Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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 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. 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≥ 10gr 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)

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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≥ 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 Haghighi

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 Haghighi

Position

Associated 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