Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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 3insensivity 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 fallow 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
danial 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
City
tabriz
Province
West Azarbaijan
Postal code
1234567891
Phone
+98 41 3335 7310
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
Street address
golgasht ave,imam reza hospital
City
tabriz
Province
West Azarbaijan
Postal code
1212121212
Phone
+98 41 3337 6923
Email
dr.ramezanireza70@gmail.com

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
City
Tabriz
Province
East Azarbaijan
Postal code
1212121212
Phone
+98 41 2321 0333
Fax
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

Street address

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

City

Tabriz

Province

East Azarbaijan

Postal code

1212121212

Phone

+98 41 2321 0333

Fax

Email

Dr.ramezanireza70@gmail.com

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