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)

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+98 25 3107 1300

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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
Ghoum
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
Ghoum University of Medical Sciences

Full name of responsible person
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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

Ghoum 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
Ghoum 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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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