

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jul 2026

Comparison of Radiation Dose Calculated by treatment planning System (TPS) of Radiation Therapy in CT Imaging of three Prostate Cancer Patients groups that have been Imaging with Three Different contrast agents Omnipaque, Visipaque and Ultravist

Protocol summary

Study aim

Comparison of the effect of 3 different prescription contrast agents in CT scan on radiation dose calculation in prostate cancer patients

Design

Among the patients referred to the CT department for treatment planning, 30 patients will be selected and each of them will have a CT scan of the abdomen and pelvis. A computer-generated randomization list will be prepared by the statistical consultant to select patients and, based on the list, another person (off-site person) who is unaware of the aims of the study (CT technologists) will inject three different contrast agents omnipaque, visipaque and ultravist to patients. Patients will be divided into three groups based on three different contrast agents, each containing ten patients. Finally, CT images will be given separately to the treatment planning software to calculate the dose distribution difference.

Settings and conduct

This study will be performed in CT scan department of Ahvaz Golestan hospital

Participants/Inclusion and exclusion criteria

Inclusion criteria: Prostate cancer patients referred to the CT scan department. Non-inclusion criteria: Patients under 18 years; Kidney disease; Diabetes; Asthma; drug allergies

Intervention groups

Intervention group 1: Patients with prostate cancer whose CT scan will be done by intravenous injection of Omnipaque. One ml injection per body weight will be given for all 3 contrast agents. Intervention group 2: Patients with prostate cancer whose CT scan will be done by intravenous injection of Visipaque. Intervention group 3: Patients with prostate cancer whose CT scan will be done by intravenous injection of Ultravist.

Main outcome variables

radiation dose in the tumor volume , bladder and rectum

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190814044528N1**

Registration date: **2020-02-02, 1398/11/13**

Registration timing: **prospective**

Last update: **2020-02-02, 1398/11/13**

Update count: **0**

Registration date

2020-02-02, 1398/11/13

Registrant information

Name

Marzieh Reshadatian

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-04-03, 1399/01/15

Expected recruitment end date

2020-09-20, 1399/06/30

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of Radiation Dose Calculated by treatment planning System (TPS) of Radiation Therapy in CT Imaging of three Prostate Cancer Patients groups that have been Imaging with Three Different contrast agents Omnipaque, Visipaque and Ultravist

Public title
The effect of using different contrast agents in CT scan on radiation dose during radiotherapy

Purpose
Basic science

Inclusion/Exclusion criteria
Inclusion criteria:
Prostate cancer patients who are referred to the CT scan ward for CT imaging and don't have the exclusion criteria
Exclusion criteria:
Patients under 18 years old Patients with kidney problems Diabetic patients Patients with a history of asthma and immunological allergies People who had allergy to the use of contrast agents in the past

Age
No age limit

Gender
Male

Phase
4

Groups that have been masked
No information

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description
A computer-generated randomization list will be developed for patients by the statistical consultant and another off-site person with no knowledge of goals of study(CT expert) according to this list,will give patients three different contrast agents: Omnipaque, Visipaque and Ultravist.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Ahvaz Jundishapur University of Medical Sciences
Street address
Esfand avenue, Golestan street
City
Ahvaz
Province
Khouzestan
Postal code
6135715794

Approval date
2019-11-23, 1398/09/02

Ethics committee reference number
IR.AJUMS.REC.1398.627

Health conditions studied

1

Description of health condition studied
Prostate Cancer

ICD-10 code
C61

ICD-10 code description
Malignant neoplasm of prostate

Primary outcomes

1

Description
Radiation dose of the patient

Timepoint
After CT imaging with injection of contrast material

Method of measurement
Radiotherapy treatment planning software (TPS)

Secondary outcomes

empty

Intervention groups

1

Description
First Intervention group: prostate cancer Patients whose CT imaging done with intravenous injection of Visipaque contrast agent and it will be given a standard injection of 1 ml per kg of body weight. Imaging will take one to two minutes after intravenous injection.

Category
Diagnosis

2

Description
Second Intervention group:prostate cancer Patients

whose CT imaging done with intravenous injection of Omnipaque contrast agent and it will be given a standard injection of 1 ml per kg of body weight. Imaging will take one to two minutes after intravenous injection.

Category

Diagnosis

3**Description**

Third Intervention group: prostate cancer Patients whose CT imaging done with intravenous injection of Ultravist contrast agent and it will be given a standard injection of 1 ml per kg of body weight. Imaging will take one to two minutes after intravenous injection.

Category

Diagnosis

Recruitment centers**1****Recruitment center****Name of recruitment center**

Golestan hospital

Full name of responsible person

Sasan Razmjoo

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Ahvaz University of Medical Sciences

Full name of responsible person

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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

Ahvaz 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**

Ahvaz University of Medical Sciences

Full name of responsible person

Marzieh Reshadatian

Position

professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Physics

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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 need to publish raw patient data and the results of the study should be published comparatively.

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

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

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When the data will become available and for how long

...

To whom data/document is available

...

Under which criteria data/document could be used

....

From where data/document is obtainable

...

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

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Comments

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