

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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 assigned 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 transfusion and 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

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Email address

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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 than 5 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 surgery.

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 heures

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