

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jul 2026

Assessment the influence of CT scan administrated contrast agents on radiation dose calculation in treatment planning of radiotherapy compared to the calculation based on non-enhanced CT scan in patients with cancer of the rectum, prostate and cervix

Protocol summary

Summary

The aim of this self-controlled clinical trial study with before/after method is to assess the influence of CT scan administrated contrast (oral-intravenous) results in significant difference on radiation dose calculation compared to the standard calculation based on non-enhanced CT scans. Eleven patients with cancer of pelvic region (rectum, prostate and cervix) are included in this study and undergo computed tomography simulation without and with administrated contrast in the same position and coordinates. Patients with renal diseases, diabetes, asthma, prior reactions to drugs and contrast agents are excluded. First, each patient will receive one to two 20mL vial of the Meglumine compound (Gastrografin) with a concentration of 370 mg of iodine per ml. This oral solution dissolved in 1.5L of mineral water and a fourth of the solution administrated to each patient every half an hour. Then, each patient will receive 1-2mL per kilogram Iodixanol (Visipaque) 320mg/ml as intravenous contrast agent. Contrast-enhanced images were obtained 65 seconds after intravenous contrast. Finally, obtained CT images (without and with contrast) will be transferred to the ISOGRA treatment planning software (made by France) for calculating the differences in radiation dose distribution.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015051922319N1**

Registration date: **2015-06-03, 1394/03/13**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-06-03, 1394/03/13

Registrant information

Name

Sahel Heydarheydari

Name of organization / entity

Kermanshah University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Kermanshah University of Medical Sciences

Expected recruitment start date

2015-05-22, 1394/03/01

Expected recruitment end date

2015-08-21, 1394/05/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment the influence of CT scan administrated contrast agents on radiation dose calculation in treatment planning of radiotherapy compared to the calculation based on non-enhanced CT scan in patients

with cancer of the rectum, prostate and cervix

Public title

CT scan administrated contrast agents effect on radiation dose calculation in treatment planning of radiotherapy

Purpose

Diagnostic

Inclusion/Exclusion criteria

Inclusion criteria: Patients referred to the Radiotherapy-Oncology ward because of the rectum, prostate and cervix cancers; Exclusion criteria: Renal diseases, Diabetes, Allergic asthma, Food and Drug allergies, Prior reactions to contrast agents and taking some drugs like Metformin

Age

From **15 years** old to **85 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **11**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

This study is a self controlled clinical trial in a before/after method

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee, Vice chancellor for research, Kermanshah University of Medical sciences

Street address

Vice chancellor for research, Building number two, Shahid Beheshti Blvd

City

Kermanshah

Postal code

6714673159

Approval date

2015-02-17, 1393/11/28

Ethics committee reference number

kums.rec.1394.12

Health conditions studied

1

Description of health condition studied

Rectum cancer

ICD-10 code

C20

ICD-10 code description

Malignant neoplasm of rectum

2

Description of health condition studied

Prostate cancer

ICD-10 code

C61

ICD-10 code description

Malignant neoplasm of prostate

3

Description of health condition studied

Cervix cancer

ICD-10 code

C53, C53.0

ICD-10 code description

Malignant neoplasm of cervix uteri

Primary outcomes

1

Description

Radiation dose

Timepoint

Before and after the intervention

Method of measurement

Dosimetry with treatment planning system

Secondary outcomes

empty

Intervention groups

1

Description

Interventions 1: Meglumine compound 370mg/ml as oral contrast and Iodixanol 320mg/ml as intravenous contrast

Category

Diagnosis

Recruitment centers

1

Recruitment center

Name of recruitment center

Radiotherapy Oncology Unit , Imam Reza Hospital

Full name of responsible person

Dr. Negin Farshchian

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Web page address

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Vice chancellor for research, Kermanshah University of Medical Sciences

Full name of responsible person

Dr.Abbas Haghparast

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Vice chancellor for research, Building number two, Shahid Beheshti Blvd,

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Kermanshah

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

Yes

Title of funding source

Vice chancellor for research, Kermanshah University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries

Contact**Name of organization / entity**

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Full name of responsible person

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty

Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty