

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 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

Country

Iran (Islamic Republic of)

Phone

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Email address

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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 Bahrar 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

Shahid Bahonar Blovard

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

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

Ph.D.

Other areas of specialty/work

Biochemistry

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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	make this available
Study Protocol	Clinical Study Report
No - There is not a plan to make this available	Not applicable
Statistical Analysis Plan	Analytic Code
Not applicable	Not applicable
Informed Consent Form	Data Dictionary
Undecided - It is not yet known if there will be a plan to	Not applicable