Clinical Trial Protocol
Iranian Registry of Clinical Trials

12 Nov 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
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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
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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
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
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Person responsible for updating data

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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
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