

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jul 2026

Effect of low dose vs standard dose abiraterone on biochemical failure in metastatic prostate cancers

Protocol summary

2022-04-30, 1401/02/10

Study aim

Assessment of the effect of low dose vs standard dose abiraterone on biochemical failure in metastatic prostate cancers

Design

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

Settings and conduct

High volume metastatic hormone sensitive prostate cancer patients who are candidates for triplet therapy were divided into two groups based on the physician opinion: 1- Hormone therapy + docetaxel + low dose abiraterone (250mg daily) up to one year later 2- Hormone therapy + docetaxel + standard dose abiraterone (1000mg daily) up to one year later

Participants/Inclusion and exclusion criteria

Metastatic prostate cancer patients who are candidates for triplet therapy were included in the study; patients who are resistant to hormone therapy were excluded.

Intervention groups

1- Hormone therapy + docetaxel + low dose abiraterone.
2- Hormone therapy + docetaxel + standard dose abiraterone

Main outcome variables

biochemical free survival

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120618010057N3**

Registration date: **2022-04-30, 1401/02/10**

Registration timing: **registered_while_recruiting**

Last update: **2022-04-30, 1401/02/10**

Update count: **0**

Registration date

Registrant information

Name

Abolfazl Razzaghdoust

Name of organization / entity

shahid beheshti medical University

Country

Iran (Islamic Republic of)

Phone

+98 21 8882 5904

Email address

razzaghdoust@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-04-30, 1401/02/10

Expected recruitment end date

2023-04-29, 1402/02/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of low dose vs standard dose abiraterone on biochemical failure in metastatic prostate cancers

Public title

Comparison of low dose vs standard dose abiraterone in prostate cancer patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Metastatic prostate cancer patients who are candidates for triplet therapy

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.1401.011

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**

Intervention group: Hormone therapy + docetaxel + low dose abiraterone. Androgen deprivation therapy (ADT)+ docetaxel + abiraterone 250mg daily + prednisolone daily until one year later. Abiraterone will be administered with low fat food. ADT as triptorelin 3.75mg will be administered monthly.

Category

Treatment - Drugs

2**Description**

Control group: Hormone therapy + docetaxel + standard dose abiraterone. Androgen deprivation therapy (ADT) + docetaxel + abiraterone 1000mg daily + prednisolone daily until one year later. ADT as triptorelin 3.75mg will be administered monthly.

Category

Treatment - Drugs

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

Shohada-e-Tajrish hospital

Full name of responsible person

Bahram Mofid

Street address

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

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tehran

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Email

mofid429@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Abbas Basiri

Street address

Velenjak St.

City

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Province

Tehran

Postal code

1985717443

Phone

+98 21 2256 7222

Email

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

Full name of responsible person

Abolfazl Razzaghdoust

Position

Researcher

Latest degree

Ph.D.

Other areas of specialty/work

Medical Biology

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Person responsible for scientific inquiries

Contact**Name of organization / entity**

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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@sbm.ac.ir
What processes are involved for a request to access data/document
A formal email to make a request
Comments