

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 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

#### Street address

Shahid Bahonar Blovard

#### City

Qazvin

#### Province

Qazvin

#### Postal code

34197-59811

#### Phone

+98 28 3333 6001

#### Fax

#### Email

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

#### City

Qazvin

#### Province

Qazvin

#### Postal code

34156-13911

#### Phone

+98 28 3333 7006

#### Email

a.peymani@gmail.com

#### 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  
**Street address**  
Shahid Bahonar Blovard  
**City**  
Qazvin  
**Province**  
Qazvin  
**Postal code**  
34197-59811  
**Phone**  
+98 28 3333 6001  
**Email**  
mirhashemism@gmail.com

## Person responsible for scientific 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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## 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