Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Assessment of intraoperative Local administration of tranexamic acid effect on haemorrhage in patients undergoing open prostatectom

Protocol summary

Study aim
Assessment of intraoperative Local administration of tranexamic acid effect on haemorrhage in patients undergoing open prostatectom

Design
Clinical trial with control group, with parallel groups, single blinded, randomized, phase 3 on 140 patients

Settings and conduct
In this randomized, single-blind, phase 3 clinical trial, 140 eligible patients referred to Imam Khomeini hospital in Urmia undergoing open prostatectomy are selected to receive tranexamic acid topically.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age between 18-80 years-Having no coagulopathy-Consent to participate in the study.
Exclusion criteria: Sensitivity to tanxemaci acid-History of severe heart problems (high risk, very high risk) based on Pre-operative cardiac risk assessment

Intervention groups
In the intervention group, 1 gr of tranexamic acid is diluted in 100 cc of normal saline and injected into the prostate fossa during surgery. After surgery, up to 3 doses of 1 gr which are injected into the lavage serum, and then the bladder and prostate fossa are washed. The control group will be washed with normal saline only.

Main outcome variables
Hemoglobin level, length of hospital stay

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180625040232N8**
Registration date: **2022-03-26, 1401/01/06**
Registration timing: **prospective**

Last update: **2022-03-26, 1401/01/06**
Update count: **0**

Registration date
2022-03-26, 1401/01/06

Registrant information

Name
Saman Farshid

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 44 3346 9931

Email address
farshid.s@umsu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-04-03, 1401/01/14

Expected recruitment end date
2022-06-22, 1401/04/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Assessment of intraoperative Local administration of tranexamic acid effect on haemorrhage in patients undergoing open prostatectom

Public title
Intraoperative Local administration of tranexamic acid effect on haemorrhage

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age between 18-80 years Having no coagulopathy Consent to participate in the study

Exclusion criteria:

Sensitivity to tranexamic acid History of severe heart problems (high risk, very high risk) based on pre-operative cardiac risk assessment

Age

From **18 years** old to **80 years** old

Gender

Male

Phase

3

Groups that have been masked

- Data analyser

Sample size

Target sample size: **140**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will conduct based on permuted block randomization method. Each block will have capacity for 4 subjects; it means we will have 35 blocks (Totally 140 patients). Then, within each block, subjects will be randomly assigned to intervention or control group . Random assignment will be done using a random number table

Blinding (investigator's opinion)

Single blinded

Blinding description

Given that the surgical technique should be reported to patients preoperatively , the researcher and patients participating in the study should be aware of the surgical technique, but the analyst is unaware of which patient belongs to which intervention group.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Urmia University of Medical Sciences

Street address

UMSU Central Site, Orjhans Street, Resalat Blvd, Urmia , Iran

City

Urmia

Province

West Azarbaijan

Postal code

5714783734

Approval date

2021-04-07, 1400/01/18

Ethics committee reference number

IR.UMSU.REC.1400.030

Health conditions studied

1

Description of health condition studied

Hemorrhage following prostatectomy due to enlarged prostate

ICD-10 code

N40

ICD-10 code description

Enlarged prostate

Primary outcomes

1

Description

Hemoglobin level

Timepoint

Before surgery and 48 hours after surgery

Method of measurement

Blood test

Secondary outcomes

1

Description

length of hospital stay

Timepoint

Once, at the discharge time

Method of measurement

patient's file

Intervention groups

1

Description

Intervention group: In the intervention group, 1 gr of tranexamic acid (produced by Caspian company) is diluted in 100 cc of normal saline and injected into the prostate fossa during surgery. After surgery, up to 3 doses of 1 gr which are injected into the lavage serum, and then the bladder and prostate fossa are washed.

Category

Treatment - Drugs

2

Description

Control group: The control group will be washed with normal saline only.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Urmia Imam Khomeini hospital

Full name of responsible person
Saman Farshid

Street address
Imam Khomeini hospital, Ershad Ave, Urmia

City
Urmia

Province
West Azarbaijan

Postal code
5714783734

Phone
+98 44 3346 9931

Email
samanf63@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Oroumia University of Medical Sciences

Full name of responsible person
Dr Iraj Mohebbi

Street address
Urmia University of Medical Sciences-Resalat Blvd-Emergency Alley. Urmia Vest Azarbaijan

City
Urmia

Province
West Azarbaijan

Postal code
5714783734

Phone
+98 44 3223 4897

Fax
+98 44 3223 4896

Email
mohebbi_iraj@yahoo.co.uk

Web page address
http://faculty.umsu.ac.ir/Site/CV.aspx?STID=15&Ln=fa

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Oroumia 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
Oroumia University of Medical Sciences

Full name of responsible person
Saman Farshid

Position
Assistant professor

Latest degree
Subspecialist

Other areas of specialty/work
Urology

Street address
Imam Hospital , Ershad Ave.,Urmia

City
Urmia

Province
West Azarbaijan

Postal code
5714783734

Phone
009833457286

Email
samanf63@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Oroumia University of Medical Sciences

Full name of responsible person
Saman Farshid

Position
Assistant professor

Latest degree
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Other areas of specialty/work
Urology

Street address
Imam Hospital , Ershad Ave.,Urmia

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Email
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Person responsible for updating data

Contact

Name of organization / entity
Oroumia University of Medical Sciences
Full name of responsible person
Saman Farshid
Position
Assistant professor
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Other areas of specialty/work
Urology
Street address
Imam Hospital , Ershad Ave.,Urmia
City
Urmia
Province
West Azarbaijan
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5714783734
Phone
009833457286
Email
samanf63@gmail.com

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
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available