

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jul 2026

The comparison of intravenous tranexamic acid and topical tranexamic acid efficacy on postoperative bleeding after total hip arthroplasty surgery.

Protocol summary

Summary

1-major objective: The comparison of 2 method of tranexamic acid administration on bleeding after TOTAL HIP ARTHROPLASTY surgery. 2-Design: This study will perform after ethical committee agreement of Guilan University of Medical Sciences and based on a double blind randomized clinical trial study. 3- Setting and Conduct: The patients divided in 2 groups Based on randomization block. In intravenous tranexamic acid group (15mg/kg), transamine will administer by anesthesiologist and based on body weight in a time of 10 minute. Each vial consists of 500mg of tranexamic acid in 5 ml. In tranexamic topical group, patients will receive 3gr of tranexamic acid (6 vials) that diluted with normal saline intraoperatively by orthoped. After rimming of acetabulum 30 ml of above solution inserted in acetabulum and wound and keeping there about 1 minute. After broaching the femoral canal 30 ml of topical tranexamic acid inserted and keeping there about 1 min. the remain solution (30 ml) insert in the wound after hip joint reduction and will repaired. 4- Participants: All patients who will undergoing total hip arthroplasty surgery, ranging in age from 50-20 years old, ASA (American Society of Anesthesia) I-II, having $HB \geq 10$ gr dl before surgery and not receiving transfusion before surgery. 5-Intervention: The comparison of 2 method of topical tranexamic acid or intravenous tranexamic acid administration on bleeding after surgery. 6-Main Outcome: The study of intraoperative and postoperative bleeding after total hip arthroplasty surgery and need to blood transfusion as secondary outcome.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201509056280N8**

Registration date: **2015-10-24, 1394/08/02**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-10-24, 1394/08/02

Registrant information

Name

Mohammad Haghighi

Name of organization / entity

Guilan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 13 3211 1319

Email address

mohaghighi@gums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor For Research OF Guilan University of Medical Sciences

Expected recruitment start date

2015-10-23, 1394/08/01

Expected recruitment end date

2017-02-19, 1395/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison of intravenous tranexamic acid and

topical tranexamic acid efficacy on postoperative bleeding after total hip arthroplasty surgery.

Public title

the use of topical tranexamic acid in total hip arthroplasty

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: patients who undergoing total hip arthroplasty surgery; 50-20 years old; ASA (American Society of Anesthesia) I-II; having HB \geq 10gr dl before surgery ; not receiving transfusion before surgery. The exclusion criteria: Emergency surgery; Hb<10mg/dl; The evidence for any condition of IHD or treatment; The evidence for hemorrhagic CVA ; SAH OR STROK; The evidence for TBI; Use of anticoagulant drug; any history of renal ; liver and anemia before operation; History of OCP consumption.

Age

From **20 years** old to **50 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **100**

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

Ethical Comeetee of Guilan University of Medical Sciences

Street address

Namjoo Avenue, Deputy department OF Guilan University of Medical Sciences

City

Rasht

Postal code

4193713189

Approval date

2015-08-24, 1394/06/02

Ethics committee reference number

IR.GUMS.REC.1394.209

Health conditions studied

1

Description of health condition studied

Patients candidate for total hip arthroplasty

ICD-10 code

S79.7

ICD-10 code description

Multiple injuries of hip and thigh

Primary outcomes

1

Description

intraoperative and postoperative hemorrhage

Timepoint

after operation and 24 hours after that

Method of measurement

based on blod on suction and gauze counting and gilcher formula

Secondary outcomes

1

Description

packed cell

Timepoint

intraoperative and 24 hours after surgery

Method of measurement

number of packed cell

Intervention groups

1

Description

. In intravenous tranexamic acid group (15mg/kg), transamine will administer by anesthesiologist and based on body weight in a time of 10 minute. Before skin incision and surgery, all the patients receive only the intravenous form of tranexamic acid .Tranexamic acid is produced in CASPIAN TAMIN pharmaceutical co. Each vial consists of 500mg of tranexamic acid in 5 ml.

Category

Treatment - Drugs

2

Description

In tranexamic topical group,patients will recieve 3gr of tranexamic acid(6 vials) that diluted with normal saline intraoperatively by orthoped.After rimming of acetabulom 30 ml of above solution inserted in acetabulom and wound and keeping there about 1 minute. After broaching the femoral canal 30 ml of

topical tranexamic acid inserted and keeping there about 1 min. the remain solution (30 ml)insert in the wound after hip joint reduction and will repaired.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Poursina Hospital ,Teachin and Research Center

Full name of responsible person

Mohammad Haghghi

Street address

Poursina Hospital, Crossroad Poursina, Namjoo Avenue

City

Rasht

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Vice Chancellaor foe Research of Guilan University of Medical Sciences

Full name of responsible person

Abtin Heydarzadeh Dr

Street address

Shahid beheshti Highway , Rasht, Guilan Province, Iran , Islamic Republic Of

City

Rasht

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice Chancellaor foe Research of 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

Mohammad Haghghi

Position

Associated Professor

Other areas of specialty/work**Street address**

Anesthesiology Research Centre,Velayat Hospital ,Rasht, Guilan Province

City

Rasht

Postal code**Phone**

+1 313210434

Fax**Email**

manesthesist@gmail.com

Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Guilan University of Medical Sciences

Full name of responsible person

Mohammad Haghghi

Position

Associated Professor

Other areas of specialty/work**Street address**

Anesthesiology Research Center,Velayat hospital,crossroad poursina

City

Rasht

Postal code

4193713189

Phone

+98 133332304700

Fax**Email**

manesthesist@gmail.com

Web page address**Person responsible for updating data****Contact****Name of organization / entity**

Guilan University Of Medical Sciences

Full name of responsible person

Mohammad Haghghi

Position

Assoicated Professor

Other areas of specialty/work**Street address**

Anesthesiology Research Center,Velayat Hospital,Crossroad Poursina.

City

Rasht

Postal code**Phone**

00

Fax**Email**

manesthesist@gmail.com

Web page address

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