Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Effect of tranexamic acid on blood loss after coronary artery bypass grafting in patients treated with clopidogrel

Protocol summary

Summary

Clopidogrel is an inhibitor of platelet aggregation. It is frequently administered to patients undergoing coronary angiography in anticipation of percutaneous coronary artery intervention. Some of these patients will go on to require an urgent operative procedure. Recent studies have shown that clopidogrel treatment before CABG is associated with increased postoperative bleeding, transfusion, and reexploration rates. Antifibrinolytic drugs, aminocaproic acid and tranexamic acid, reduce bleeding and postoperative transfusion requirements after coronary artery bypass. 80 patients scheduled for on-pump coronary artery bypass grafting that treated with clopidogrel less than 5 days before the operation participated in study. Patients were assiened to treatment with tranexamic acid (15mg/kg bolus before skin incision and 15mg/kg bolus after protamine neutralization) or placebo (saline solution of equivalent volume). post-operative bleeding,red blood cell transfusionand re-exploration rate in the first 24 h were recorded

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201309125381N8**
Registration date: **2013-09-21, 1392/06/30**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2013-09-21, 1392/06/30

Registrant information

Name

Nadia Banihashem

Name of organization / entity

Babol University Of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 22 38296

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Recruitment status

Recruitment complete

Funding source

Vice-chancellor of Research Babol University of Medical Sciences

Expected recruitment start date

2013-08-23, 1392/06/01

Expected recruitment end date

2015-07-23, 1394/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of tranexamic acid on blood loss after coronary artery bypass grafting in patients treated with clopidogrel

Public title

Effect of tranexamic acid on blood loss after coronary artery bypass grafting in patients treated with clopidogrel

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: patients undergoing on-pump CABG who received clopidogrel with their last ingestion less than5 days preoperatively. Exclusion criteria: previous cardiac surgery; hematocrit less than 33%; platelet count

less than 100,000/mL; or allergy to tranexamic acid; renal failure(cr>2), hepatic failure; history of bleeding diasthesis; abnormal coagulation test; previous cardiac surgerry.

Age
From **36 years** old to **75 years** old

Gender
Female

Phase
2-3

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
Ethics committee of Babol University Of Medical Sciences

Street address
Daneshgah Square, Ganjafrooz Avenue

City
Babol

Postal code

Approval date
2013-08-27, 1392/06/05

Ethics committee reference number
3012/30/پ/ژ

Health conditions studied

1

Description of health condition studied
Bleeding after CABG

ICD-10 code
T81.0

ICD-10 code description
Haemorrhage and haematoma complicating a procedure, not elsewhere classified

Primary outcomes

1

Description
bleeding after CABG

Timepoint
24 houres

Method of measurement
Measuring mediastinal drainage into the chest bottle

Secondary outcomes

1

Description
Blood and blood products transfusion after CABG

Timepoint
24 hours

Method of measurement
Measuring units of blood and blood products tranfused during and after CABG

Intervention groups

1

Description
15 mg/kg tranexamic acid was infused intravenously before surgical incision, and 15 mg/kg after protamine neutralization.

Category
Treatment - Drugs

2

Description
normal saline was infused intravenously before surgical incision, and after protamine neutralization.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Ayatollah Ruhani Hospital

Full name of responsible person
Dr Nadia Banihashem

Street address

City
babol

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-chancellor of Research Babol University Of Medical Sciences

Full name of responsible person

Dr Amrolah Mostafazadeh

Street address

Daneshgah Square, Ganjafrooz Avenue, Vice-chancellor Of Research

City

Babol

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice-chancellor of Research Babol 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

Babol University of Medical Sciences

Full name of responsible person

Dr Nadia Banihashem

Position

Assistant Professor of Anesthesiology

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