Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of addition of low dose abiraterone to the ADT+RT in local recurrent prostate cancers after previous surgery, in terms of biochemical recurrence

Protocol summary

Study aim
Assessment of the effect of addition of low dose abiraterone to the ADT+RT in local recurrent prostate cancers after previous surgery, in terms of biochemical recurrence

Design
Non-randomized, parallel group trial with non-blinded outcome assessment. Phase 2 trial in 64 patients.

Settings and conduct
After recurrent confirmation, the patients were divided into two groups based on the physician opinion 1- Treatment with ADT and radiotherapy until one year 2- Treatment with ADT and radiotherapy plus abiraterone until one year Patients were treated with radiotherapy in Shohada-e-Tajrish hospital

Participants/Inclusion and exclusion criteria
Prostate cancer patients with local recurrence after radical prostatectomy were included in the study; patients who are resistant to hormone therapy were excluded.

Intervention groups
1- Androgen deprivation therapy (ADT) and radiotherapy
2- ADT and radiotherapy plus abiraterone

Main outcome variables
biochemical free survival

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20120618010057N2**
Registration date: **2022-04-25, 1401/02/05**
Registration timing: **registered_while_recruiting**

Last update: **2022-04-25, 1401/02/05**
Update count: **0**

Registration date
2022-04-25, 1401/02/05

Registrant information

Name
Abolfazl Razzaghdoust
Name of organization / entity
shahid beheshti medical University
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-04-25, 1401/02/05

Expected recruitment end date
2023-04-25, 1402/02/05

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of addition of low dose abiraterone to the ADT+RT in local recurrent prostate cancers after previous surgery, in terms of biochemical recurrence

Public title
The effect of addition of low dose abiraterone to the ADT+RT in local recurrent prostate cancers

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Prostate cancer patients with local recurrence after radical prostatectomy

Exclusion criteria:

Hormone resistant

Age

No age limit

Gender

Male

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **64**

Randomization (investigator's opinion)

Not randomized

Randomization description

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

Urology and Nephrology Research Center

Street address

No. 103, Shahid Jafari St., Pasdaran Ave., Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1666677951

Approval date

2022-03-06, 1400/12/15

Ethics committee reference number

IR.SBMU.UNRC.REC.1401.012

Health conditions studied

1

Description of health condition studied

Prostate cancer

ICD-10 code

C61

ICD-10 code description

Malignant neoplasm of prostate

Primary outcomes

1

Description

Biochemical free survival

Timepoint

3 months interval

Method of measurement

Prostate-Specific Antigen (PSA) test

Secondary outcomes

empty

Intervention groups

1

Description

Hormone therapy and radiotherapy plus abiraterone. Androgen deprivation therapy (ADT) and radiotherapy + abiraterone 250mg daily + prednisolone 5mg daily until one year later. Abiraterone will be administered with low fat food. ADT and triptorelin 3.75mg will be administered monthly.

Category

Treatment - Drugs

2

Description

Hormone therapy and radiotherapy. ADT and triptorelin 3.75mg will be administered monthly.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Shohada-e-Tajrish hospital

Full name of responsible person

Bahram Mofid

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No. 103, Shahid Jafari St., Pasdaran Ave., Tehran, Iran

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Abbas Basiri
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Velenjak St.
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1985717443
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basiri_a@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences
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Position
Researcher
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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

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

Primary outcome data

When the data will become available and for how long

After publication of the results

To whom data/document is available

Academic organs

Under which criteria data/document could be used

No restriction

From where data/document is obtainable

Abolfazl Razzaghdoust razzaghdoust@sbmu.ac.ir

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

A formal email to make a request

Comments