

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jun 2026

Assessment of a high-pass radiation shield on image quality in patients undergoing computed tomography (CT)

Protocol summary

Study aim

Assessment of the effect of the high-pass radiation shield on the image quality of patients undergoing thoracic, head and neck, pelvis and stomach CT examination

Design

A single-blinded for outcome assessment, controlled trial with a parallel-group design

Settings and conduct

In the CT scan imaging department, after filling the informed consent form, a high-pass radiation shield will be placed over the target organs of patients undergoing CT examination. For blinding, before assessing CT images by radiologists, pictures of the shield will be removed from CT images. A questionnaire will be filled by the radiologists about the quality of images. Different levels of artifacts will be scored by radiologists.

Participants/Inclusion and exclusion criteria

Patients undergoing thoracic, head and neck, pelvis and stomach CT examination will be recruited in the study except those with contrast-enhancement agent injection

Intervention groups

Intervention group: High-pass radiation shield will be placed over breasts, thyroid, eyes, testes, and ovaries of the patients undergoing thoracic, head and neck, and stomach and pelvis CT examination. The high-pass radiation shield was constructed by the researcher of the current study and tested on phantom recently. During imaging, the shield will be positioned over a foam of a 3 cm width over the target organs of the patients and will not have any contact with the patient's body. The shield will be used once on every patient and the patients do not need any education about it. Control group: patients will undergo routine CT imaging of head, neck or thorax and pelvis and stomach without any further action.

Main outcome variables

Image quality

General information

Reason for update

1. During the registering process of this trial, the name of "copper-bismuth" was considered as the name of the constructed shield. This is only a writing mistake and the name of the constructed shield is "high-pass shield". copper and bismuth are the materials used in the shield composition; however, the name of the shield is not "copper-bismuth". 2. The end of the trial was extended until August 2020. 3. It was not possible to recruit patients in gonabad hospital. so, the Imam Reza hospital is considered as the sole center for recruiting the patients.

Acronym

IRCT registration information

IRCT registration number: **IRCT20180730040642N1**
Registration date: **2018-11-15, 1397/08/24**
Registration timing: **registered_while_recruiting**

Last update: **2020-05-06, 1399/02/17**

Update count: **1**

Registration date

2018-11-15, 1397/08/24

Registrant information

Name

Valiallah Saba

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 38 3268 5305

Email address

vsaba@aut.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-10-23, 1397/08/01
Expected recruitment end date
2020-08-22, 1399/06/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Assessment of a high-pass radiation shield on image quality in patients undergoing computed tomography (CT)

Public title
Effect of high-pass radiation shield on image quality of CT scan

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
Patients undergoing head, neck, pelvis and stomach or thoracic CT examinations

Exclusion criteria:
Patients with contrast- enhancement agents injection

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

Gender
Both

Phase
N/A

Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **160**

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description
The CT images will be analysed and interpreted by radiologists. To have unbiased interpretation, the radiologists will be blinded by removing the image of shield from the reconstructed images.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1
Ethics committee

Name of ethics committee
Ethics committee of AJA University of Medical Sciences
Street address
Etemadzadeh street, Fatemi street, Tehran
City
Tehran
Province
Tehran
Postal code
1411718541
Approval date
2018-09-25, 1397/07/03
Ethics committee reference number
IR.AJAUMS.REC.1397.027

Health conditions studied

1
Description of health condition studied
Protection of radiosensitive organs against radiation in CT scan

ICD-10 code
ICD-10 code description

Primary outcomes

1
Description
Image quality
Timepoint
After thoracic, head and neck, or pelvis and stomach CT imaging
Method of measurement
Filling a questionnaire about image quality by 3 radiologists

Secondary outcomes

empty

Intervention groups

1
Description
Intervention group: high-pass radiation shield will be placed over breasts, thyroid, eyes, testes, and ovaries of the patients undergoing thoracic, head and neck, and stomach and pelvis CT examination. The high-pass radiation shield was constructed by the researcher of the current study and tested on phantom recently. during imaging, the shield will be positioned over a foam of 3 cm width over the target organs of the patients and will not have any contact with the patient's body. the shield will be used once on every patient and the patients do not need any education about it.

Category
Prevention

2

Description

Control group: Patients will undergo routine CT imaging of head, neck or thorax and pelvis and stomach without any further action.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital

Full name of responsible person

Valiallah Saba

Street address

Imam Reza hospital, Etemadzadeh street, Fatemi Street, Tehran

City

Tehran

Province

Tehran

Postal code

1411718541

Phone

+98 21 4382 2449

Email

vsaba@aut.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Artesh University of Medical Sciences

Full name of responsible person

Dr Armin Zareian

Street address

AJA university of medical sciences, Etemadzadeh Street, Fatemi Street, Tehran

City

Tehran

Province

Tehran

Postal code

1411718541

Phone

+98 21 8609 6350

Email

info@ajaums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Artesh 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

Artesh University of Medical Sciences

Full name of responsible person

Valiallah Saba

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Imaging Technology

Street address

Etemadzadeh Street, Fatemi Street

City

Tehran

Province

Tehran

Postal code

1411718541

Phone

+98 21 4382 2449

Fax

Email

vsaba@aut.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Artesh University of Medical Sciences

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Person responsible for updating data

Contact

Name of organization / entity
Artesh University of Medical Sciences
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Valiallah Saba
Position
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Other areas of specialty/work
Medical Imaging Technology
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Etemadzadeh Street, Fatemi Street
City
Tehran
Province
Tehran
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information

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

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

The study protocol, data analysis method, the study outcomes and results will be shared.

When the data will become available and for how long

When the study is completed.

To whom data/document is available

researchers in academic institutions

Under which criteria data/document could be used

Any analysis is permissible.

From where data/document is obtainable

Referring to Dr. Valiallah Saba by email: vsaba@aut.ac.ir

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

Submission of request by email

Comments