

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Investigating the effect of curcumin tablets on pain, blood pressure and blood coagulation in patients undergoing surgery for benign prostatic hyperplasia through urethral incision

Protocol summary

Study aim

Investigating the effect of curcumin tablets on pain, blood pressure and blood coagulation in patients with benign prostatic hyperplasia undergoing urethral resection surgery

Design

Clinical trial with a control group, with parallel groups, double-blind, randomized, phase 4 on 184 patients. Randomized block method was used for randomization.

Settings and conduct

This study will be conducted in Golpayegani Hospital, Qom. This study is double blind. The patients and the person who collects the patients' information do not know which group the patient belongs to. In the control group, 25 mg pethidine ampoule every 8 hours and a placebo pill will be prescribed daily. In the intervention group, in addition to 25 mg pethidine ampoule every 8 hours, a 47.5 mg curcumin tablet will be prescribed daily.

Participants/Inclusion and exclusion criteria

Patients who have undergone prostate urethral resection surgery; Not having coagulation disorders; and Not having an allergy to curcumin Not having drug addiction.

Intervention groups

In the control group, 25 mg pethidine ampoule every 8 hours and a placebo pill will be prescribed daily. In the intervention group, in addition to 25 mg pethidine ampoule every 8 hours, a 47.5 mg curcumin tablet will be prescribed daily.

Main outcome variables

Pain reduction, better control of blood pressure and improvement of blood coagulation of patients.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231022059810N1**

Registration date: **2023-12-06, 1402/09/15**

Registration timing: **registered_while_recruiting**

Last update: **2023-12-06, 1402/09/15**

Update count: **0**

Registration date

2023-12-06, 1402/09/15

Registrant information

Name

Atye Babaii

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 25 3107 1300

Email address

a.babaii@muq.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-11-22, 1402/09/01

Expected recruitment end date

2024-09-20, 1403/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of curcumin tablets on pain, blood pressure and blood coagulation in patients undergoing surgery for benign prostatic hyperplasia

through urethral incision

Public title

Investigating the effect of curcumin tablets on pain, blood pressure and blood coagulation in patients undergoing surgery for benign prostatic hyperplasia through urethral incision

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients who have undergone prostate urethral resection surgery Not having coagulation disorders Not having an allergy to curcumin Not having drug addiction

Exclusion criteria:

Abnormal bleeding after surgery (more than 300 cc)
Criticality of the patient's vital signs

Age

From **18 years** old

Gender

Male

Phase

4

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **184**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants will be assigned to intervention and control groups using block randomized method. The link "<https://www.sealedenvelope.com/simple-randomiser/v1/lists>" will be used for block randomization. For this purpose, the target number of samples (250 samples including sample loss), number of groups (two groups A and B) and number of blocks (4) will be entered and the system will provide the researcher with a list of 4 blocks. Based on the output list, it will be determined in which group the patients who enter the study should be placed in order. Items A represent the intervention group and items B represent the control group.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients do not know whether they are using a placebo or the real drug. The person who collects the information also does not know whether the patient used a placebo or the real drug.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Qom University of Medical Sciences

Street address

Qom University of Medical Science, Saheli Ave.

City

Qom

Province

Ghous

Postal code

3713649373

Approval date

2023-10-02, 1402/07/10

Ethics committee reference number

IR.MUQ.REC.1402.154

Health conditions studied

1

Description of health condition studied

Hyperplasia of prostate

ICD-10 code

N40

ICD-10 code description

Enlarged prostate

Primary outcomes

1

Description

Pain

Timepoint

Immediately before the intervention and every 6 hours after the intervention until discharge

Method of measurement

Visual Analogue Scale

Secondary outcomes

1

Description

Blood pressure

Timepoint

Immediately before the intervention and every 6 hours after the intervention until discharge

Method of measurement

Vital Sign Monitoring Device

2

Description

Blood coagulation tests

Timepoint

Immediately before the intervention and every 24 hours after the intervention until discharge

Method of measurement

Using PT, PTT, INR laboratory tests

Intervention groups

1

Description

In the control group, 25 mg Pethidine ampoule every 8 hours and a placebo pill will be prescribed daily.

Category

Placebo

2

Description

In the intervention group, in addition to 25 mg Pethidine ampoule every 8 hours, a 47.5 mg Curcumin tablet will be prescribed daily.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Golpayegani Hospital

Full name of responsible person

Atye Babaii

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ghous University of Medical Sciences

Full name of responsible person

Rahim Ali

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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

Ghous 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

Ghous University of Medical Sciences

Full name of responsible person

Atye Babaii

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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

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Other areas of specialty/work

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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

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