

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

31 May 2026

### Comparing diagnostic yield of high-pitch CT angiography with low-dose radiation and normal breathing with routine breath hold CT angiography

#### Protocol summary

Registration timing: **registered\_while\_recruiting**

#### Study aim

Evaluating the diagnostic performance of low-dose high-pitch CT angiography in evaluating pulmonary thromboembolism

Last update: **2018-06-06, 1397/03/16**

Update count: **0**

#### Registration date

2018-06-06, 1397/03/16

#### Design

Patients referring to the Imam Reza hospital imaging center (Mashhad) during the study period will be enrolled in the study. After obtaining written consent, the patients are randomized into two groups. One group will be imaged routinely and imaging will be performed with high-pitch, low-dose, free breathing in the other group. CT angiographic images will be blinded and interpreted by radiologists. Image quality, contrast to noise ratio, signal to noise ratio, and motion artifact will be recorded. Patient's effective dose will also be calculated using imaging data.

#### Registrant information

##### Name

Bitra Abbasi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 3852 5004

##### Email address

abbasib@mums.ac.ir

#### Settings and conduct

The study will be conducted in the Radiology Department, Imam Reza hospital, Mashhad, Iran.

#### Recruitment status

**Recruitment complete**

#### Funding source

#### Participants/Inclusion and exclusion criteria

Inclusion criteria: clinical suggestion of pulmonary thromboemboli age more than 18 year-old weight over 45 kg conscious patients Exclusion criteria: Unconscious patient weight over 80 kg Allergy to contrast material

#### Expected recruitment start date

2018-05-26, 1397/03/05

#### Expected recruitment end date

2019-03-20, 1397/12/29

#### Intervention groups

Patients undergoing pulmonary CT angiography to evaluate pulmonary thromboembolism

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Main outcome variables

Image quality Signal to noise ratio Contrast to noise ratio Motion artifact Patient's effective dose Image acquisition speed

#### Trial completion date

empty

#### General information

#### Scientific title

Comparing diagnostic yield of high-pitch CT angiography with low-dose radiation and normal breathing with routine breath hold CT angiography

#### Reason for update

#### Acronym

#### IRCT registration information

IRCT registration number: **IRCT20180519039721N1**

Registration date: **2018-06-06, 1397/03/16**

#### Public title

Low-dose, high-pitch pulmonary CT angiography in evaluating pulmonary thromboembolism

## Purpose

Diagnostic

## Inclusion/Exclusion criteria

### Inclusion criteria:

Ability to hold the breathing Clinical suggestion of pulmonary thromboembolism Conscious patient weight over 45 kg

### Exclusion criteria:

Weight over 80 kg unconsciousness contrast material allergy

## Age

From **18 years** old

## Gender

Both

## Phase

N/A

## Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

## Sample size

Target sample size: **40**

## Randomization (investigator's opinion)

Randomized

## Randomization description

simple randomization with 1:1 allocation

## Blinding (investigator's opinion)

Triple blinded

## Blinding description

The only person who knew the technique used for each patient, was the radiology technician, who saved the regarding data for further reference.

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethic committee, Mashhd University of Medical Sciences, Mashhad, Iran.

##### Street address

Radiology Department, Imam Reza hospital, Razi Sq.

##### City

Mashhad

##### Province

Razavi Khorasan

##### Postal code

98

## Approval date

2017-10-11, 1396/07/19

## Ethics committee reference number

IR.MUMS.fm.REC.1396.421

## 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

Image quality

#### Timepoint

immediately after the intervention

#### Method of measurement

Osirix imaging software

## Secondary outcomes

### 1

#### Description

Radiation dose

#### Timepoint

Immediately after the intervention

#### Method of measurement

DICOM data

## Intervention groups

### 1

#### Description

Intervention group: High-pitch, low-dose CT angiography

#### Category

Diagnosis

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Imam Reza hospital, Mashhad

##### Full name of responsible person

Bitra Abbasi

##### Street address

Radiology Department, Imam Reza hospital, Mashhad

##### City

Mashhad

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## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Mashhad University of Medical Sciences  
**Full name of responsible person**  
Masoud Pezeshki-Rad  
**Street address**  
Imam Reza hospital  
**City**  
Mashhad  
**Province**  
Razavi Khorasan  
**Postal code**  
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+98 51 3852 5004  
**Email**  
pezeshkiradm@mums.ac.ir  
**Grant name**  
**Grant code / Reference number**  
**Is the source of funding the same sponsor organization/entity?**  
No  
**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**  
Bitab Abbasi  
**Position**  
Assistant professor  
**Latest degree**  
Subspecialist  
**Other areas of specialty/work**  
Radiology

## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**  
Mashhad University of Medical Sciences  
**Full name of responsible person**  
Bitab Abbasi  
**Position**  
Assistant professor  
**Latest degree**  
Specialist  
**Other areas of specialty/work**  
Radiology  
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## Person responsible for updating data

#### Contact

**Name of organization / entity**  
Mashhad University of Medical Sciences  
**Full name of responsible person**  
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**Position**  
Assistant professor  
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**Phone**

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**Fax****Email**

abbasib@mums.ac.ir

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

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is 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**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

All data will be available upon individual request

**When the data will become available and for how long**

for three months after publication

**To whom data/document is available**

Academic investigators

**Under which criteria data/document could be used**

no further information

**From where data/document is obtainable**

Upon individual request by the corresponding author

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

Email by verified organization

**Comments**