

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Dr Iraj Mohebbi

Street address

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Web page address

<http://faculty.umsu.ac.ir/Site/CV.aspx?STID=15&Ln=f>
a

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

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Person responsible for scientific inquiries

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Full name of responsible person

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Position

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Other areas of specialty/work

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Person responsible for updating data

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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

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