

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jul 2026

Assessing the effect of platelet infusion in reducing hemorrhage during CABG surgery in patients under plavix treatment

Protocol summary

Study aim

assessing the effectiveness of platelet treatment in reducing bleeding during CABG surgery

Design

A double blinded single arm parallel randomised trial

Settings and conduct

this clinical trial is designed to evaluate the effect of Prophylactic Platelet infusion to reduce Bleeding after CABG in Patients who receive Plavix Drug

Participants/Inclusion and exclusion criteria

patients who need CABG surgery and we can not hold plavix treatment

Intervention groups

5 unit Platelet infusion in the intervention group routine treatment in the control group (no platelet injection)

Main outcome variables

Bleeding amount

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200902048590N1**

Registration date: **2020-10-31, 1399/08/10**

Registration timing: **retrospective**

Last update: **2020-10-31, 1399/08/10**

Update count: **0**

Registration date

2020-10-31, 1399/08/10

Registrant information

Name

hamidreza hoseinikhah

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3801 2748

Email address

hoseinikhahh@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-10-30, 1396/08/08

Expected recruitment end date

2018-04-22, 1397/02/02

Actual recruitment start date

2017-10-30, 1396/08/08

Actual recruitment end date

2017-10-30, 1396/08/08

Trial completion date

2018-04-23, 1397/02/03

Scientific title

Assessing the effect of platelet infusion in reducing hemorrhage during CABG surgery in patients under plavix treatment

Public title

Assessing the effect of platelet infusion in reducing hemorrhage during CABG surgery in patients under plavix treatment

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Using plavix Need for coronary artery bypass Being unable to hold plavix Informed consent

Exclusion criteria:

Patient's dissatisfaction and the desire to cut off cooperation Incidence of complications

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **120**

Actual sample size reached: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization Individually by using Random number table Consecutive numbers Allocation Concealment with SNOSE (sequentially numbered, opaque, sealed envelopes.)

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients and the therapist and outcome assessor are unaware of the allocation The nurse assigns the subjects to the study group into one of two groups

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Mashhad University of Medical Sciences

Street address

Ghoreishi building, Daneshgah Ave, Ahmad Abad Blv, Mashhad, Razavi Khorasan Province, Iran

City

Mashhad

Province

Razavi Khorasan

Postal code

9138813944

Approval date

2017-01-23, 1395/11/04

Ethics committee reference number

IR.MUMS.MEDICAL.REC.139511

Health conditions studied

1

Description of health condition studied

بیماری عروق کرونر

ICD-10 code

T82.8

ICD-10 code description

Other specified complications of cardiac and vascular prosthetic devices, implants and grafts

Primary outcomes

1

Description

bleeding amount

Timepoint

1, 6, 12, 24, and 48 hours after surgery

Method of measurement

Assessing the amount of packed cell needed

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: platelet infusion

Category

Treatment - Drugs

2

Description

Control group: Routine treatment (NO platelet injection)

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza hospital

Full name of responsible person

Dr. Seyyed Hamidreza Hosseinikhah

Street address

Imam Reza hospital, Ibne Sina street, Ahmad Abad Blv, Mahhad, Khorasan Razavi Province, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr. Mohsen Tafaghodi

Street address

Mashhad University Of Medical Science, Azadi Square, Vakil Abad Blv, Mashhad, Khorasan Razavi Province, Iran

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tafaghodim@mums.ac.ir

Web page address

<https://v-research.mums.ac.ir/>

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Mashhad University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Academic

Person responsible for general inquiries

Contact**Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Dr. Seyyed Hamid Reza Hoseinikhah

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Cardiology

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Person responsible for scientific inquiries

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Full name of responsible person

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

The whole data can be assessed

When the data will become available and for how long

six months after the termination of the study

To whom data/document is available

researcher and analyst

Under which criteria data/document could be used

only in case of assessment and analysis for research article

From where data/document is obtainable

researcher

What processes are involved for a request to access data/document

researcher assessment and confirmation

Comments