Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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- enhancment 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

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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
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Artesh University of Medical Sciences
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Postal code
1411718541
Phone
+98 21 4382 2449

Fax

Email

vsaba@aut.ac.ir

Person responsible for updating data

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

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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

Their 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 protocle, data analysis method, the study outcomes and results will be shared.

When the data will become available and for how long

When the study completed.

To whom data/document is available

researchers in academic institutions

Under which criteria data/document could be used

Any analyses 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