Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

comparison of crystalloid and colloid solutions effect on clot formation time and clot firmness after 10 minutes during the upper or lower limbs surgeries

Protocol summary

Summary

The aim of this single blind randomized clinical trial is comparing of crystalloid and colloid solutions effect on clot formation time and clot firmness after 10 minutes during theupper or lower limbs surgeries. In this study, 30 patients who were eligible to be placed in one of three groups. The first group will receive only crystalloid solutions. Second group will receive modified gelatin and the third group will receive hydroxyethyl Starch6%. Patients will received 55 ml / kg of Solutions. Once before and one hour after administration of the solution, blood samples will be taken from three groups of patients. Using Fibtem inhibitor solution, clot formation time and clot firmness after 10 minutes are measured by Thromboelastometry.After data entry statistical analysis is carried out.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201210223773N6**
Registration date: **2013-03-10, 1391/12/20**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2013-03-10, 1391/12/20

Registrant information

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Farsad Imani
Name of organization / entity
Tehran University of Medical Sciences and Health Services
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2012-11-21, 1391/09/01

Expected recruitment end date

2013-11-22, 1392/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

comparison of crystalloid and colloid solutions effect on clot formation time and clot firmness after 10 minutes during the upper or lower limbs surgeries

Public title

comparison of crystalloid and colloid solutions effect on clot formation time and clot firmness after 10 minutes during the upper or lower limbs surgeries

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria; patients weighing more than 40 kg; Patients undergoing upper or lower limbs surgeries under general anesthesia or regional. Exclusion criteria: Patients received solutions other than standard maintenance solutions prior to the induction of anesthesia; Nonsteroidal anti-inflammatory drug use;

taking any anticoagulant medications; Patients who have more than 100 cc of blood loss during the test period.

Age
From **15 years** old to **70 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Tehran University of Medical Sciences-Research administration

Street address
Keshavarz Bv. Ghods st. Cross

City
Tehran

Postal code

Approval date
2012-09-16, 1391/06/26

Ethics committee reference number
1289/130/91/د

Health conditions studied

1

Description of health condition studied
clot firmness after 10 minutes

ICD-10 code
D69.9

ICD-10 code description
Haemorrhagic condition, unspecified

2

Description of health condition studied
clot formation time

ICD-10 code
D65

ICD-10 code description
Consumption coagulopathy

Primary outcomes

1

Description
clot firmness after 10 minutes

Timepoint
Before and one hour after administration of solutions

Method of measurement
by Thromboelastometer

2

Description
clot formation time

Timepoint
Before and one hour after administration of solutions

Method of measurement
by Thromboelastometer

Secondary outcomes

1

Description
Side effects

Timepoint
during and after surgery

Method of measurement
Physical examination

Intervention groups

1

Description
The first group will receive only crystalloid solutions. Solutions will be prescribed to the 55 ml / kg. Once before and one hour after administration of the solution, blood samples will be taken from three groups of patients. Using Fibtem inhibitor solution, clot formation time and clot firmness after 10 minutes are measured by Thromboelastometer.Statistical analysis of patient records, prescribing of these solutions will be compared.

Category
Treatment - Drugs

2

Description
Solutions will be prescribed to the 55 ml / kg. Once before and one hour after administration of the solution, blood samples will be taken from three groups of patients. Using Fibtem inhibitor solution, clot formation time and clot firmness after 10 minutes are measured by Thromboelastometer.Statistical analysis of patient records, prescribing of these solutions will be compared. Second group will receive modified gelatin

Category
Treatment - Drugs

3

Description
third group will receive hydroxyethyl Starch6%. Solutions will be prescribed to the 55 ml / kg. Once before and one hour after administration of the solution, blood samples will be taken from three groups of patients. Using Fibtem inhibitor solution, clot formation time and clot firmness after 10 minutes are measured by Thromboelastometer.Statistical analysis of patient records, prescribing of these solutions will be compared.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Sina Hospital
Full name of responsible person
Farsad Imani
Street address
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences, Medical Faculty
Full name of responsible person
Dr Farsad Imani
Street address
Hasan'abad Sq., Imam Khomeini St.
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 Sciences, Medical Faculty
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
Tehran University of Medical Sciences
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Person responsible for scientific inquiries

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Person responsible for updating data

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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