Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of intravenous Tranexamic acid effect on blood loss during and post transurethral resection of prostate (TURP) surgery: A Randomized Placebo-controlled Trial

Protocol summary

Summary

The aim of study is to evaluate the effect of intravenous Tranexamic acid on bleeding, during and/or post TURP. Patients with BPH that are 50-80 years old and categorized in class 1 -3 ASA and no contraindication for TURP will be included in this study. Patients randomly will be divided into two groups. The first group receives 500cc of the Tranexamic acid and second group (control group) receives Normal saline solely (placebo). Prostate weight, Hb and Hct will be measured before the surgery. During the surgery, if it is necessary, packed cell will be infused. At the end of the surgery, surgeon satisfaction, infused serum or blood volume and duration of surgery (minute) will be recorded. After 6 hrs. Hb, Hct and probable side effects will be evaluated. Then the results in both groups will be compared by utilizing SPSS 23 software.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015030111822N5**
Registration date: **2017-06-06, 1396/03/16**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2017-06-06, 1396/03/16

Registrant information

Name

Behrooz Karkhanei

Name of organization / entity

Hamadan University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for Research and Technology, Hamadan University of Medical Sciences

Expected recruitment start date

2014-09-01, 1393/06/10

Expected recruitment end date

2015-04-30, 1394/02/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of intravenous Tranexamic acid effect on blood loss during and post transurethral resection of prostate (TURP) surgery: A Randomized Placebo-controlled Trial

Public title

Tranexamic Acid and its effect on TURP operation

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Patients with BPH; that are 50-80 years old. their prostate gland weight was measured by sonography. measuring of Hb, Hct before the surgery. ASA≤II. Exclusion criteria: patient disagreement.renal dysfunction .color vision dysfunction .coagulopathy. IHD or arrhythmia .anticoagulant consumption, CVA. Hx of

tranexamic acid allergy. Hx of PTE or DVT.

Age

From **50 years** old to **80 years** old

Gender

Male

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

A Randomized Placebo-controlled Trial

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Local Human Subject Review Board, Hamadan University of Medical Sciences

Street address

Shaheed Famideh Street, Hamadan University Of Medical Sciences

City

Hamadan

Postal code

6517838695

Approval date

2014-01-20, 1392/10/30

Ethics committee reference number

P/16/35/9/3563

Health conditions studied

1

Description of health condition studied

benign hypertrophy of prostate

ICD-10 code

N40

ICD-10 code description

Hypertrophy (benign) of prostate

Primary outcomes

1

Description

Hct

Timepoint

before and 6hr after surgery

Method of measurement

automatic analysor.(cell count)

2

Description

Hb

Timepoint

before and 6hr after surgery

Method of measurement

automatic analysor.(cell count)

3

Description

prostate weight

Timepoint

before the surgery

Method of measurement

by sonography in mg

4

Description

duration of the surgery

Timepoint

after the surgery

Method of measurement

as soon as entering to urinary urethral until foley catheter fixation

5

Description

sergeon satisfaction

Timepoint

after the surgery

Method of measurement

surgeon opinion

6

Description

transfusion

Timepoint

after the surgery

Method of measurement

amount of unit packed cell

7

Description

serum volume during the surgery

Timepoint

after the surgery

Method of measurement
intake serum volume in cc

Secondary outcomes

1

Description
Nausea
Timepoint
6 hr after surgery
Method of measurement
Ask the patient

2

Description
Seizure
Timepoint
6 hr after surgery
Method of measurement
Ask the patient

3

Description
Vomiting
Timepoint
6 hr after surgery
Method of measurement
Ask the patient

Intervention groups

1

Description
as starting the serum therapy for case group, the 500cc Tranexamic acid in 500cc ringer serum with 1mg/ml concentration and maximum flow 100mg/min
Category
Prevention

2

Description
transfusion of 500cc ringer serum solely
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Beheshti Hospital
Full name of responsible person
Behruz Karkhanei
Street address
Shahid Beheshti Hospital, Eram Blvd., Hamadan
City
Hamadan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for Research and Technology, Hamadan University of Medical Science
Full name of responsible person
Ahmad Tavilani
Street address
Hamadan University of Medical Sciences, Vice chancellor for Research and Technology, Shaheed Fahmideh St
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Hamadan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for Research and Technology, Hamadan University of Medical Science
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Hamadan University of Medical sciences
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Behrooz Karkhanei
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty

Study Protocol
empty

Statistical Analysis Plan
empty

Informed Consent Form
empty

Clinical Study Report
empty

Analytic Code
empty

Data Dictionary
empty