Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Nov 2026

Dosimetric and radiobiologic assessment of adaptive radiotherapy by using contour based dose painting method drived from multi-parametric MRI (mpMRI) in prostate cancer patients

Protocol summary

Study aim
Dosimetric and radiobiologic assessment of treatment planning procedures DP, IMRT, 3DCRT.

Design
A randomized, clinical trial with a parallel group design of 40 patients, enrolled between September 2019 and September 2020, and followed for four month.

Settings and conduct
This study is a randomized clinical trial. The study is done on the patients with advanced prostate cancer. Processing, imaging, measuring data and treatment plannings (DP, IMRT, and 3DCRT) of the patients will be made according to specific protocols in Roshana Cancer Center.

Participants/Inclusion and exclusion criteria
The inclusion criteria : Patients with localised high-risk prostate carcinoma. Exclusion criteria : contraindications to MRI such as cardiac pacemakers.

Intervention groups
intervention group:adaptive radiotherapy by using dose painting method . control group:radiotherapy by using common method.

Main outcome variables
tumor recurrence,,tumor volume, Apparent Diffusion Coefficient(ADC)

General information

Reason for update

Acronym
dose painting

IRCT registration information
IRCT registration number: **IRCT20181006041257N1**
Registration date: **2019-10-23, 1398/08/01**
Registration timing: **retrospective**

Last update: **2019-10-23, 1398/08/01**
Update count: **0**

Registration date
2019-10-23, 1398/08/01

Registrant information

Name
Seyedmasoud Rezaei

Name of organization / entity
Tarbiat Modares University

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-10-23, 1397/08/01

Expected recruitment end date
2019-04-22, 1398/02/02

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Dosimetric and radiobiologic assessment of adaptive radiotherapy by using contour based dose painting method drived from multi-parametric MRI (mpMRI) in prostate cancer patients

Public title
adaptive radiotherapy in prostate cancer patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with localised high-risk prostate carcinoma

Exclusion criteria:

previousprostatectomy general contraindications for MRI (i.e. cardiac pacemaker,metal implants)

Age

No age limit

Gender

Male

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization is performed by an independent trial center. If a patient meets the inclusion criteria and has provided informed consent, the physician contacts the trial center.The most common and basic method of simple randomization is flipping a coin, with two treatment groups (control versus treatment).This randomization approach is simple and easy to implement in a clinical research.Simple randomization works well for the large clinical trails (n>100) and for small to moderate clinical trials (n<100) without covariates

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 tarbiat modares University

Street address

Tarbiat Modares University, Al-Ahmad and Chamran Cross

City

Tehran

Province

Tehran

Postal code

1411713116

Approval date

2018-09-30, 1397/07/08

Ethics committee reference number

IR.MODARES.REC.1397.163

Health conditions studied

1

Description of health condition studied

prostate cancer

ICD-10 code

N42.3

ICD-10 code description

Dysplasia of prostate

Primary outcomes

1

Description

Tumor volume

Timepoint

Before treatment and four months after radiotherapy

Method of measurement

diffusion weighted Images (DWI)

2

Description

ADC

Timepoint

Before treatment and four months after radiotherapy

Method of measurement

diffusion weighted Images (DWI)

3

Description

Prostate-specific antigen (PSA)

Timepoint

Before treatment and four months after radiotherapy

Method of measurement

blood test

Secondary outcomes

empty

Intervention groups

1

Description

Dosimetric and radiobiologic assessment by using contour based dose painting method drived from multi-parametric MRI.

Category

Treatment - Other

2

Description

Control group: intensity-modulated radiotherapy for patients with prostate cancer

Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Roshana Radiation Oncology Center (Tehran, Iran)
Full name of responsible person
Bijan Hashemi
Street address
Tarbiat Modares University, Al-Ahmad and Chamran Cross
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for Research and Technology
Full name of responsible person
Yaghoub Fathollahi
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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
Vice Chancellor for Research and Technology
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
The University of tarbiat modares
Full name of responsible person
Bijan Hashemi
Position
Associate professor
Latest degree
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Person responsible for scientific inquiries

Contact
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Shahid Beheshti University of Medical Sciences
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Person responsible for updating data

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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
Imaging data and treatment planning will be reported
When the data will become available and for how long
after the publication of results
To whom data/document is available
It will be available to researchers working in academic and scientific institutions
Under which criteria data/document could be used
for patients undergoing prostate cancer
From where data/document is obtainable
tarbiat modares universality
What processes are involved for a request to access data/document
Refer to Tarbiat Modarres University, Faculty of Medicine, Department of Medical Physics
Comments