

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jul 2026

Clinical evaluation and comparison of rectal toxicity and absorbed dose effects of radiation therapy with and without rectal retractor on patients with prostate cancer

Protocol summary

Study aim

Rectal toxicity and absorptive dose effects of radiation therapy with and without rectal retractor on patients with prostate cancer will be compared and clinically evaluated

Design

A non blinded clinical trial with two parallel groups of 36 patients

Settings and conduct

In this clinical trial prostate cancer patients who are referred to Firuzgar hospital and their cancer is pathologically approved and have not undergone prostate surgery are included. Patients (36 patients) are randomly assigned in to intervention group and control group (each group consists of 18 patients). Patients in intervention group are treated with rectal retractor and patients in control group are treated without rectal retractor. Lower gastrointestinal complications will be assessed during treatment and 1-3 months later and 9-12 months later.

Participants/Inclusion and exclusion criteria

Inclusion criteria include: pathologically confirmed prostate cancer and patients who are 40 years old or older Exclusion criteria include: anorectal disorders (Hemorrhoids, rectal fistula)

Intervention groups

Intervention group: patients who are treated with rectal retractor Control group: patients who are treated without rectal retractor Intervention:A previously designed rectal retractor by Mahdavi et.al which was designed by CATIA V5R2 software and is made of Acrylic that is equivocal to body texture. The device is used in 20 sessions of 35 sessions of radiation therapy.

Main outcome variables

early and late lower gastrointestinal complications grade based on RTOG criteria, Rectum to prostate distance in CT scan images, Dose volume histograms for rectum and planning treatment volume (PTV), Dosimetrics

parameters including: maximum dose (Dmax) ,minimum dose (Dmin), mean dose (Dmean), the dose which covers 30% of rectum volume (D30%), the dose that covers 50% of rectum volume (D50%)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180919041070N4**

Registration date: **2020-04-21, 1399/02/02**

Registration timing: **retrospective**

Last update: **2020-04-21, 1399/02/02**

Update count: **0**

Registration date

2020-04-21, 1399/02/02

Registrant information

Name

Pedram Fadavi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Email address

fadavi.p@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-10-22, 1398/07/30

Expected recruitment end date

2020-01-19, 1398/10/29

Actual recruitment start date

2019-12-21, 1398/09/30
Actual recruitment end date
2020-02-23, 1398/12/04
Trial completion date
2020-05-18, 1399/02/29

Scientific title
Clinical evaluation and comparison of rectal toxicity and absorbed dose effects of radiation therapy with and without rectal retractor on patients with prostate cancer

Public title
Rectal retractor in prostate cancer

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
Patients with localized prostate cancer who are candidates for radiation therapy with 5 fields technique pathologically confirmed prostate cancer in patients who have not undergone prostate surgery

Exclusion criteria:
Anorectal disorders (Hemorrhoids, rectal fistula)

Age
From **40 years** old

Gender
Male

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **36**
Actual sample size reached: **36**

Randomization (investigator's opinion)
Randomized

Randomization description
Block randomization is used to randomize subjects. The block size is Four (Two patients in the intervention group and Two patient in the control group). For random allocation, since 36 patients should be allocated in two groups of 18, nine random blocks (each block consisting of four patients) are generated using an online software (WWW.sealedenvelope.com).

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
Research Ethics Committee of Medical School of Iran University of Medical Sciences
Street address
Iran University of Medical Sciences, Shahid Hemmat Highway
City
Tehran
Province
Tehran
Postal code
۱۴۴۹۶۱۴۵۳۵

Approval date
2017-10-07, 1396/07/15

Ethics committee reference number
IR.IUMS.FMD.REC.1396.9411188001

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
early and late lower gastrointestinal complications grade based on Radiation therapy oncology group (RTOG) criteria

Timepoint
During treatment course, 1-3 months after treatment, 9-12 months after treatment

Method of measurement
according to Radiation therapy oncology group (RTOG) criteria

2

Description
Rectum to prostate distance in CT scan images

Timepoint
At the beginning of study (During intervention)

Method of measurement
Axial CT scan images

Secondary outcomes

1

Description
Maximum dose (Dmax)

Timepoint
at the intervention time

Method of measurement
Radiation therapy treatment planning system (Varian

Eclipse v.13.6)

2

Description

Minimum dose (Dmin)

Timepoint

at the intervention time

Method of measurement

Radiation therapy treatment planning system (Varian Eclipse v.13.6)

3

Description

Mean dose (Dmean)

Timepoint

at the intervention time

Method of measurement

Radiation therapy treatment planning system (Varian Eclipse v.13.6)

4

Description

Dose 30% (D30%): The dose that covers 30% of rectum

Timepoint

at the intervention time

Method of measurement

Radiation therapy treatment planning system (Varian Eclipse v.13.6)

5

Description

Dose 50% (D50%): The dose that covers 50% of rectum

Timepoint

at the intervention time

Method of measurement

Radiation therapy treatment planning system (Varian Eclipse v.13.6)

6

Description

Dose volume histograms for rectum and planning treatment volume (PTV)

Timepoint

at the intervention time

Method of measurement

Radiation therapy treatment planning system (Varian Eclipse v.13.6)

Intervention groups

1

Description

Intervention group: Patients who are treated with rectal retractor in order to retract the rectum and distance it from prostate, Intervention: A rectal retractor probe which is designed with CATIA V5R2 software and is constructed by Mahdavi et. al. in Iran University of

Medical Sciences. The probe is made of Acrylic which is equivalent to body tissue. The rectal retractor is used in the intervention group for 20 sessions of 35 sessions of radiation therapy treatment sessions.

Category

Rehabilitation

2

Description

Control group: Patients with localized prostate cancer who are treated with 35 sessions radiation therapy without rectal retractor

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Firoozgar Hospital

Full name of responsible person

Pedram Fadavi

Street address

Firoozgar Hospital, Beh Afarin St, Karim khan zand St, Valiasr Sq., District 6

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Seyed Abbas Motevalian

Street address

Fifth Floor, Central Headquarters, Iran University of Medical Sciences, Hemet Highway Between Chamran and Sheikh Fazlollah

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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

Iran 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**

Iran University of Medical Sciences

Full name of responsible person

Mahshid Abbasi

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Radiotherapy

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

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Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

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Full name of responsible person

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Position

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Latest degree

Medical doctor

Other areas of specialty/work

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

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

Information about main outcomes of the study

When the data will become available and for how

long

Six months after publishing the results

To whom data/document is available

Researchers in universities and scientific and research centers

Under which criteria data/document could be used

In order to improve the treatment of the disease and subsequent research and with the permission of the

authors

From where data/document is obtainable

Department of Radiation Oncology of Iran University of Medical Sciences

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

Sending the request in writing or by email to the authors

Comments