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 ≥ 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 ≥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.)
Age
From **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
Khouzestan
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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Ahvaz University of Medical Sciences

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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

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

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Person responsible for updating data

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Position
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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
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