

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jul 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)

##### Phone

+98 21 8288 3236

##### Email address

m\_rezaei@modares.ac.ir

##### 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

IR.MODARES.REC.1397.163

## 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

## 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

**Street address**

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**Email**

bhashemi@modares.ac.ir

**Web page address**[https://fa.irct.ir/user/trial/34305/update/recruitment\\_center](https://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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fatollahi@modares.ac.ir

**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 address**[https://fa.irct.ir/user/trial/34305/update/public\\_queries\\_contact](https://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

**Street address**

Farahzadi Boulevard

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Tehran

**Province**

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53571-16589

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**Fax**

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**Web page address**[https://fa.irct.ir/user/trial/34305/update/scientific\\_queries\\_contact](https://fa.irct.ir/user/trial/34305/update/scientific_queries_contact)**Person responsible for updating data****Contact****Name of organization / entity**

Tarbiat Modares University

**Full name of responsible person**

Seyedmasoud Rezaei

**Position**

Phd student at medical physics

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Medical Physics

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Tehran Province, Tehran, Al Ahmad Street, No. 7, Jalal

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**Web page address**[https://fa.irct.ir/user/trial/34305/update/data\\_updater\\_contact](https://fa.irct.ir/user/trial/34305/update/data_updater_contact)**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**