Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparative study on the effectiveness and safety of tamsulosin Oral-Controlled Absorption System (OCAS®) with tamsulosin Modified Release (MR) and placebo in improving lower urinary tract symptoms (LUTS) in men with benign prostatic hyperplasia (BPH)

Protocol summary

Study aim
Compararison of the efficacy and safety of tamsulosin Oral-Controlled Absorption System (OCAS®) with tamsulosin Modified Release (MR) and placebo in improving lower urinary tract symptoms (LUTS) in men with benign prostatic hyperplasia (BPH)

Design
Phase 3 clinical trial with control group, with parallel groups, double-blind, randomized with random allocation method, with a sample size of 260 patients

Settings and conduct
Medications are separately packed in 4 groups from 1 to 4 by one of the co-workers and delivered to the main researcher. So that neither patients nor the main researcher who prescribes the medication do not know the type of drug they receive or is prescribed. The location of the study is the Urology Clinic of Razi Educational and Research Hospital. Drugs are randomly distributed among eligible patients after necessary examinations.

Participants/Inclusion and exclusion criteria
Patients complained of lower urinary tract symptoms due to benign prostatic hyperplasia with age of at least 40 years, Prostate-Specific Antigen (PSA) in age-specific range and score of 8 or greater in the international prostate symptom score (IPSS) questionnaire are included and patient with renal, cardiovascular and liver disorders are not included.

Intervention groups
Group 1: Tamsulosin Capsule 0.4 mg (MR) with brand name Portral made by Tasnim Pharmaceutical Co., daily oral administration for 12 weeks; Group 2: Talsulosin 0.4 mg (OCAS) with brand name Protral OPAS, made by Tasnim Pharmaceutical Co., daily oral administration for 12 weeks; Group 3: Tamsulosin 0.4 mg (OCAS) with brand name Omnic OCAS, daily oral administration for 12 weeks; Group 4: Placebo, made by Tasnim Pharmaceutical Co., daily oral administration for 12 weeks;

Main outcome variables
International prostate symptom score (IPSS) questionnaire

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20100817004582N8**
Registration date: **2018-02-17, 1396/11/28**
Registration timing: **registered_while_recruiting**

Last update: **2018-02-17, 1396/11/28**
Update count: **0**

Registration date
2018-02-17, 1396/11/28

Registrant information

Name
Ali Hamidi Madani

Name of organization / entity
Urology Research Center, Guilan University of Medical Sciences

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-01-21, 1396/11/01
Expected recruitment end date
2019-01-21, 1397/11/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparative study on the effectiveness and safety of tamsulosin Oral-Controlled Absorption System (OCAS®) with tamsulosin Modified Release (MR) and placebo in improving lower urinary tract symptoms (LUTS) in men with benign prostatic hyperplasia (BPH)

Public title
Comparison of the efficacy and safety of tamsulosin OCAS with tamsulosin MR and placebo in improving lower urinary tract symptoms
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients who are at least 40 years of age. Prostate-Specific Antigen (PSA) score should be at age-specific range. International Prostate Symptom Score (IPSS) should be greater than or equal to 8. The maximum urine flow (Qmax) should be in the range of greater than and/or equal to 4 ml/s and smaller and/or equal to 15 ml/s. The urine residual should be below 120 ml.
Exclusion criteria:
History of prostatectomy Severe liver dysfunction Severe renal dysfunction Severe cardiovascular dysfunction History of syncope. Other conditions that can be causing voiding dysfunction, such as neurogenic bladder, bladder or urinary stones, frequent urinary tract infection, bladder cancer, prostate cancer, urethral stenosis, and large diverticulum bladder. History of allergy to tamsulosin History of recent retention and nocturnal polyuria Patients with benign prostatic hyperplasia (BPH) who are candidates for surgery on the basis of clinical and paraclinical symptoms. History of use of 5α-reductase inhibitors in the last 3 months History of taking diuretics and hypnotic tablets Use of other therapies such as other alpha blockers or herbal extracts in the last month Use of other drugs, such as alpha-agonists, cholinergic or anticholinergic drugs that may affect the effects of tamsulosin pharmacodynamics.
Age
From **40 years** old
Gender
Male

