

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jun 2026

Impact of Proton Pump Inhibitors (pantoprazol) on Arrhythmia and Hypomagnesaemia Following off pump CABG

Protocol summary

Summary

Serum magnesium levels have changed following CABG so that Statistics hypomagnesaemia after CPB is 70 percent. Recently, the potential relationships between chronic administration of PPI and hypomagnesaemia have been reported. In this study believe that PPI effect on blood magnesium levels and its relationship with ventricular arrhythmia and AF in patients undergoing CABG- Off surgery were assessed. For stress ulcer prophylaxi, patients randomly assigned to a group of pantoprazole 40 mg twice a day intravenously when they are stay in the ICU and NPO. And 40 mg once a day orally during hospitalization in ICU (PO patient) and cardiac surgery (POST-ICU). and administered to the other half (the control group) Ranitidine 50 mg three times a day intravenously on days of hospitalization in ICU and NPO and famotidine 40 mg tablet once a day orally during hospitalization in ICU (PO patient), and cardiac surgery (POST-ICU). Hypomagnesaemia frequency will be compared between two groups.

General information

Acronym

Proton Pump Inhibitors (pantoprazol)

IRCT registration information

IRCT registration number: **IRCT201511088384N5**

Registration date: **2016-07-17, 1395/04/27**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2016-07-17, 1395/04/27

Registrant information

Name

Arash Peivandi Yazdi

Name of organization / entity

Mashhad University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Mashhad university of medical sciences

Expected recruitment start date

2016-08-31, 1395/06/10

Expected recruitment end date

2016-12-21, 1395/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Impact of Proton Pump Inhibitors (pantoprazol) on Arrhythmia and Hypomagnesaemia Following off pump CABG

Public title

Effect of Proton Pump Inhibitors (pantoprazol) on Hypomagnesaemia

Purpose

Treatment

Inclusion/Exclusion criteria

وارد مطالعه خواهند off-pump به روش CABG بیماران کاندید جراحی شد. معیارهای خروج از مطالعه شامل این موارد می باشد: عدم رضایت بیمار؛ بیماران تحت اعمال جراحی قلبی غیر کرونری؛ بیمارانی قرار میگیرند؛ on-pump به روش CABG که به هر دلیلی تحت جراحی سابقه بیماری شناخته شده کلیه شامل ناهنجاری های ساختمانی؛

؛ بیماری که دچار ایست single kidney نارسایی کلیه و یا بیمارانی اورژانس؛ بیمارانی CABG طولانی شده است؛ موارد CPR قلبی شده و مبتلا به سوء تغذیه شدید؛ سابقه حساسیت به داروهای مورد استفاده و یا بروز علائم افزایش حساسیت یا مسمومیت با دارو؛ بیمارانی مبتلا به وجود هرگونه آریتمی قلبی قبل عمل؛ EF < 35% نارسایی قلبی با قلبی؛ داشتن اختلال CABG سابقه مصرف داروهای ضد آریتمی؛ سابقه الکترولیتی (هیپو یا هیپر کالسی/کلسمی) قبل از شروع مطالعه؛ کوتاه، QT، طولانی QT بیمارانی با ریسک فاکتور آریتمی مانند سندرم بروگادا و غیره؛ بیمارانی با سابقه ناراحتی معده و تحت درمان با بلوکر H2 پنتوپرازول و

Age

From 6 years old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: 380

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Mashhad Research deputy of university of Medical Sciences

Street address

Mashhad university of medical sciences

City

Mashhad

Postal code

Approval date

2015-08-01, 1394/05/10

Ethics committee reference number

IR.MUMS.fm.REC.1394.292

Health conditions studied

1

Description of health condition studied

Atherosclerotic heart disease

ICD-10 code

I25.1

ICD-10 code description

Coronary (artery): atheroma atherosclerosis disease sclerosis

Primary outcomes

1

Description

Hypomagnesaemia

Timepoint

Before/ after surgery

Method of measurement

serum

Secondary outcomes

1

Description

Arrhythmia

Timepoint

After surgery

Method of measurement

ECG

Intervention groups

1

Description

Ranitidine 50 mg three times a day intravenously on days of hospitalization in ICU and NPO and famotidine 40 mg tablet once a day orally during hospitalization in ICU (PO patient), and cardiac surgery (POST-ICU).

Category

Treatment - Drugs

2

Description

Pantoprazole 40 mg twice a day intravenously when they are stay in the ICU and NPO. And 40 mg once a day orally during hospitalization in ICU (PO patient) and cardiac surgery (POST-ICU).

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Reza hospital

Full name of responsible person

Dr Arash Peivandi and Dr Shahram Amini

Street address

Emam Reza Hospital, Emam Reza Square, Ebne Sina Avenue, Mashhad - 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. Arash Peivandi Yazdi
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University St., Ghoraisy Building, Mashhad - Iran
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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

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

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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