Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Effect of combination therapy of coenzyme Q10 and L carnitine and finasteride on treatment management in patients with lower urinary tract symptoms (LUTS) due to benign prismatic hyperplasia (BPH)

Protocol summary

Study aim
Determining the effectiveness of combination therapy of coenzyme Q10 and L carnitine and finasteride on treatment management in patients with lower urinary tract symptoms due to benign prismatic hyperplasia

Design
Clinical trial with control group, randomization, double blind,3 phase in to 50 patients ,four blocks are used to randomization

Settings and conduct
In faghihi hospital،double blind clinical trial, at the patient and evalutor level the outcome is blind, everyone consumes finasteride, we give the coenzyme Q10 and L carnitine in to intervention group and placebo in to control group

Participants/Inclusion and exclusion criteria
Prostate volume :40-60cc IPSS(International prostate symptom score):40-60cc 50-75 years old

Intervention groups
Intervention gruop: finasteraid, L carnitine, coenzyme Q10 Control group : finasteraid, placebo

Main outcome variables
prostate volume, IPSS(International prostate symptom score),IIEF(International index of erectile function), PSA(prostate specific antigen), Quality of life

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200623047893N1**
Registration date: **2020-07-26, 1399/05/05**
Registration timing: **registered_while_recruiting**

Last update: **2020-07-26, 1399/05/05**
Update count: **0**

Registration date
2020-07-26, 1399/05/05

Registrant information
Name
Mahsa Norouzi
Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 71 3822 9875
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mahsanorouzi89@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-06-25, 1399/04/05

Expected recruitment end date
2020-08-26, 1399/06/05

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of combination therapy of coenzyme Q10 and L carnitine and finasteride on treatment management in patients with lower urinary tract symptoms (LUTS) due to benign prismatic hyperplasia (BPH)

Public title
"coenzyme Q10 and L carnitine in Benign prismatic hyperplasia"

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

50-75 years old IPSS=8-19 Prostate volume 40-60 cc

Exclusion criteria:

urinary tract infections severe liver disease diabetes recent treatment with 5 alpha reductase recent treatment with phototherapy treatment with antiandrogens and antidepressants neurological bladder bladder cancer prostate cancer Take atorvastatin blood pressure

Age

From **50 years** old to **75 years** old

Gender

Male

Phase

3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization is done by the method of 4 blocks. The study is based on random allocation and is done by block balanced randomization method. Preparing a list of blocks and assigning numbers to them, selecting random numbers between 1 and 6, specifying the treatment allocation list

Blinding (investigator's opinion)

Double blinded

Blinding description

This study is a double-blind clinical trial. Thus, the study at the level of the patient and the evaluator of the outcome of the results became blind. The drug and placebo capsules were divided into four-block blocks before filling. Only the researcher could decipher the contents of each capsule based on the original stored form of the random results. The person in charge of delivering the medicine, the patient, the doctor, and the person in charge of evaluating the consequences were not aware of the coding.The results of the control and intervention group under the headings of groups A and B were delivered to the statistical analyst.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shiraz University of Medical sciences

Street address

No 18, niyayesh 5 Ave,tohidy rad Blvd, Shiraz Town

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Province

Fars

Postal code

713451978

Approval date

2018-04-11, 1397/01/22

Ethics committee reference number

IR.SUMS.REC.1397.002

Health conditions studied

1

Description of health condition studied

Benign prostatic hyperplasia

ICD-10 code

ICD-10 code description

2

Description of health condition studied

Lower urinary tract symptoms

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Changes in prostate volume

Timepoint

The beginning the study and the end of study

Method of measurement

Sonography

Secondary outcomes

1

Description

IIEF

Timepoint

The beginning and the end of study

Method of measurement

Questionnaire

Intervention groups

1

Description

Intervention group: finasteraid, coenzyme Q10 100 mg , L carnitine 1000mg ,1tablet daily for 8 weeks

Category

Treatment - Drugs

2

Description

Control group: finasteraid, plasebo ,1tablet daily for 8 weeks

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid faghihi Hospital

Full name of responsible person

Mahsa norouzi

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2

Recruitment center

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Yones ghasemi

Street address

Deputy Director and Technology,7th Standard,Zandani Street, Shiraz University of Medical Sciences Standard ,Shiraz Town

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Postal code

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Phone

+98 71 3230 5410

Email

ghasemiy@sums.ac.ir

Web page address

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Mahsa norouzi

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Nutrition

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
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
Part of the data can be shared

When the data will become available and for how long
6 months after printing the results

To whom data/document is available
Employed researchers

Under which criteria data/document could be used
Employed researchers

From where data/document is obtainable
Mahsa norouzi ,mahsanorouzi89@gmail.com

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

Comments