Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Investigating the effect of cellulose oxide powder on the amount of bleeding following simple open prostatectomy using the transvesical method

Protocol summary

Study aim

Determining the effect of cellulose oxide powder on the amount of bleeding following simple open prostatectomy by transvesical method

Design

A clinical trial with a control group, with parallel groups, double-blind, phase 2-3 on 30 patients. Excel's rand function will be used for randomization.

Settings and conduct

This clinical trial will be conducted in Shahid Beheshti Hospital affiliated to Hamedan University of Medical Sciences on patients with benign prostate enlargement and candidates for open prostatectomy. Transvesical prostatectomy will be performed with spinal anesthesia. Patients will be under spinal anesthesia using 2.5-4 cc bupivacaine. Then they will be placed in the lithotomy position. prostatectomy is performed using the Freire technique. The patient and the outcome assessor will be blind of the method used to control bleeding (double-blind).

Participants/Inclusion and exclusion criteria

Criteria for entering the study: suffering from benign prostate enlargement, candidate for simple open prostatectomy, negative urine culture. Criteria for not entering the study: malignant prostate size, history of any previous surgery or intervention on the prostate (except prostate biopsy), current use of anticoagulant and antiplatelet drugs, history of genetic bleeding disorders, severe increase in blood pressure during surgery, occurrence of complications during surgery Surgery such as capsule rupture or bladder injury

Intervention groups

After transvesical prostatectomy using the Freire technique, in order to stop the blood in the surgical site, the amount of 5 grams of Ketohem powder (Parsa Teb Company, Iran) will be pumped into the prostate fossa.

Main outcome variables

control of bleeding after surgery; Reducing the need for transfusion, reducing the drop in hemoglobin and hematocrit

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151123025202N42**
Registration date: **2024-11-10, 1403/08/20**
Registration timing: **prospective**

Last update: **2024-11-10, 1403/08/20**
Update count: **0**

Registration date

2024-11-10, 1403/08/20

Registrant information

Name

Abbas Moradi

Name of organization / entity

Hamedan University of Medical Of Science

Country

Iran (Islamic Republic of)

Phone

+98 81 3838 0097

Email address

a.moradi@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-11-21, 1403/09/01

Expected recruitment end date

2025-08-22, 1404/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of cellulose oxide powder on the amount of bleeding following simple open prostatectomy using the transvesical method

Public title

Effect of cellulose oxide powder on prostatectomy bleeding rate

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Having benign prostatic hyperplasia Candidate for simple open prostatectomy surgery Negative urine culture

Exclusion criteria:

Prostate hyperplasia by cancer History of any previous surgery or intervention on the prostate (except prostate biopsy) Current use of anticoagulant and antiplatelet drugs History of genetic bleeding disorders

Age

No age limit

Gender

Male

Phase

2-3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

We made 30 cards and write letter I (Intervention) on 15 and on the other 15 letter C (Control). Then put them inside the envelope with aluminum wrap and put in a box. At the time of patient arrival, one of the envelopes randomly will be selected and open it, based on selected letter (I or C) patients will be assigned to intervention (with cellulose oxide powder) or control (without cellulose oxide powder).

Blinding (investigator's opinion)

Double blinded

Blinding description

The person evaluating the outcome of bleeding and the patient will not know how to allocate the groups (intervention/control).

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Hamadan Univercity of Medical Science

Street address

Shahid fahmideh

City

Hamadan

Province

Hamadan

Postal code

6517838697

Approval date

2024-10-26, 1403/08/05

Ethics committee reference number

IR.UMSHA.REC.1403.518

Health conditions studied

1

Description of health condition studied

Benign prostate enlargement

ICD-10 code

D29.1

ICD-10 code description

Benign neoplasm of prostate

Primary outcomes

1

Description

Blood hemoglobin level

Timepoint

Before surgery, 24 and 48 hours after surgery

Method of measurement

blood test

2

Description

Blood hematocrit

Timepoint

Before surgery, 24 and 48 hours after surgery

Method of measurement

blood test

Secondary outcomes

1

Description

The amount of transfusion required

Timepoint
Discharge time from the hospital
Method of measurement
Patient's medical record

Intervention groups

1

Description
Intervention group: In the intervention group, in order to stop the blood in the surgical site, the amount of 5 grams of Ketohem powder will be pumped into the prostate fossa.
Category
Prevention

2

Description
Control group: In the control group, bleeding will be controlled by the usual method (without the use of Ketohem powder), a 24F three-way Foley catheter is inserted, a Foley balloon is filled and traction is established.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Beheshti hospital
Full name of responsible person
Mohsen Alemi
Street address
Eram Blv, Ghaem Sq, Hamedan, Iran
City
Hamadan
Province
Hamadan
Postal code
6517953371
Phone
+98 81 3838 0283
Email
Shahidbeheshti@umsha.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
Reza Shokohi
Street address
Shahid Fahmide Ave
City
Hamadan
Province
Hamadan
Postal code
6517838677
Phone
+98 81 3838 0717
Fax
+98 81 3838 0130
Email
vc_research@umsha.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
Hamedan 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
Hamedan University of Medical Sciences
Full name of responsible person
Abbas Moradi
Position
Coach
Latest degree
Master
Other areas of specialty/work
Epidemiology
Street address
Shahid Fahmideh
City
Hamadan
Province
Hamadan
Postal code
6517838736
Phone
+98 81 3838 0097
Fax
+98 81 3838 0208
Email
a.moradi@umsha.ac.ir

Person responsible for scientific

inquiries

Contact

Name of organization / entity
Hamedan University of Medical Sciences

Full name of responsible person
Abbas Moradi

Position
MSc in epidemiology/ Comunity Medicine MS

Latest degree
Master

Other areas of specialty/work
Epidemiology

Street address
Shahid Fahmideh

City
Hamadan

Province
Hamadan

Postal code
6517838736

Phone
+98 81 3838 0557

Fax

Email
a.moradi@umsha.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity
Hamedan University of Medical Sciences

Full name of responsible person
Abbas Moradi

Position
MSc in epidemiology/ Comunity Medicine MS

Latest degree
Master

Other areas of specialty/work
Epidemiology

Street address
Shahid Fahmideh

City
Hamadan

Province
Hamadan

Postal code
6517838736

Phone
+98 81 3838 0557

Fax

Email
a.moradi@umsha.ac.ir

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available

Title and more details about the data/document
All data can be shared except for authors names

When the data will become available and for how long
From 2026 onwards it is permissible

To whom data/document is available
Clinical professionals and Researchers in all fields

Under which criteria data/document could be used
For treatment of patients and develop research and science

From where data/document is obtainable
Correspond to the email address of the scientific responsible for the study

What processes are involved for a request to access data/document
Send and receive email

Comments