Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effect of Stinging Nettle (Urtica dioica L.) extract on insulin resistance, sexual hormones and oxidative stress and inflammatory biomarkers in patients with in patients with Benign Prostate Hyperplasia

Protocol summary

Study aim
The aim of the present study was to investigate the effect of nettle extract on insulin resistance, sex hormones and biomarkers of oxidative stress and inflammation in patients with Benign Prostate Hyperplasia.

Design
This study is a double blind clinical trial study.This study also has a control group that receives a placebo. Random assignment was done by the use of computer-generated random numbers.

Settings and conduct
In the study 60 patients with BPH among males of eligible and referred to Velayat hospital affiliated to Qazvin University of Medical Sciences, Qazvin, Iran, will be selected. Patients and researchers are blind until the end of the study.

Participants/Inclusion and exclusion criteria
In this study, men aged 50 to 80, with Benign Prostate Hyperplasia will be included. Unwillingness to cooperate, diabetes, hyper and hypothyroidism, and so anticoagulant use will be excluded.

Intervention groups
Patients will be assigned to receive either Stinging Nettle (Urtica dioica L.) extract (intervention group: n=30) or placebo (control group: n=30).

Main outcome variables
Insulin resistance, sexual hormones and oxidative stress and inflammatory biomarkers in patients with Benign Prostate Hyperplasia will be measured before and after of the intervention.

General information

Reason for update
Four outcomes that were not recorded by mistake at the time of initial registration were recorded

Acronym
BPH

IRCT registration information
IRCT registration number: **IRCT20170430033730N4**
Registration date: **2018-07-27, 1397/05/05**
Registration timing: **registered_while_recruiting**

Last update: **2019-12-01, 1398/09/10**
Update count: **1**

Registration date
2018-07-27, 1397/05/05

Registrant information

Name
Seyyed Mehdi Mirhashemi
Name of organization / entity
Qazvin University of Medical Sciences
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-05-26, 1397/03/05

Expected recruitment end date
2018-08-25, 1397/06/03

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of Stinging Nettle (Urtica dioica L.) extract on insulin resistance, sexual hormones and oxidative stress and inflammatory biomarkers in patients with in patients with Benign Prostate Hyperplasia

Public title
Effect of Stinging Nettle (Urtica dioica L.) extract in patients with Benign Prostate Hyperplasia

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Patients with benign prostatic hyperplasia
Exclusion criteria:
Patients who use anticoagulant Diabetic patients Patients with hypo and/or hyperthyroidism

Age
From **50 years** old to **80 years** old

Gender
Male

Phase
2-3

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple randomization, Random assignment was done by the use of computer-generated random numbers.

Blinding (investigator's opinion)
Double blinded

Blinding description
A placebo was used to blind. Researchers and Patients will be blinded by the professional analyst until final analysis.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Qazvin University of Medical Sciences
Street address
Shahid Bahonar Boulevard
City
Qazvin
Province
Qazvin
Postal code
34197-59811
Approval date
2018-01-22, 1396/11/02
Ethics committee reference number
IR.QUMS.REC.1396.396

Health conditions studied

1

Description of health condition studied
Benign Prostate Hyperplasia
ICD-10 code
N40
ICD-10 code description
Enlarged prostate

Primary outcomes

1

Description
International Prostate Symptom Score (I-PSS)
Timepoint
At the beginning of the study and 12 weeks after the intervention
Method of measurement
Standard questionnaire

2

Description
Insulin
Timepoint
At the beginning of the study and 12 weeks after the intervention
Method of measurement
calculation based on standard formula

Secondary outcomes

1

Description
Glutathion
Timepoint
At the beginning of the study and 12 weeks after the intervention
Method of measurement
Spectrophotometry

2

Description
MDA
Timepoint
At the beginning of the study and 12 weeks after the intervention
Method of measurement

Spectrophotometry

3

Description
hs-CRP
Timepoint
At the beginning of the study and 12 weeks after the intervention
Method of measurement
ELISA

4

Description
Testosterone
Timepoint
At the beginning of the study and 12 weeks after the intervention
Method of measurement
ELISA

5

Description
DHT
Timepoint
At the beginning of the study and 12 weeks after the intervention
Method of measurement
ELISA

6

Description
Estradiole
Timepoint
At the beginning of the study and 12 weeks after the intervention
Method of measurement
ELISA

7

Description
Angiopoitin-2
Timepoint
At the beginning of the study and 12 weeks after the intervention
Method of measurement
ELISA

8

Description
superoxide dismutase
Timepoint
At the beginning of the study and 12 weeks after the intervention
Method of measurement
Spectrophotometry

9

Description
Omentin
Timepoint
At the beginning of the study and 12 weeks after the intervention
Method of measurement
ELISA

10

Description
PSA
Timepoint
At the beginning of the study and 12 weeks after the intervention
Method of measurement
ELISA

Intervention groups

1

Description
Intervention group: Three pills of nettle extract of 150 mg three times a day for 12 weeks
Category
Treatment - Drugs

2

Description
Control group: Three pills of Placebo of 150 mg three times a day for 12 weeks.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Velayat Hospital
Full name of responsible person
Seyyed Mehdi Mirhashemi
Street address
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Qazvin University of Medical Sciences
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Amir Peimani
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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
Qazvin 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
Qazvin University of Medical Sciences
Full name of responsible person
Seyyed Mehdi Mirhashemi
Position
Associate professor
Latest degree
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Other areas of specialty/work
Biochemistry
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Person responsible for scientific inquiries

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Person responsible for updating data

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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

There is no further information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

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

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable