Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Jun 2026

Effect of Carvedilole and combination of Terazosin plus Enalapril on blood pressure and urinary symptoms among patients with Hypertension and Benign Prostatic Hyperplasia

Protocol summary

Study aim

1-comparative study of carvedilol with combination of terazosin and enalaprilon on blood pressure and obstructive urinary symptoms in patients with moderate HTN and BPH. 2-comparative study of carvedilol with combination of terazosin and enalaprilon on maximum Urine flow rate (Qmax), serum PSA and post voiding residual (PVR) in patients with moderate HTN and BPH.

Design

Randomized, double-blind, crossover clinical trial in which 40 eligible patients will participate

Settings and conduct

This study will be conducted at urology clinic of Imam Reza hospital, Patients in 2 groups were receive the carvedilol (starting dose 12.5 mg/d) and placebo, other group terazosin 5 mg and enalapril (10 mg/d). Full clinical evaluations were performed during 4 visits: at baseline, after 12 W of treatment, at the end of the washout period, and after the next 12 W of treatment.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Moderate hypertension according to the European Society of Hypertension guidelines, defined as diastolic blood pressure (BP) between 90 and 99 mm Hg or systolic BP between 140 and 159 mm Hg (or both)]; men over than 40 years with BPH and persisted LUTS during the last 6 months. Non-inclusion criteria: previous prostate surgery; prostate malignancy; Uncontrolled or urgency Hypertension; Use of other drugs during this study, history of using anti-hypertensive and prostate drugs.

Intervention groups

Intervention group 1: treatment with carvedilol and placebo, then 12 weeks wash out period and after that treatment with Terazosin and Enalapril. Intervention group 2: treatment with Terazosin and Enalapril, then 12 weeks wash out period and after that treatment with carvedilol and placebo.

Main outcome variables

Q max(maximum urine flow in uroflowmetry)؛ PVR (post void residue)؛ IPSS score (international prostate symptoms score)؛ Serum PSA (prostate specific antigen) ؛ systolic and diastolic blood pressure.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181128041777N1**
Registration date: **2019-03-14, 1397/12/23**
Registration timing: **retrospective**

Last update: **2019-03-14, 1397/12/23**
Update count: **0**

Registration date

2019-03-14, 1397/12/23

Registrant information

Name

Nooriyeh Dalir akbari

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 41 3335 9633

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-12-22, 1397/10/01

Expected recruitment end date

2018-12-29, 1397/10/08

Actual recruitment start date
2018-09-21, 1397/06/30
Actual recruitment end date
2018-10-02, 1397/07/10
Trial completion date
2018-10-22, 1397/07/30

Scientific title
Effect of Carvedilole and combination of Terazosin plus Enalapril on blood pressure and urinary symptoms among patients with Hypertension and Benign Prostatic Hyperplasia

Public title
Effect of Carvedilole compared to Terazosin plus Enalapril in treatment of Hypertension and benign prostatic hyperplasia
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Moderate hypertension (according European guide line blood pressure between 140-159 in systolic and 90-99 in diastolic) Men above 40 years with benign prostatic hyperplasia that diagnosis with permanent LUTS during the last 6 months ,physical examination, ultrasonography and serum PSA
Exclusion criteria:
History of using alfa blockers during the last 6 months history of uncontrolled or malignant urgency HTN history of using anti hypertensive and prostate drugs history of prostate cancer history of prostate surgery
Age
From **40 years** old
Gender
Male

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **40**
Actual sample size reached: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
block, simple randomization
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Used
Assignment
Crossover
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tabriz University of Medical Sciences
Street address
central building of Tabriz University of Medical Sciences, Golgasht avenue, Azadi street
City
Tabriz
Province
East Azarbaijan
Postal code
5156954567
Approval date
2018-08-26, 1397/06/04
Ethics committee reference number
IR.TBZMED.REC.1397.604

Health conditions studied

1

Description of health condition studied
Hypertension
ICD-10 code
I10
ICD-10 code description
Essential (primary) hypertension

2

Description of health condition studied
Benign prostate hyperplasia
ICD-10 code
N40.1
ICD-10 code description
Enlarged prostate with lower urinary tract symptoms

Primary outcomes

1

Description
Q max: Maximum urinary flow rate show in uroflowmetry
Timepoint
in 4 time: before treatment. after carvedilol. before enalapril and terazosin and after that.
Method of measurement
uroflowmetry

Secondary outcomes

1

Description
PVR :Post Voiding Residual
Timepoint

in 4 time: before treatment. after carvedilol. before enalapril and terazosin and after that.

Method of measurement

Sonography

2

Description

IPSS : international prostate symptom score

Timepoint

in 4 time: before treatment. after carvedilol. before enalapril and terazosin and after that.

Method of measurement

International prostate symptom score questionnaire

3

Description

PSA : prostate specific antigen

Timepoint

in 4 time: before treatment. after carvedilol. before enalapril and terazosin and after that.

Method of measurement

Blood test

4

Description

Systolic blood pressure

Timepoint

in 4 time: before treatment. after carvedilol. before enalapril and terazosin and after that.

Method of measurement

mercury manometer

5

Description

Diastolic blood pressure

Timepoint

in 4 time: before treatment. after carvedilol. before enalapril and terazosin and after that.

Method of measurement

mercury manometer

Intervention groups

1

Description

Intervention group 1: After random allocation in 2 groups, first group was treated with Carvedilol, produced by SOHA company, 12.5 mg (Max 25 mg) and Blood pressure was kept in normal range (120 over 80 mmHg). Tab VitB complex-DP was used as placebo. Prostate examination, recording urinary symptoms and blood pressure control were done every month. Treatment period was 12 weeks and after that there was a 12-week wash out period with blood pressure checking every month. Then this group was treated with terazosin produced by ARYA company, 5 mg up to 20 mg and enalapril produced by SOBHAN company, 2.5 mg max 20 mg to achieve normal blood pressure. Examinations and blood pressure recording were done every month. Treatment periods were 12 weeks.

Category

Treatment - Drugs

2

Description

Intervention group 2 received terazosin, produced by ARYA company, 5 mg up to 20 mg and enalapril, produced by SOBHAN company, 2.5 mg max 20 mg to control blood pressure in normal range. Treatment period was 12 weeks and after that there was a 12-week wash out period with blood pressure checking every month. Then this group received carvedilol, produced by SOHA company, 12.5 mg max 25 mg with Vitamin-B complex DP as placebo. Blood pressure and prostate examination was done each month. Treatment period was 12 weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Tabriz Imam Reza hospital

Full name of responsible person

Nooriyeh Dalir Akbari

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Golgasht Avenue, Azadi street

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Web page address

https://www.tbzmed.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Mohammad Reza rashidi

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Central building of Tabriz University of Medical Sciences, Golgasht avenue, Azadi street

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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
Nooriyeh Dalir Akbari

Position
Medical resident

Latest degree
Specialist

Other areas of specialty/work
Urology

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Person responsible for scientific inquiries

Contact

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Position
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Latest degree
Specialist

Other areas of specialty/work
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Person responsible for updating data

Contact

Name of organization / entity
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

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
Yes - There is 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

Yes - There is a plan to make this available

Title and more details about the data/document

All data without patients' name can be accessible through email.

When the data will become available and for how long

accessible after publication on 2019

To whom data/document is available

all researchers

Under which criteria data/document could be used

after written permission of author

From where data/document is obtainable

Tabriz university of medical science
http://pazhoohan.tbzmed.ac.ir

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

accessible after email on Tabriz university of medical science site

Comments

0