

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jul 2026

A comparative study of the effect of tranexamic acid dissolved in hot ,cold and room temperature washing fluid on reducing bleeding during surgery and postoperative complications in TURP surgery

Protocol summary

Study aim

Comparison of the effect of tranexamic acid dissolved in hot, cold and operating room temperature washing fluids on the amount of bleeding during surgery and complications of TURP.

Design

A controlled, parallel-group, single-blind, randomized, phase 2 clinical trial on 80 patients. Randomization was done by block of four method.

Settings and conduct

Candidates for TURP surgery in Imam Khomeini Hospital of Aeshtar city were randomly divided into four control groups (routine intraoperative washing), intervention 1 (washing with a combination of warm solution and tranexamic acid), intervention 2 (washing with a combination of cold solution and tranexamic acid), intervention 3 (washing They were divided by the combination of room temperature solution and tranexamic acid) and intraoperative washing in each group was determined according to the method. The patients did not know about the washing method in the operating room.

Participants/Inclusion and exclusion criteria

Entry criteria: age over 18 years, prostate weight less than 70 grams, no history of coagulation disorders, no history of cardiovascular diseases, no history of prostate cancer, hemoglobin greater than or equal to 10, no history of atrial fibrillation and coronary artery disease, thrombophilia, severe form Chronic renal failure. Exclusion criteria: the presence of sensitivity to tranexamic acid drug, the need to perform anesthesia other than spinal anesthesia.

Intervention groups

Control group: routine intraoperative washing
Intervention group 1: intraoperative washing with a combination of warm solution and tranexamic acid
Intervention group 2: intraoperative washing with a

combination of cold solution and tranexamic acid
Intervention group 3: intraoperative washing with a combination of room temperature solution and tranexamic acid

Main outcome variables

Bleeding Shivering

General information

Reason for update

Acronym

TURP (Transurethral Resection of the Prostate)

IRCT registration information

IRCT registration number: **IRCT20230521058247N1**

Registration date: **2023-10-16, 1402/07/24**

Registration timing: **retrospective**

Last update: **2023-10-16, 1402/07/24**

Update count: **0**

Registration date

2023-10-16, 1402/07/24

Registrant information

Name

Masoomah Salehi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 66 3253 0455

Email address

masoomah.salehi1367@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-05-15, 1402/02/25

Expected recruitment end date

2024-03-02, 1402/12/12

Actual recruitment start date

2023-05-15, 1402/02/25

Actual recruitment end date

2023-09-16, 1402/06/25

Trial completion date

2023-09-16, 1402/06/25

Scientific title

A comparative study of the effect of tranexamic acid dissolved in hot ,cold and room temperature washing fluid on reducing bleeding during surgery and postoperative complications in TURP surgery

Public title

the effect of tranexamic acid dissolved in hot ,cold and room temperature washing fluid on complications of TURP surgery

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age over 18 years prostate weight less than 70 grams no coagulation disorders no history of cardiovascular diseases no history of prostate cancer hemoglobin greater than or equal to 10 no history of atrial fibrillation and coronary artery disease thrombophilia severe form of chronic renal failure allergy to tranexamic acid

Exclusion criteria:

The presence of sensitivity to tranexamic acid drug the duration of surgery is more than 3 hours the need for anesthesia other than spinal anesthesia

Age

From **18 years** old

Gender

Male

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **80**

More than 1 sample in each individual

Number of samples in each individual: **20**

20 patients were candidates for TURP surgery in each group

Actual sample size reached: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

In the four-Block Random Sampling Method, Different Modes of the four Groups are Written on four Cards and Each is Placed in a Package in an Envelope. These Envelopes are Placed in a Box and the Researcher Does not Know in Which Group the Research units Will be Located until the Card is Selected. Before Confronting the Research units, the Ward Nurse removes One of the Envelopes from the Box without Knowing the Study and the Groups determine which Group the Three Patients

who will Enter the Study will be in, Respectively.

Blinding (investigator's opinion)

Single blinded

Blinding description

The participants were not aware of the washing method in the operating room.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics Committee of Hamadan University of Medical Sciences

Street address

Shahid Fahmideh St., Hamadan

City

hamadan

Province

Hamadan

Postal code

6517838736

Approval date

2023-05-12, 1402/02/22

Ethics committee reference number

IR.UMSHA.REC.1402.132

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

Benign hyperplasia of prostate

ICD-10 code

N40

ICD-10 code description

Enlarged prostate

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

Bleeding

Timepoint

From the start of the operation to the end of the operation

Method of measurement

Homeco photometer

2

Description

Shivering

Timepoint

Immediately after the operation

Method of measurement

Mahajan and Grossely shivering scale

Secondary outcomes

empty

Intervention groups

1

Description

Control group: Use of routine washing solution during operation

Category

Treatment - Drugs

2

Description

Intervention1 group: Use of warm washing solution (37°C) in combination with tranexamic acid

Category

Treatment - Drugs

3

Description

Intervention group: Use of cold washing solution (2°C) in combination with tranexamic acid

Category

Treatment - Drugs

4

Description

Intervention group3: Use of washing solution at room temperature (21.5°C) in combination with tranexamic acid

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Alashtar Hospital

Full name of responsible person

Hamed Haghi Abi

Street address

Faraj Elahi house, Koche Gardan Kamil East, Borujerdi St., Lorestan Province

City

Alashtar

Province

Lorestan

Postal code

6891646549

Phone

+98 916 539 3026

Email

masoomah.salehi1367@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Behzad Imani

Street address

Tawheed Square, Shahid Fahmideh Street

City

Hamadan

Province

Hamadan

Postal code

6517838736

Phone

+98 918 811 4036

Email

webda@umsha.ac.ir

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

Dr. Behzad Imani

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Shahid Fahmideh St
City
Hamadan
Province
Hamadan
Postal code
6517838736
Phone
0098918811436
Email
Behzadiman@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
Dr. Behzad Imani
Position
Associate Professor
Latest degree
Ph.D.
Other areas of specialty/work
Nursery
Street address
Research Square, Fahmedeh St
City
Hamadan
Province
Hamadan
Postal code
6517838736
Phone
009899188114036
Email
Behzadimani@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
Dr. Behzad Imani
Position
Associate Professor
Latest degree
Ph.D.
Other areas of specialty/work

Nursery
Street address
Shahid Fahmideh St
City
Hamadan
Province
Hamadan
Postal code
65178338736
Phone
+98 918 811 4036
Email
Behzadimani@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is 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

Not applicable

Title and more details about the data/document

داده های دریافتی از شرکت کنندگان به صورت فردی محرمانه خواهد ماند اما نتایج کلی بدون شناسایی فردی منتشر خواهد شد

When the data will become available and for how long

It can be accessed after completing the research

To whom data/document is available

عموم افراد

Under which criteria data/document could be used

In order to reduce problems caused by bleeding in patients undergoing prostate resection surgery, it can be used through the urethra

From where data/document is obtainable

To access the data, refer to the selected journal where the data was published

What processes are involved for a request to access data/document

Getting to know how to search and access reliable sites and magazines

Comments