Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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

Masoomeh Salehi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 66 3253 0455

Email address

masoomeh.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
masoomeh.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 ماندااما 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