Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Clinical tial on the effects of intravenous tranexamic acid on amount of transfusion in patients undergoing trans urethral resection of prostate(TURP)

Protocol summary

Summary

The aim of this study investigate the effect of Tranexamic acid in prostate surgery(TURP). Patients with BPH that are over 50 years of age are cathegorized as class 1 -3 ASA and their prostate gland weights less than 80 grams, not carrying PCA(Prostate Cancer Antigen), PSA≤4 ng/ml and are candidates for TURP with no indication for open surgery are included in ithis study. patients are randomly divided into two groups. First group recieves . Second group (control group) recieves Normal saline (placebo) instead (to the same volume as the first group). All patients undergo spinal anesthesia. patient's Hemoglobin levels are measured one hour after the start of surgery, then right after patient is taken to recovery room, then again 6 and 24 hours after surgery. For any of the samples that Hemoglobin is less than 10 g/dl, packed cell Isogroup and RH is added to keep hemoglobin over 10 g/dl. Then results in two groups are compared and softwares are used to analyze and do the statistics.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138904164345N1**
Registration date: **2013-08-13, 1392/05/22**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2013-08-13, 1392/05/22

Registrant information

Name

Ali Mirmansouri

Name of organization / entity

Guilan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Guilan University of Medical Sciences

Expected recruitment start date

2013-06-18, 1392/03/28

Expected recruitment end date

2013-12-19, 1392/09/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical tial on the effects of intravenous tranexamic acid on amount of transfusion in patients undergoing trans urethral resection of prostate(TURP)

Public title

Control of bleeding in prostate surgery

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:Patients with BPH; that are over 50 years of age; cathegorized as class 1 -3 ASA ; their prostate gland weights less than 80 grams; not carrying PCA(Prostate Cancer Antigen), by sonography , ; PSA≤4 ng/ml; no history of prostatic Cancer. Exclusion

criteria:Duration of surgery is more than 3 hours ; other condition which complicats surgery.

Age

From **50 years** old to **100 years** old

Gender

Male

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Guilan University of Medical Sciences

Street address

Namjoo Avenue,Deputy department

City

Rasht

Postal code

4193833697

Approval date

2013-06-17, 1392/03/27

Ethics committee reference number

1920101204

Health conditions studied

1

Description of health condition studied

BPH

ICD-10 code

N42.3

ICD-10 code description

Dysplasia of prostate Low grade dysplasia

Primary outcomes

1

Description

Hematocrit

Timepoint

one hour after the start of surgery, then right after patient is taken to recovery room, then again 6 and 24 hours after surgery.

Method of measurement

%,sysmex kx-21

2

Description

Hemoglobin

Timepoint

one hour after the start of surgery, then right after patient is taken to recovery room, then again 6 and 24 hours after surgery.

Method of measurement

g/dl,Sysmex k x-21

3

Description

PSA

Timepoint

before surgery

Method of measurement

ng/ml, Elisa

4

Description

Blood pressure

Timepoint

Every 5 Minutes

Method of measurement

mmHg with NIBP

Secondary outcomes

empty

Intervention groups

1

Description

First group that recieved Tranexamic acid after anesthisia 15 mg/kg that dilute in 100 cc normal saline inject during 15 minutes, to be continued with 1mg/kg/1h during 5 hours.

Category

Treatment - Drugs

2

Description

Second group (control group) recieve Normal saline (placebo) instead (to the same volume as the first group).

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Anesthisia research centre

Full name of responsible person
Ali mirmansouri

Street address
Namjoo Avenue, research centre, Velaiat hospital

City
Rasht

2

Recruitment center

Name of recruitment center
Razi hospital

Full name of responsible person
Ali mirmansouri

Street address
Sardar jangal Avenue.Razi hospital

City
Rasht

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Guilan University of Medical Sciences

Full name of responsible person
Abdol Rasool sobhani

Street address
Emam Khomeini Blv.,top of the Iran Radiator Co.

City
Rasht

Grant name

Grant code / Reference number

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

Title of funding source
Guilan University of Medical Sciences

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
Guilan University of Medical Sciences

Full name of responsible person
Ali mirmansouri

Position
Assistant Professor

Other areas of specialty/work

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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