

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Study of the effect of curcumin on insulin resistance, sexual hormones and oxidative stress and inflammatory biomarkers in patients with Benign Prostate Hyperplasia

Protocol summary

Study aim

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

Design

Random assignment was done by the use of computer-generated random numbers. Population and sample size: 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.

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.

Participants/Inclusion and exclusion criteria

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

Intervention groups

Patients will be assigned to receive either curcumin (intervention group: n=30) or placebo (control group: n=30).

Main outcome variables

Insulin, 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

one outcome that was not recorded by mistake at the

time of initial registration, was recorded

Acronym

IRCT registration information

IRCT registration number: **IRCT20170430033730N3**

Registration date: **2018-07-08, 1397/04/17**

Registration timing: **retrospective**

Last update: **2020-06-09, 1399/03/20**

Update count: **1**

Registration date

2018-07-08, 1397/04/17

Registrant information

Name

Seyyed Mehdi Mirhashemi

Name of organization / entity

Qazvin University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 28 3333 6001

Email address

sm.mirhashemi@qums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-05-26, 1397/03/05

Expected recruitment end date

2018-05-27, 1397/03/06

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study of the effect of curcumin on insulin resistance, sexual hormones and oxidative stress and inflammatory biomarkers in patients with Benign Prostate Hyperplasia

Public title

Study of effect of curcumin in patients with Benign Prostate Hyperplasia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with benign prostatic hyperplasia

Exclusion criteria:

patients who do not want to cooperate 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

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.1396.408

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 (IPSS)

Timepoint

At the beginning of the study and 12 weeks after the intervention

Method of measurement

Standard questionnaire for International Prostate Symptom Score evaluation

2

Description

Insulin

Timepoint

At the beginning of the study and 12 weeks after the intervention

Method of measurement

ELISA

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

Intervention groups

1

Description

Intervention group: Two capsules of 80 mg of curcumin were taken twice daily for twelve weeks

Category

Treatment - Drugs

2

Description

Control group: Two capsules of 80 mg of placebo are given twice 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

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Shahid Bahonar Blovard

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mirhashemism@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Amir Peimani

Street address

Shahid Beheshti Blvd - Valiasr Square

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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
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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