

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Fabrication and assessment the effect of optimized radiation shield made of silicone-barium sulfate on radiation dose of breast in thoracic CT imaging

Protocol summary

Study aim

Fabrication and determination of the effect of optimal radiation shield made of silicon-barium sulfate on breast radiation dose in chest CT scan imaging

Design

Clinical trial, one blind, randomized, on 23 patients

Settings and conduct

After obtaining an informed consent form from the patients referred for a chest CT scan at Allameh Bahloul Gonabad Hospital, a radiation shield is placed on the chest of the patients undergoing chest CT imaging. It should be noted that the shield will be made for one breast so that one breast (on which the radiation shield is placed) can be used as the case group and the other breast as the control group. After taking thirty images T is removed from the breast using Shadow Shields software so that the right and left breast images are the same and the images are evaluated

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age 18 or older Consent to participate in the study Non-entry criteria: Patients with unilateral or bilateral mastectomy Patients with a low level of consciousness

Intervention groups

Placing a silicon barium sulfate shield on the left breast during chest CT scan imaging in women referred to Allameh Bahloul Gonabadi Hospital and evaluating its effect and comparing the image of the left breast (with radiation shielding) and the right side (without shielding).

Main outcome variables

Artifact, radiation dose, noise, signal to noise ratio

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230413057892N1**

Registration date: **2023-04-29, 1402/02/09**

Registration timing: **prospective**

Last update: **2023-04-29, 1402/02/09**

Update count: **0**

Registration date

2023-04-29, 1402/02/09

Registrant information

Name

Saeede Yazdanifar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 5722 3028

Email address

s.yadanifar1130@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-04-30, 1402/02/10

Expected recruitment end date

2023-06-20, 1402/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Fabrication and assessment the effect of optimized radiation shield made of silicone-barium sulfate on radiation dose of breast in thoracic CT imaging

Public title

Fabrication and assessment the effect of optimized radiation shield made of silicone-barium sulfate on radiation dose of breast in thoracic CT imaging

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Age 18 or older Consent to participate in the study

Exclusion criteria:

Age

From 18 years old

Gender

Female

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: 23

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

After taking the CT images, the shields are removed from the breast using the shadow software so that the right and left breast images are the same, and then the radiologist checks the images.

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Gonabad University of Medical Sciences

Street address

Gonabad university of medical sciences , DR Mahdiade street

City

Gonabad

Province

Razavi Khorasan

Postal code

9691793718

Approval date

2022-12-24, 1401/10/03

Ethics committee reference number

IR.GMU.REC.1401.112

Health conditions studied

1

Description of health condition studied

Fabrication and assessment the effect of optimized radiation shield made of silicone-barium sulfate on radiation dose of breast in thoracic CT imaging

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Breast radiation dose

Timepoint

After chest CT scan

Method of measurement

Pen dosimeter

2

Description

Image artifact

Timepoint

After chest CT scan

Method of measurement

Checklist or questionnaire

3

Description

Image noise

Timepoint

After chest CT scan

Method of measurement

Software

4

Description

Signal to noise ratio

Timepoint

After chest CT scan

Method of measurement

Software

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Placing the shield on the right breast

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Allameh Bahloul Gonabad Hospital

Full name of responsible person

Saeede Yazdanifar

Street address

Gonabad university of medical sciences , DR
Mahdiade street

City

Gonabad

Province

Razavi Khorasan

Postal code

9691793718

Phone

+98 51 5722 3028

Email

S.yazdanifar1130@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Gonabad University of Medical Sciences

Full name of responsible person

Dr Leila Sadeq moghadam

Street address

Gonabad university of medical sciences , DR
Mahdiade street

City

Gonabad

Province

Razavi Khorasan

Postal code

9691793718

Phone

+98 51 5722 3028

Email

S.yazdanifar1130@gmail.com

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Gonabad 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**

Gonabad University of Medical Sciences

Full name of responsible person

Saeede Yazdanifar

Position

student

Latest degree

A Level or less

Other areas of specialty/work

General Practitioner

Street address

Gonabad university of medical sciences , DR
Mahdiade street

City

Gonabad

Province

Razavi Khorasan

Postal code

9691793718

Phone

+98 51 5722 3028

Email

S.yazdanifar1130@gmail.com

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Gonabad University of Medical Sciences

Full name of responsible person

Saeede Yazdanifar

Position

student

Latest degree

A Level or less

Other areas of specialty/work

General Practitioner

Street address

Gonabad university of medical sciences , DR
Mahdiade street

City

Gonabad

Province

Razavi Khorasan

Postal code

9691793718

Phone

+98 51 5722 3028

Email

S.yazdanifar1130@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Gonabad University of Medical Sciences

Full name of responsible person

Saeede Yazdanifar

Position

student

Latest degree

A Level or less

Other areas of specialty/work

General Practitioner

Street address

Gonabad university of medical sciences , DR

Mahdiade street

City

Gonabad

Province

Razavi Khorasan

Postal code

9691793718

Phone

+98 51 5722 3028

Email

S.yazdanifar1130@gmail.com

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

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