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 toltrodine 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 Zafaranian

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 Mediacal History of Prostatic cancer Age underb 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 sciens, 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 begening and 1 month later
Method of measurement
uroflowmetri

Secondary outcomes

1

Description
urine rezidual
Timepoint
at beginnig 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 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.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
vasei hospital
Full name of responsible person
amirhosein zafaranian
Street address
Vasei Hospital , shohadaye hastei blvd
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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
Street address
sabzevar university of medical sciens , next to shohadaye gomnam,shohadaye hastei Blvd
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Fax
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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 Zafaranian
Position
Student
Latest degree
A Level or less
Other areas of specialty/work
General Practitioner
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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Position
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Person responsible for updating data

Contact

Name of organization / entity
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Amirhosein Zafaranian

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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