

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jul 2026

Comparison of serum profile of inflammatory cytokines in high or unfavorable intermediate-risk localized prostate cancer patients treated with definitive whole pelvis radiation therapy plus external beam boost versus high dose rate brachytherapy boost.

Protocol summary

Study aim

Boost with interstitial brachytherapy with high dose rate compared to boost with conformal three-dimensional radiotherapy technique, stimulates the patient's immune system against prostate cancer with a different mechanism, and this may lead to improved treatment outcomes in these patients. Be

Design

The clinical trial consisted of two parallel not blind groups and Randomization is done by envelope method on 20 patients

Settings and conduct

20 patients with moderate (undesirable) and high risk local prostate cancer who were referred to the clinical oncology ward of Golestan Hospital in Ahvaz in 1400 and are candidates for radiotherapy only in addition to neo-adjuvant hormone therapy (2 months), simultaneous and adjuvant (minimum). 3 months), will enter the study. After completion of full pelvic radiotherapy, patients will be randomly divided into two groups: external radiotherapy boost and interstitial brachytherapy with high dose rate. Serum levels of inflammatory cytokines, including interleukin-6, interleukin-8, and TNF-alpha, will be measured in all patients two weeks before the start of radiotherapy, and one and three months after the end of radiotherapy

Participants/Inclusion and exclusion criteria

1) Age \geq 18 years 2) Eastern Cooperative Oncology Group (ECOG) Performance scale zero or one 3) Localized prostate adenocarcinoma confirmed by pathology with moderate (Unfavorable) and high risk according to National Comprehensive Cancer Network (NCCN) criteria (first version 2021)

Intervention groups

In group A, the effect of external radiotherapy and in group B, the effect of brachytherapy on the patient's

immune system are evaluated.

Main outcome variables

Serum levels of inflammatory cytokines including interleukin-6, interleukin-8 and TNF-alpha will be measured

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211004052674N1**

Registration date: **2021-12-11, 1400/09/20**

Registration timing: **registered_while_recruiting**

Last update: **2021-12-11, 1400/09/20**

Update count: **0**

Registration date

2021-12-11, 1400/09/20

Registrant information

Name

Iman Amiri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3374 3001

Email address

dr.iman1369@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-11-11, 1400/08/20

Expected recruitment end date

2022-02-20, 1400/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of serum profile of inflammatory cytokines in high or unfavorable intermediate-risk localized prostate cancer patients treated with definitive whole pelvis radiation therapy plus external beam boost versus high dose rate brachytherapy boost.

Public title

Comparison of serum profile of inflammatory cytokines in localized prostate cancer patients

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age \geq 18 year Eastern Cooperative Oncology Group (ECOG) performance zero or one Localized prostate adenocarcinoma confirmed by pathology with moderate (Unfavorable) and high risk according to National Comprehensive Cancer Network criteria(NCCN) (first edition 2021)

Exclusion criteria:

Severe physical illness or mental disorder that, according to the researcher, prevents treatment according to the protocol Patients who cannot be followed up regularly Contraindications for external radiotherapy or brachytherapy Previous history of external radiotherapy or prostate brachytherapy History of any prostate surgery Any history of malignancy (except for non-melanoma skin cancers) History of Chemotherapy, Targeted Therapy and the use of immunosuppressive drugs History of chronic infectious diseases (HIV, viral hepatitis, etc.)

AgeFrom **18 years** old**Gender**

Male

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **20****Randomization (investigator's opinion)**

Randomized

Randomization description

Simple individual randomization with a sealed envelope Twenty letters are used in the form of ten group A numbers and ten group B numbers People in group A will only receive external beam radiotherapy, and people in group B will be treated with brachytherapy

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 Ahvaz Jundishapur University

Street address

Golestan hospital, Farvardin street

City

ahvaz

Province

Khuzestan

Postal code

3311861357

Approval date

2021-11-05, 1400/08/14

Ethics committee reference number

IR.AJUMS.HGOLESTAN.REC.1400.099

Health conditions studied**1****Description of health condition studied**

Prostate Cancer

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Serum profile of inflammatory cytokines

Timepoint

Serum levels of inflammatory cytokines are measured two weeks before the start of radiotherapy, and one and three months after the end of radiotherapy.

Method of measurement

Blood test

Secondary outcomes

empty

Intervention groups**1****Description**

Control group: This group undergoes external

radiotherapy. Before the start of treatment and after one month and three months after the end of external radiotherapy, the level of inflammatory cytokines of interleukin 6, interleukin 8 and TNF alpha are evaluated

Category

Treatment - Devices

2**Description**

Intervention group: In addition to external radiotherapy, this group undergoes brachytherapy. Before the start of treatment and one month and then three months after the end of treatment, inflammatory levels of interleukin 6, interleukin 8 and TNF alpha are evaluated

Category

Treatment - Devices

Recruitment centers**1****Recruitment center****Name of recruitment center**

Golestan hospital

Full name of responsible person

Ali Bagheri

Street address

Golestan hospital, Farvardin street

City

Ahvaz

Province

Khuzestan

Postal code

3311861357

Phone

+98 61 3374 3001

Email

dr.iman1369@gmail.com

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Ahvaz University of Medical Sciences

Full name of responsible person

Ali bagheri

Street address

Golestan hospital, Farvardin street

City

Ahvaz

Province

Khuzestan

Postal code

6135715794

Phone

+98 61 3311 2206

Email

Ahvaz.Eleaning@mail.com

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Ahvaz 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**

Ahvaz University of Medical Sciences

Full name of responsible person

Ali bagheri

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Radiotherapy

Street address

Golestan hospital, Farvardin street

City

Ahvaz

Province

Khuzestan

Postal code

3311861357

Phone

+98 61 3374 3001

Email

alibagheri.md@gmail.com

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

Ahvaz University of Medical Sciences

Full name of responsible person

Ali bagheri

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Radiotherapy

Street address

Golestan hospital, Farvardin street

City

Ahvaz

Province

Khouzestan

Postal code

3311861357

Phone

+98 61 3374 3001

Email

alibagheri.md@gmail.com

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

Ahvaz University of Medical Sciences

Full name of responsible person

Ali bagheri

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Radiotherapy

Street address

Golestan hospital, Farvardin street

City

Ahvaz

Province

Khouzestan

Postal code

3311861357

Phone

+98 61 3374 3001

Email

alibagheri.md@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 the main outcome or the like can be shared

When the data will become available and for how long

Access period starts 6 months after the results are published

To whom data/document is available

Academic and scientific community

Under which criteria data/document could be used

Use in clinical studies

From where data/document is obtainable

Ahvaz Jundishapur University

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

Send request to Ahvaz Jundishapur University

Comments