Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Effect of prophylactic administration of fibrinogen concentrate on volume of transfused packed RBC during and after totla hip arthroplasty in sina hospital during 2011-2012.

Protocol summary

Summary

According to limitations and costs of preparation and transfusion of blood products,to prevent eaely transfusion of PRBC and consequences adverse effects,by prophylactic administration of fibrinogen concentrate we provide a good level of seum fibrinogen, that is the first procoagulant decreseanig during hemorrhage, to evaluate volume of blood loss and need for packed RBC transfusion.the patients fulfill the inclusion criteria randomized into 2 groups receiving 30 mg/kg fibrinogen concentrate or equivalent volume of normal saline after induction of anesthesia.blood loss and volume of PRBC and probabale consequent reactions would be evaluated.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201012264784N2**
Registration date: **2012-06-11, 1391/03/22**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2012-06-11, 1391/03/22

Registrant information

Name
Reza Shariat Moharari
Name of organization / entity
Sina hospital
Country
Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Terhan University of Medical Sciencs

Expected recruitment start date

2011-04-21, 1390/02/01

Expected recruitment end date

2012-06-21, 1391/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of prophylactic administration of fibrinogen concentrate on volume of transfused packed RBC during and after totla hip arthroplasty in sina hospital during 2011-2012.

Public title

Effect of prophylactic administration of fibrinogen concentrate on volume of transfused packed RBC during and after totla hip arthroplasty.

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: 1- patients aged 35-75 years old scheduled for total hip arthroplasty 2-ASA physical status I and II 3-hemoglubin level more than 10 4-MET more than 4 5-completely fill and sign the informed consent. Exclusion criteria: 1-ASA class more than 3 2-MET<4 3-pregnancy 4-history of allergic reaction to blood products specially fibrinogen concentrate 5-history of DVT and pulmunary emboli and any embolic events. 6-recent MI

and CVA during last 6 month 7-known cases of coagulopathy and thrombocytopenia.

Age
From **35 years** old to **75 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
committee of ethics in research-Tehran University of Medical Sciences

Street address
keshavarz Blv- edge of qods St-6 th floor -central organisation of TUMS

City
tehran

Postal code
1417653761

Approval date
2011-07-28, 1390/05/06

Ethics committee reference number
90/130/662/ɔ

2

Ethics committee

Name of ethics committee
TUMS committe of ethics in research

Street address
keshavarz Blv- edge of qods St-central organisation of TUMS

City
tehran

Postal code
1417653761

Approval date
2011-07-28, 1390/05/06

Ethics committee reference number
90/D/130/662

Health conditions studied

1

Description of health condition studied
totla hip arthroplasy

ICD-10 code
Z96.6

ICD-10 code description
Hip-joint replacement (partial)(total)

Primary outcomes

1

Description
volume of transfused packed RBC during and after totla hip arthroplasty surgery

Timepoint
any time during and after surgery that needs transfusion

Method of measurement
in mili liter

2

Description
volume of bleeding during and after totla hip arthroplasty surgery

Timepoint
during and after surgery

Method of measurement
calculating number of gauzes and longauze and suction fluid in mililiter

3

Description
level of hemoglobin during and after surgery

Timepoint
during and 24 hour after surgery

Method of measurement
check of hemoglobin level in perioperative period by CBC test

4

Description
complications of transfusion

Timepoint
during and after surgery

Method of measurement
subjective if the patient is awakw and objective if the patient is anesthesized

Secondary outcomes

1

Description

volume of transfused other blood products

Timepoint

during and after surgery

Method of measurement

as mililiter or unit of transfused product

2

Description

thromboembolic events

Timepoint

during hospitalisation and after discharge up to 2 weeks(according to fibrinogen half life)

Method of measurement

by post operative visit and examination, phone follow up until 2 weeks after discharge

3

Description

transfusion related long term complication

Timepoint

long term after surgery

Method of measurement

subjective by patient declarement or complain or objective by take history and physical exam and labratory tests if needed

4

Description

cardiovascular complications due to bleeding

Timepoint

during and after surgery

Method of measurement

ECG monitoring and 12 lead ECG trace record during aneshtesia ,history and physical exam after surgery

Intervention groups

1

Description

In case group after induction of anesthesia we infuse 30mg/kg fibrinogen concentrtate IV in 15 minutes.before infusion by means of arterial catheter blood sampling perform and check it for serum level of fibrinogen in both groups(for baseline).during surgery with 30 minute intervals mean atreial pressure would be registered.blood loss is estimated by means of caclculating number of guazes an longuazes and suction container.each guaze and longuaze consist of 20 and 50 ml respectively.maximum allowable blood loss would be calculated by this equationABL=65 X body weightX(patient Hb - desired Hb for sex an age)/optimal Hb.volume of packed RBC contains about 250 ml RBC which would be diluted with 250 ml warm normal saline and transfused for compensation of blood loss.during surgery with warm crystaloids and warm forced air and thermal monitoring maintaining normothermia.monitoring of acid base would be performed.

Category

Prevention

2

Description

In control(placebo) group after induction of anesthesia we infuse normal saline in equivalent volume of fibrinogen.before infusion by means of arterial catheter blood sampling perform and check it for serum level of fibrinogen in both groups(for baseline).during surgery with 30 minute intervals mean atreial pressure would be registered.blood loss is estimated by means of caclculating number of guazes an longuazes and suction container.each guaze and longuaze consist of 20 and 50 ml respectively.maximum allowable blood loss would be calculated by this equationABL=65 X body weightX(patient Hb - desired Hb for sex an age)/optimal Hb.volume of packed RBC contains about 250 ml RBC which would be diluted with 250 ml warm normal saline and transfused for compensation of blood loss.during surgery with warm crystaloids and warm forced air and thermal monitoring maintaining normothermia.monitoring of acid base would be performed.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Tehran University of Medical Sciences-SINA hospital

Full name of responsible person

Dr.Reza Shariat Moharari

Street address

Sina hospital, Imam Khomeini street

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Siences- Vice-chancellor for reseach

Full name of responsible person

Dr.Akbar Fotouhi

Street address

Sixth Floor,Tehran University of Medical Siences, Ghods street, Keshavarz blv.

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran University of Medical Siences- Vice-chancellor for reseach

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
sina hospital-tehran university of medical sciences

Full name of responsible person
Dr.Reza shariat Moharari

Position
associated professor of department of anesthesia and critical care

Other areas of specialty/work

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Person responsible for scientific inquiries

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associated professor-department of anesthesia and critical care-sina hospital TUMS

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Person responsible for updating data

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Full name of responsible person
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Fax

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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