

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 2026

Survey The Effect Of Anticholinergic Drug On Uroflowmetry In Patients With Benign Prostatic Hyperplasia

Protocol summary

Study aim

Survey The effect of Anticholinergic Drug On Uroflowmetri In Patient with Benign Prostatic Hyperplasia

Design

Clinical trial with out control

Settings and conduct

Add tolterodine to standard medication in patient with benign prostatic hyperplasia with irritative symptoms refer to the urology clinic of Vasei Hospital during 1 month and do uroflowmetry and sonography before and after it.

Participants/Inclusion and exclusion criteria

All patients over the age of 50 with benign prostate enlargement who were treated with standard alpha-blockers and have irritable symptoms referred to the urology clinic of Vasei Hospital enrolled in the study. patient who had history of prostate or urinary tract surgery, history of prostate cancer, history of Neurological and spinal disease, history of use anticholinergic drug in 2 past weeks, have urinary residual over 250 cc disenrolled in study.

Intervention groups

Tolterodine 1 mg every 12 hours is added for one month to patients with benign prostate enlargement who have been pre-treated tamsulin 0/4 daily. tolterodine is anticholonergic drug. The drug work By blocking the muscarinic receptor. Side effects include dry mouth, drowsiness, urinary retention and constipation. chemical formula is C₂₂H₃₁NO. The brand name is Tolerin, manufactured by Tehran Drug Company

Main outcome variables

uroflowmetri ; prostate volume ; urine rezidual

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190928044913N1**

Registration date: **2019-11-11, 1398/08/20**

Registration timing: **retrospective**

Last update: **2019-11-11, 1398/08/20**

Update count: **0**

Registration date

2019-11-11, 1398/08/20

Registrant information

Name

Amirhosein Zafarianian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 3223 1465

Email address

zaferaniana91@medsab.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-21, 1398/02/01

Expected recruitment end date

2019-06-22, 1398/04/01

Actual recruitment start date

2019-04-21, 1398/02/01

Actual recruitment end date

2019-06-24, 1398/04/03

Trial completion date

2019-06-24, 1398/04/03

Scientific title

Survey The Effect Of Anticholinergic Drug On Uroflowmetry In Patients With Benign Prostatic Hyperplasia

Public title

Effect of Anticholinergic Drug On uroflowmetry

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patient Whit Benign Prostatic Hyperplasia treat with a Blaker

Exclusion criteria:

Past Medical History of Prostatic cancer Age under 50 years Past Medical History Prostatic surgery Past Medical History Of neurology illness History Of Use Anticholinergic In 2 Past Week

Age

From 50 years old

Gender

Male

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: 60

Actual sample size reached: 60

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Sabzevar University of Medical Sciences

Street address

sabzevar university of medical sciences, next to shohadaye gomnam, tohidshahr Blvd,

City

Sabzevar

Province

Razavi Khorasan

Postal code

9613873136

Approval date

2016-08-31, 1395/06/10

Ethics committee reference number

IR.Medsab.rec.1395.41

Health conditions studied

1

Description of health condition studied

Benign Prostatic Hyperplasia

ICD-10 code

N40

ICD-10 code description

Enlarged prostate

Primary outcomes

1

Description

Q max in uroflowmetry

Timepoint

at beginning and 1 month later

Method of measurement

uroflowmetry

Secondary outcomes

1

Description

urine residual

Timepoint

at beginning and 1 month later

Method of measurement

sonography

2

Description

Prostate volume

Timepoint

at beginning and 1 month later

Method of measurement

sonography

Intervention groups

1

Description

Intervention group: Tolterodine 1 mg every 12 hours is added for one month to patients with benign prostate enlargement who have been pre-treated with tamsulosin 0/4 daily. Tolterodine is an anticholinergic drug. The drug works by blocking the muscarinic receptor. Side effects include dry mouth, drowsiness, urinary retention and constipation. Chemical formula is C₂₂H₃₁NO. The brand name is Tolerin, manufactured by Tehran Drug Company.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

vasei hospital

Full name of responsible person

amirhosein zafarianian

Street address

Vasei Hospital , shohadaye hastei blvd

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sabzevar

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9617699117

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+98 51 4401 1000

Email

zaferaniana91@medsab.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Sabzevar University of Medical Sciences

Full name of responsible person

fereshte ghorat

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sabzevar university of medical sciens , next to shohadaye gomnam,shohadaye hastei Blvd

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drghorat@gmail.com

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Sabzevar 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

Sabzevar University of Medical Sciences

Full name of responsible person

Amirhosein Zafarianian

Position

Student

Latest degree

A Level or less

Other areas of specialty/work

General Practitioner

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Fax**Email**

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Sabzevar University of Medical Sciences

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Student

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Person responsible for updating data

Contact

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Fax**Email**

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

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

Study Protocol

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

Statistical Analysis Plan

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

Informed Consent Form

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

Clinical Study Report

Undecided - It is not yet known if there will be 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