

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)

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+98 51 3802 2553

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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.

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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),

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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

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

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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