

# 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

**City**

tehran

**Province**

Tehran

**Postal code**

1666677951

**Phone**

+98 21 2256 7222

**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**

Tehran

**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

**Street address**

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

**City**

Tehran

**Province**

Tehran

**Postal code**

1666677951

**Phone**

+98 21 2256 7222

**Email**

razzaghdoust@sbmu.ac.ir

## Person responsible for scientific 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

**Street address**

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

**City**

Tehran

**Province**

Tehran

**Postal code**

1666677951

**Phone**

+98 21 2256 7222

**Email**

razzaghdoust@sbmu.ac.ir

## Person responsible for updating data

**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

**Street address**

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

**City**

Tehran

**Province**

Tehran

**Postal code**

1666677951

**Phone**

+98 21 2256 7222

**Email**

razzaghdoust@sbmu.ac.ir

## 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**