Phase
4
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **260**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients are randomly assigned through random allocation method with block size 8 to 4 groups.
Blinding (investigator's opinion)
Double blinded
Blinding description
Medications are separately packaged in 4 groups of 1 to 4 by one of the co-workers and delivered to the main researcher.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Guilan University of Medical Sciences
Street address
Opposite of 17 Shahrivar Hospital, Shahid Siadati Street, Namjoo Street
City
Rasht
Province
Guilan
Postal code
41446-66949
Approval date
2017-11-11, 1396/08/20
Ethics committee reference number
IR.GUMS.REC.1396.318

Health conditions studied

1

Description of health condition studied
Lower Urinary Tract Symptoms (LUTS)
ICD-10 code
N40.1
ICD-10 code description
Enlarged prostate with lower urinary tract symptoms

Primary outcomes

1

Description
The International Prostate Symptom Score (IPSS) Questionnaire

Timepoint
The beginning of the study (before the intervention) and 6 and 12 weeks after the start of the intervention
Method of measurement
The International Prostate Symptom Score (IPSS) Questionnaire

Secondary outcomes

1

Description
Side effects
Timepoint
The beginning of the study (before the intervention) and 6 and 12 weeks after the start of the intervention
Method of measurement
Ask the patient

Intervention groups

1

Description
Intervention group 1: Tamsulosin capsule 0.4 mg (MR) with brand name Portral, manufacturing by Tasnim Pharmaceutical Co., daily for 12 weeks orally
Category
Treatment - Drugs

2

Description
Intervention group 2: Tamsulosin Tablets 0.4 mg (OCAS) with brand name Protral OPAS, manufacturing by Tasnim Pharmaceutical Co., daily for 12 weeks orally
Category
Treatment - Drugs

3

Description
Intervention group 3: Tamsulosin Tablets 0.4 mg (OCAS) with brand name Omnic OCAS, daily for 12 weeks orally
Category
Treatment - Drugs

4

Description
Control group: Placebo, manufacturing by Tasnim Pharmaceutical Co., daily for 12 weeks orally
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Razi Hospital
Full name of responsible person
Ali Hamidi Madani
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Razi Hospital, Sardar Jangal Street
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Urology Research Centre, Guilan University of Medical Sciences
Full name of responsible person
Head of Urology Research Centre, Dr. Siavsh Falahatkar
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Urology Research Centre, Razi Hospital, Sardar Jangal St.
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Grant name
10506
Grant code / Reference number
32
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Urology Research Centre, Guilan University of Medical Sciences
Proportion provided by this source
20
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

2

Sponsor
Name of organization / entity
Tasnim Pharmaceutical Co.
Full name of responsible person
Dr. Abbas Movahednia
Street address
Unit 6, 2nd floor, No. 11, 1st Alley, Beginning at Gandhi Street
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1517615814
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+98 21 8877 2958
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+98 21 8877 2072
Email
tasnimpharam@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tasnim Pharmaceutical Co.
Proportion provided by this source
80
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Industry

Person responsible for general inquiries

Contact
Name of organization / entity
Urology Research Center, Guilan University of Medical Sciences
Full name of responsible person
Kourosh Mojtabavi
Position
Medical student
Latest degree
Medical doctor
Other areas of specialty/work
Urology
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Person responsible for scientific inquiries

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Person responsible for updating data

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Full name of responsible person
Samaneh Esmaeili
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Researcher of Urology Research Center
Latest degree
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
It is not ethically possible to release patient data. The questionnaires are kept at the Urology Research Center of Guilan University of Medical Sciences and only if necessary, natural and legal persons with legal permission will be allowed to examine them.
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Not applicable
Title and more details about the data/document
All patient data will be reported after a statistical analysis in the form of the results of a scientific study.
When the data will become available and for how long
Start the access period after printing the results in a scientific article
To whom data/document is available
All researchers in Iran who are affiliated with one of the academic or research institutes approved by the Ministry of Health and Medical Education.
Under which criteria data/document could be used
In case of doing Cohort studies or multicentre studies by other eligible researchers
From where data/document is obtainable
Dr. Ali Hamidi Madani, executor of project and Dr. Siavash Falahtakar, Head of Urology Research Center
Address: Urology Research Center, Razi Hospital, Rasht
Phone: 013- 33525259
What processes are involved for a request to access data/document
Submitting a written request for the head of the Urology Research Center, stating the request to the project executive other colleagues and getting their approval, writing a written opinion to the applicant, taking the moral obligation of the applicant, sending the data and documentation to the applicant
Comments