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

+98 21 5522 8584

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 (Hemorrhoidsm, 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 35sessions 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
City
Tehran
Province
Tehran
Postal code
15937-47811
Phone
+98 21 8214 1201
Fax
+98 21 8214 1201
Email
Fadavi.p@iums.ac.ir

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
City
Tehran
Province
Tehran
Postal code
14496-14535
Phone
+98 21 8670 2503

Fax
+98 21 8670 2703
Email
research@iums.ac.ir
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
Street address
Firoozgar Hospital, Beh Afarin St, Valiasr Sq., District 6
City
Tehran
Province
Tehran
Postal code
15937-47811
Phone
+98 21 8214 1201
Email
mahshid.abbasi2011@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Pedram Fadavi
Position
Assistant professor
Latest degree
Specialist
Other areas of specialty/work
Radiotherapy
Street address
Firoozgar Hospital, Beh Afarin St, Valiasr Sq., District 6
City
Tehran
Province
Tehran
Postal code
15937-47811
Phone
+98 21 8214 1201
Email
Fadavi.p@iums.ac.ir

Person responsible for updating data

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
Street address
Firoozgar Hospital, Beh Afarin St, Valiasr Sq., District 6
City
Tehran
Province
Tehran
Postal code
15937-47811
Phone
+98 21 8214 1201
Email
mahshid.abbasi2011@gmail.com

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