

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Dosimetric and radiobiologic assessment of adaptive radiotherapy by using contour based dose painting method driven 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

Country

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 driven 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:
previous prostatectomy 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 trials (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 driven 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

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bhashemi@modares.ac.ir

Web page addresshttps://fa.irct.ir/user/trial/34305/update/recruitment_center**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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Web page address<https://fa.irct.ir/user/trial/34305/update/sponsor>**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

Ph.D.

Other areas of specialty/work

Medical Physics

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Web page addresshttps://fa.irct.ir/user/trial/34305/update/public_queries_contact**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Bahram Mofid

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Radiotherapy

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Person responsible for updating data

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Seyedmasoud Rezaei
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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