Study aim

Determination of the effect of contrast agent reduction on image quality of the pulmonary Computed Tomography, reconstructed by the standard algorithm 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. A table of random numbers will be used to allocate samples to control (standard protocol) and intervention (contrast agent reduction) groups randomly.

Settings and conduct

This randomized clinical trial with inpatients suspected of pulmonary embolism, will be conducted at the Namazi Hospital, Shiraz. The patients will be allocated into control 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, lower extremity deep vein thrombosis Exclusion: 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

Intervention groups

Intervention group: patients will be scanned with a 0.7 ml/kg contrast agent and 100kVp. Control group: patients will be scanned by a standard protocol containing a 1 ml/kg contrast agent and 120 kVp. CT images will be reconstructed by the standard algorithm (FBP) in both control and intervention groups.

Main outcome variables

Independent variables: The amount of contrast agent. Dependent variable: Image quality of pulmonary CT angiography

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220313054273N2**
Registration date: **2022-09-27, 1401/07/05**
Registration timing: **registered_while_recruiting**

Last update: **2022-09-27, 1401/07/05**
Update count: **0**

Registration date

2022-09-27, 1401/07/05

Registrant information

Name

Rezvan Ravanfar Haghighi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-09-23, 1401/07/01

Expected recruitment end date

2023-02-20, 1401/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Evaluation of contrast agent reduction on the image quality of pulmonary Computed Tomography using a standard reconstruction available in the conventional CT system

Public title
The effect of contrast agent reduction on the image quality of pulmonary Computed Tomography

Purpose
Diagnostic

Inclusion/Exclusion criteria

Inclusion criteria:
Suspicion pulmonary emboly as seen from clinical indication Abnormal levels of plasma D-dimer Lower extremity deep vein thrombosis

Exclusion criteria:
Severe pneumonia and atelectasis Confirmed pregnancy or suspected but unconfirmed pregnancy Critically ill patient or patients hospitalized in ICU Allergy to iodine contrast agents Creatinine>1.36 mg/dL Age < 18 years GFR less than 60ml/min/1.73m2 Body-Mass Index (BMI) greater than 30 kg/m2

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
To allocate patients in intervention and control groups, simple random allocation method will be used. We asked the SPSS software to provide us 20 values randomly between 1 to 40. The software gave us the values 5, 3, 13, 18, 2, 14, 10, 1, 35, 37, 23, 32, 8, 16, 33, 36, 39, 9, 22, 28. By drawing lots between the control and intervention groups, we assigned these numbers to the intervention group. Then, the rest of the numbers, between 1 and 40, were assigned to the control group. In this way, we will assign the patients as control and intervention groups right from the beginning of the study, among the patients who were referred to the CT scan department of Namazi hospital, with the suspension of pulmonary embolism and having the inclusion criteria for entering the study. From the above random numbers, the first, second, and third patients are to be included in the intervention group. The intervention group will be scanned by reducing contrast agent protocol (pulmonary CT Angio). The fourth, fifth, and sixth patients referred will be allocated to the control group and they will be scanned by the standard dose of the contrast agent protocol (pulmonary CT Angio). Other referred patients who are candidates for the study will be placed in the intervention or control groups based on the serial number of their referrals and the matching numbers in the above-mentioned allocations.

Blinding (investigator's opinion)
Double blinded

Blinding description
In this study, the investigator (radiologists who evaluate the quality of pulmonary CTA) and patients will not be aware of the scanning protocol (they are blind to the amount of contrast agent). Only, technologists responsible for scanning patients and the students responsible for performing the study are aware of the amount of contrast agent.

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
Medical Imaging Research Centre, 8th Floor, Mohammad Rasolallah Research Tower, Khalili street

City
Shiraz

Province
Fars

Postal code
7193635899

Approval date
2022-07-08, 1401/04/17

Ethics committee reference number
IR.SUMS.MED.REC.1401.173

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.

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 be performed.

Method of measurement
Quantitative pulmonary Computed Tomography angiography (CTA) image quality will be measured by the Signal-to-Noise Ratio (SNR). The mean CT density or CT-number of the main pulmonary arteries (left and right) will be measured. The CT-numbers will be measured by selecting the Region of Interest (ROI) inside the left and right main pulmonary arteries, filled with the contrast agent. This CT number is known as signal. The muscles surrounding the scapula is known as background, being a region without contrast agent. An ROI will be selected in the background. Then, the standard deviation of the CT-number will be measured for the background. These measured parameters will be used to calculate SNR. Qualitative pulmonary CT Angio (CTA) image quality will be measured by visual assessment. In this method, two expert radiologists will report the image quality using a scoring system. In this system measuring the image quality is measured in a scale of 5 in which the scores assigned as follows, (1) undiagnosable (2) limited diagnostic value (3) sufficient diagnostic value (4) good image quality (5) excellent diagnostic value. If the mean score equal to or greater than 3, it will be reported as an acceptable diagnostic value.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Patients suspected of pulmonary embolism referred to Namazi Hospital (Shiraz) will be scanned by contrast agent reduction protocol. The amount of injected contrast agent to the patients in the intervention group will be 0.7 ml/kg of body weight. The Pecnograph contains 300mgI/ml (milligram iodine per millilitre) made in Iran and is the most widely available contrast agent. This contrast agent will be used to scan patients in the intervention group. These patients will be scanned by a 16-Slice LightSpeed GE Healthcare CT system, made in the USA, at 100kVp. The pulmonary CT Angio images of patients in the intervention group will be reconstructed by Filter Back Projection (FBP), made in the USA. FBP is a standard image reconstruction algorithm and is available in conventional CT systems. Conventional CT systems are used to scan patients in most hospitals affiliated with the Shiraz University of Medical Sciences.

Category
Diagnosis

2

Description
Control group: Patients suspected of pulmonary embolism referred to Namazi Hospital (Shiraz) will be scanned by standard protocol (pulmonary CT Angio). The amount of injected contrast agent to the patients in the control group will be 1.0 milliliter per kilogram of the patient's body weight. The Pecnograph contains 300mgI/ml (milligram iodine per milliliter) made in Iran is the most widely available contrast agent. This contrast agent will be used to scan patients in the control group. The patients in the control group will be scanned by a 16-Slice LightSpeed GE Healthcare CT system, made in the USA, at 120kVp. The pulmonary CT Angio images of patients in the control group will be reconstructed by Filter Back Projection (FBP), made in the USA. FBP is a standard image reconstruction algorithm and is available in conventional CT systems. Conventional CT systems are used to scan patients in most hospitals affiliated with the Shiraz University of Medical Sciences.

Category
Diagnosis

Recruitment centers

1

Recruitment center

Name of recruitment center
Namazi Hospital

Full name of responsible person
Fariba Zarei

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Medical Imaging Research Centre, 8th Floor, Mohammad Rasolallah Research Tower, Khalili street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
Mahtab Memarpour

Street address

7th Floor, Central Building of Shiraz University of Medical Sciences, Next to the Red Cresent, Zand Ave

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Web page address

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
Shiraz University of Medical Sciences

Full name of responsible person
Rezvan Ravanfar Haghighi

Position
Assistant professor

Latest degree
Ph.D.

Other areas of specialty/work
Medical Physics

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
Rezvan Ravanfar Haghighi

Position
Assistant professor

Latest degree
Ph.D.

Other areas of specialty/work
Medical Physics

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Person responsible for updating data

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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

Undecided - It is not yet known if there will be 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

Part of the data can be shared after unidentified

When the data will become available and for how long

6 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 works

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 research and technology deputy.

Comments