

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

24 Jun 2026

### Evaluation of the synergistic effect of curcumin in controlling urinary irritation symptoms after endoscopic benign prostatic hyperplasia in comparison with anticholinergic treatment alone

#### Protocol summary

##### Study aim

Evaluation of the synergistic effect of curcumin on the control of urinary irritation symptoms after endoscopic benign prostatic hyperplasia in comparison with anticholinergic treatment alone

##### Design

RCT with control group, with parallel groups, single blind, randomized, on 80 patients. randomization method is by using Envelopes.

##### Settings and conduct

This study will be performed in the urology department of Imam Reza Hospital. Patients with benign prostatic hyperplasia who have undergone endoscopic surgery (TURP) and now have urinary irritation symptoms are being studied. We have two groups of intervention by random allocation method. The first group was treated with anticholinergics and curcumin and the second group was treated with anticholinergics. They are placed alone. One month later, the results of the improvement of stimulus symptoms are evaluated using a questionnaire (IPSS).

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: patients with post-operative excitatory symptoms TURP. Exclusion criteria: patients with severe preoperative irritation symptoms; existence of fever and symptoms of prostatitis; existence of bladder injury during surgery; active UTI.

##### Intervention groups

Intervention group: administration of anticholinergic drugs, one tablet twice a day with curcumin, one tablet once a day for one month in patients with benign prostatic hyperplasia who have undergone endoscopic surgery. Control group: administration of anticholinergic drugs one tablet twice a day for a month in patients with benign prostatic hyperplasia who have undergone endoscopic surgery.

##### Main outcome variables

Score obtained based on the patient's irritating symptoms questionnaire

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20170417033489N9**

Registration date: **2021-11-03, 1400/08/12**

Registration timing: **retrospective**

Last update: **2021-11-03, 1400/08/12**

Update count: **0**

##### Registration date

2021-11-03, 1400/08/12

##### Registrant information

##### Name

Salman Soltani

##### Name of organization / entity

Mashhad University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 3802 2553

##### Email address

soltanis@mums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-11-21, 1399/09/01

##### Expected recruitment end date

2021-05-05, 1400/02/15

##### Actual recruitment start date

2020-11-21, 1399/09/01

**Actual recruitment end date**

2021-05-05, 1400/02/15

**Trial completion date**

2021-06-10, 1400/03/20

**Scientific title**

Evaluation of the synergistic effect of curcumin in controlling urinary irritation symptoms after endoscopic benign prostatic hyperplasia in comparison with anticholinergic treatment alone

**Public title**

Evaluation of the synergistic effect of curcumin in controlling urinary irritation symptoms after endoscopic benign prostatic hyperplasia in comparison with anticholinergic treatment alone

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Patients with benign prostatic hyperplasia who have undergone endoscopic surgery and now have symptoms of urinary irritation.

**Exclusion criteria:**

Patients with severe preoperative irritation symptoms  
Existence of fever and symptoms of prostatitis  
Existence of bladder injury during surgery  
Existence of active urinary tract infection  
Having underlying diseases such as high blood pressure  
Glaucoma

**Age**

From **60 years** old

**Gender**

Male

**Phase**

3

**Groups that have been masked**

- Participant

**Sample size**

Target sample size: **80**

Actual sample size reached: **80**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Simple randomization; after each patient with the inclusion criteria is referred, an envelope is taken in order and according to the code written in it (for example, group A / group B), the patient enters each of the mentioned groups.

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

One side is blind. Patient

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Mashhad Ethics Committee of the Medical School

**Street address**

Department of Knowledge & Health, Shahid Fakouri blvd, Mashhad, Khorasan Razavi Mashhad

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

99191-91778

**Approval date**

2021-01-20, 1399/11/01

**Ethics committee reference number**

IR.MUMS.MEDICAL.REC.1399.630

**Health conditions studied****1****Description of health condition studied**

Benign prostatic hyperplasia

**ICD-10 code**

D29.1

**ICD-10 code description**

hyperplasia of prostate (adenomatous)

**Primary outcomes****1****Description**

Score obtained based on the patient's irritating symptoms questionnaire

**Timepoint**

Before the intervention and one month after taking curcumin

**Method of measurement**

International Prostate Symptom Score (IPSS)

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Intervention group: They are treated with anticholinergics at a dose of one tablet twice a day and oral curcumin tablets once a day. After one month from the start of treatment, the results of improving irritative symptoms using the Persian version of the questionnaire (IPSS) again. Will be evaluated.

**Category**

Treatment - Drugs

## 2

### Description

Control group: Patients are treated with anticholinergics and with the same prescription as the intervention group.

### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Emam Reza Hospital

##### Full name of responsible person

Salman Soltani

##### Street address

Margin of Imam Reza Square, Ibn Sina Blvd, Mashhad.

##### City

Mashhad

##### Province

Razavi Khorasan

##### Postal code

9137913316

##### Phone

+98 51 3858 3885

##### Email

soltanis@mums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Mashhad University of Medical Sciences

##### Full name of responsible person

Dr.Mohsen Taffaghodi

##### Street address

Khorasan Razavi, Mashhad, University Street, in front of University 18, Building No. 1 of Mashhad University of Medical Sciences (Ghorashi),

##### City

Mashhad

##### Province

Razavi Khorasan

##### Postal code

9138813944

##### Phone

+98 51 3841 1538

##### Email

tafaghodiM@mums.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

Mashhad 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

Mashhad University of Medical Sciences

##### Full name of responsible person

Salman Soltani

##### Position

Associate professor

##### Latest degree

Specialist

##### Other areas of specialty/work

Urology

##### Street address

Department of Urology, on the edge of Imam Reza Square, Ibne Sina Blvd, Mashhad.

##### City

Mashhad

##### Province

Razavi Khorasan

##### Postal code

9137913316

##### Phone

+98 51 3858 3885

##### Email

soltanis@mums.ac.ir

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Mashhad University of Medical Sciences

##### Full name of responsible person

Salman Soltani

##### Position

Associated Professor

##### Latest degree

Specialist

##### Other areas of specialty/work

Urology

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**Person responsible for updating data****Contact****Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Salman Soltani

**Position**

Assistant Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Urology

**Street address**

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**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9137913316

**Phone****Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be 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**

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

**Clinical Study Report**

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

**Analytic Code**

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

**Data Dictionary**

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