

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The effect of finasteride (compared to placebo) in preventing recurrence in patients with bladder tumor

#### Protocol summary

##### Study aim

The effect of finasteride (compared to placebo) in preventing recurrence in patients with bladder tumor

##### Design

The clinical trial has a control group, with parallel groups, double-blind, randomized, Phase 2 on 124 patients. Excel software function was used to randomize.

##### Settings and conduct

This study is a randomized clinical trial, double-blind at a time period from 2021 to 2022. The subjects of the study included all patients with bladder tumors referred to Imam Reza Hospital in Tabriz which was treated as primary and non-consecutive. After entering the study and obtaining consent, for all patients (control and intervention group) at the moment of entering the study, according to the bladder tumor, diagnostic and therapeutic measures are performed according to the physician's decision-making.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: 1-Patients with bladder tumor 2satisfaction to enter the study 3insensitivity to drug 4-patient cooperation during the study 5-age 18 to 70 years Exclusion criteria: 1-Lack of consent to enter the study 2loss of patient in pursuit 3-Age less than 18 years and more than 70 years 4death of the patient to other causes 5-Lack of proper drug use 6-sensitivity to drug and Azasteroids pharmaceutical group 7-patients with underlying hepatic disease 8-Patients with breast cancer 9-Patients with prostate cancer

##### Intervention groups

Intervention group: Patients with bladder tumors who receive finasteride 5 mg/day from 2021 to 2022 Control group: Patients with bladder tumors who receive placebo tablets, per day from 2021 to 2022

##### Main outcome variables

Urine analysis, Biopsy of bladder tumor If tumor found at follow-up cystoscopy

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200608047702N1**

Registration date: **2021-12-25, 1400/10/04**

Registration timing: **registered\_while\_recruiting**

Last update: **2021-12-25, 1400/10/04**

Update count: **0**

##### Registration date

2021-12-25, 1400/10/04

##### Registrant information

##### Name

Reza Ramezani

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 2321 0333

##### Email address

dr.ramezanireza70@gmail.com

##### Recruitment status

##### Recruitment complete

##### Funding source

##### Expected recruitment start date

2021-06-05, 1400/03/15

##### Expected recruitment end date

2022-06-20, 1401/03/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of finasteride (compared to placebo) in preventing recurrence in patients with bladder tumor

#### Public title

The effect of finasteride in the prevention of bladder tumor recurrence

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

Patients with bladder tumors, which are candidates of follow up Consent to inclusion the study insensitivity to drug Patient cooperation during the study Age 18 to 70 years

##### Exclusion criteria:

No consent to the inclusion of the study Loss of patient in f/u No regular drug use Patients with underlying disease

#### Age

From **18 years** old to **70 years** old

#### Gender

Both

#### Phase

3

#### Groups that have been masked

- Participant
- Investigator

#### Sample size

Target sample size: **124**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

124 envelopes are prepared with 62 active and 62 placebo cards and shuffled. Patients are allocated the next study number (1-124) in sequence after opening the sealed envelopes to either drug or placebo group.

#### Blinding (investigator's opinion)

Double blinded

#### Blinding description

The researcher does not know whether the patient being evaluated belongs to the placebo group or the finasteride group. The patients also do not know if they have used a placebo or finasteride. Drugs and placebos are similar in appearance, such as color, shape, and so on. The patient (placebo or treatment groups) receives the encoded drug

#### Placebo

Used

#### Assignment

Parallel

#### Other design features

### Secondary Ids

empty

### Ethics committees

#### 1

##### Ethics committee

Name of ethics committee

ethics committee of tabriz medical university

##### Street address

imam reza hospital urology department

##### City

tabriz

##### Province

West Azarbaijan

##### Postal code

1212121212

##### Approval date

2021-06-04, 1400/03/14

##### Ethics committee reference number

IR.tbzmed.REC.1400.234

### Health conditions studied

#### 1

##### Description of health condition studied

bladder cancer

##### ICD-10 code

C67.9

##### ICD-10 code description

Malignant neoplasm of bladder, unspecified

### Primary outcomes

#### 1

##### Description

prevention of recurrence of bladder cancer

##### Timepoint

before intervention and every 3 months for a period of one year

##### Method of measurement

cystoscopy pathology report

### Secondary outcomes

empty

### Intervention groups

#### 1

##### Description

Intervention group: Finasteride ( Daru Pakhsh CO. Tehran, Iran) receive 5 mg /day and complications and response to treatment are evaluated every three months

##### Category

Treatment - Drugs

#### 2

##### Description

Control group: Receive placebo (in the form of finasteride tablets) (Construction of Faculty of Pharmacy, Tabriz University of Medical Sciences) tablet per day for up to one year

##### Category

Placebo

## Recruitment centers

1

### Recruitment center

**Name of recruitment center**

imam reza hospital of tabriz

**Full name of responsible person**

daniel farhadi

**Street address**

golgasht ave,imam reza hospital

**City**

tabriz

**Province**

West Azarbaijan

**Postal code**

1212121212

**Phone**

+98 41 3526 2250

**Email**

dr.ramezanireza70@gmail.com

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

mohammad samiee

**Street address**

Golgasht Street. Research and Technology, University of Tabriz

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1234567891

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**Email**

dr.ramezanireza70@gmail.com

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Tabriz 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**

Tabriz University of Medical Sciences

**Full name of responsible person**

alireza farshi

**Position**

professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Urology

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golgasht ave,imam reza hospital

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Reza Ramezani

**Position**

Resident of urology

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Urology

**Street address**

No 1,saadi alley,azari ave,valiasr jonubi blvd,tabriz

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**Email**

Dr.ramezanireza70@gmail.com

## Person responsible for updating data

### Contact

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Reza Ramezani

**Position**

Resident of urology

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Urology

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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**

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**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available

**Title and more details about the data/document**

Part of the data on the outcome of bladder tumors is for sharing.

**When the data will become available and for how long**

Access will be 6 months after the results are printed.

**To whom data/document is available**

Urologic specialists in coordination with the presenter

**Under which criteria data/document could be used**

The use of data to improve patients' treatment processes is safe

**From where data/document is obtainable**

The person responsible for updating study information:  
dr Reza Ramezani Email: Dr.ramezanireza70@gmail.com

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

Requesting data and study documents will be done by correspondence with the person responsible for updating the study information

**Comments**