

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jun 2026

Design and fabrication of radioprotective shield to reduce the radiation dose to the breast in patients undergoing thoracic computed tomography examinations

Protocol summary

Study aim

Design and fabrication of radioprotective shield to reduce the radiation dose to the breast in patients undergoing thoracic computed tomography examinations

Design

A clinical trial with a control group with parallel group, double-blind and non-randomized on 60 female patients aged 20-75 years.

Settings and conduct

Gonabad University of Medical Sciences - Allameh Bahloul Hospital

Participants/Inclusion and exclusion criteria

The criteria for patients to enter the plan are female patients aged 20 to 75 years who are subject to a lung CT scan, and the criteria for patients to leave the plan are patients who have a decreased level of consciousness or the patient's lack of consent to continue participating in the research.

Intervention groups

The intervention group of 30 female patients who had the best radiation shield placed on their chest during lung CT and the control group of 30 female patients who did not have any radiation shield placed on their chest during lung CT

Main outcome variables

Investigation of noise and average CT number in CTDI phantom CT images with and without radiation shields, measurement of thorax and breast phantom with and without radiation shields, artifact investigation in lung CT images of female patients without radiation shield and with the best radiation shield .

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230411057881N1**

Registration date: **2023-05-21, 1402/02/31**

Registration timing: **registered_while_recruiting**

Last update: **2023-05-21, 1402/02/31**

Update count: **0**

Registration date

2023-05-21, 1402/02/31

Registrant information

Name

Marziyeh Behmadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 23 3344 1022

Email address

behmadim@semums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-03-21, 1402/01/01

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

Design and fabrication of radioprotective shield to reduce the radiation dose to the breast in patients undergoing thoracic computed tomography examinations

Public title

Examining breast dose reduction in CT scan with a new combination of x-ray absorbing materials with minimal impact on image quality.

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

20 to 75 years old woman subject to chest CT scan

Exclusion criteria:

A patient who has a reduced level of consciousness (as a result of trauma or stroke or...) the patient's lack of consent to continue participating in the research

Age

From **20 years** old to **75 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Not randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description

The radiation shield image was cut from the CT scan images of the lungs of 30 female patients with breast shields, and then the images were given to a radiologist along with the CT scans of the lungs of 30 female patients who were scanned without radiation shields on their breasts. It can be checked for the presence of artifacts (lung area, mediastinum, breast) or the absence of artifacts in the images.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Semnan University of Medical Sciences

Street address

Headquarter of Semnan University of Medical Sciences and Health Services, Bassij Blvd

City

Semnan

Province

Semnan

Postal code

35147-99442

Approval date

2022-12-03, 1401/09/12

Ethics committee reference number

IR.SEMUMS.REC.1401.223

Health conditions studied**1****Description of health condition studied**

Dosimetry with and without chest phantom radiation shields and thorax phantom - examination of noise and average CT number in the CT scan phantom CTDI image with and without radiation shields - examination of artifacts in the chest CT scan image of female patients without and with the best shield

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Investigating noise and average CT number in CTDI phantom CT image with and without radiation protection

Timepoint

During 1months

Method of measurement

Using DICOM files software

2**Description**

Chest and thorax phantom dosimetry with and without radiation shields

Timepoint

2 months

Method of measurement

Using TLD dosimeter and RTI Piranha dosimeter

3**Description**

Artifact examination in lung CT images of female patients without radiation protection and with the best protection (in terms of reducing the dose and creating the least noise on the image) is placed on their chest.

Timepoint

3 months

Method of measurement

Review of images by an experienced radiologist

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 30 female patients aged 20-75 years, on whom we put the best radiation shield (suitable dose reduction and minimal noise on the image) during lung CT.

Category

Prevention

2

Description

Control group: 30 female patients aged 20-75 years, who do not put any radiation protection on their chests during lung CT scan, and the images of this group are for comparison with the images of the intervention group in terms of image artifacts.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Allameh Bahloul Gonabad Hospital

Full name of responsible person

Mohammad Kashtkar Dastnaie

Street address

Central Headquarters of Gonabad Medical Sciences,
Imam Khomeini Street, Ghadir Square

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

Marziye Behmadi

Street address

بلوار بسیج ستاد دانشگاه علوم پزشکی و خدمات بهداشتی درمانی

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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

Semnan 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

Semnan University of Medical Sciences

Full name of responsible person

Marziye Behmadi

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Physics

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be 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

Not applicable

Data Dictionary

Not applicable