Clinical Trial Protocol
Iranian Registry of Clinical Trials

12 Jul 2026

Comparison the short-term outcomes of Ticagrelor versus Clopidogrel treatment in patients with myocardial infarction undergoing Percutaneous Coronary Intervention

Protocol summary

Study aim
Comparison the short-term outcomes of Ticagrelor versus Clopidogrel treatment in patients with myocardial infarction undergoing Percutaneous Coronary Intervention

Design
Clinical trial with control group, parallel groups, single blind, randomized, phase 2 on 128 patients. Block randomization is done using the following site: https://www.sealedenvelope.com/simple-randomiser/v1/lists

Settings and conduct
A total of 128 patients with STEMI referred to Dr. Heshmat Hospital in Rasht will be randomly divided into two treatment groups of 64 patients. The intervention group will receive ticagrelor and the control group will receive clopidogrel. Patients in both groups are followed up after a 3-month period. Patients will be blind.

Participants/Inclusion and exclusion criteria
Inclusion criteria: age 18 years and older; chest pain that lasts more than 20 minutes and no response to nitroglycerin; patients with PCI were underwent PCI less than 12 hours from the onset of symptoms. Non-inclusion criteria: cardiogenic shock in the form of systolic blood pressure less than 90 to 60 mm Hg and did not respond to hydration therapy; thrombolysis in the last 24 hours; recent anticoagulant therapy or recent use of P2Y12 antagonist; contraindications to aspirin, Clopidogrel or Ticagrelor.

Intervention groups
Control group: the first group (clopidogrel): patients receive 600 mg of Clopidogrel in a loading dose and then in addition to aspirin 81 mg daily. Clopidogrel tablets 75 mg daily will be prescribed. Intervention group: the second group (Ticagllor): for patients in this group, 180 mg of Ticagllor is loaded in a dose and then, in addition to aspirin 81 mg daily, 90 mg Ticaglor tablets twice a day and once every 12 hours will be prescribed.

Main outcome variables
Death; Myocardial Infarction; Stroke ; Thrombosis

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180205038626N9**
Registration date: **2021-07-13, 1400/04/22**
Registration timing: **prospective**

Last update: **2021-07-13, 1400/04/22**
Update count: **0**

Registration date
2021-07-13, 1400/04/22

Registrant information

Name
Zahra Ahmadnia

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 13 3361 8177

Email address
zahmadnia@gums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-08-23, 1400/06/01

Expected recruitment end date
2022-03-20, 1400/12/29

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison the short-term outcomes of Ticagrelor versus Clopidogrel treatment in patients with myocardial infarction undergoing Percutaneous Coronary Intervention

Public title
The short-term outcomes of Ticagrelor versus Clopidogrel in patients with myocardial infarction
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age 18 years and older Chest pain that lasts more than 20 minutes and no response to nitroglycerin Patients with PCI were underwent PCI less than 12 hours from the onset of symptoms. The ST segment rises more than 1 mm in at least two or more limb leads. The ST segment is more than 2 mm high in two or more precordial leads.
Exclusion criteria:
Cardiogenic shock in the form of systolic blood pressure less than 90 to 60 mm Hg and did not respond to hydration therapy Thrombolysis in the last 24 hours Recent anticoagulant therapy or recent use of P2Y12 antagonist Contraindications to aspirin, clopidogrel and ticagrelor History of coronary artery bypass grafting in recent year Patient dissatisfaction
Age
From **18 years** old
Gender
Both

Phase
2
Groups that have been masked

- Participant

Sample size
Target sample size: **128**
Randomization (investigator's opinion)
Randomized
Randomization description
According to the number of 64 people in each group and 128 people in total, 4 blocks of 32 will be used. Patients based on random blocks with number of 32 people (16 people in the intervention group and 16 people in the control group) in each block and Its format will be in a sealed envelope under the supervision of the study inspector and patients will be studied daily in the study groups. The method of concealment will be by numbered envelopes.
Blinding (investigator's opinion)
Single blinded
Blinding description
The two groups can be divided into the first group (receiving clopidogrel 75 mg daily and aspirin 81 mg daily) and the second group (receiving ticagrelor 90 mg twice daily and aspirin 81 mg daily) in the form of a sealed envelope to the evaluating researcher, and at the end the envelope will be opened and it will be determined that what are the treatments 1 and 2.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Guilan University of Medical Sciences
Street address
Technology & Research Vice-chancellor of University; Shahid Siadati St; Namjoo St., Rasht
City
Rasht
Province
Guilan
Postal code
41446-66949
Approval date
2021-06-30, 1400/04/09
Ethics committee reference number
IR.GUMS.REC.1400.140

Health conditions studied

1

Description of health condition studied
Acute myocardial infarction
ICD-10 code
I23.8
ICD-10 code description
Other current complications following acute myocardial infarction

Primary outcomes

1

Description
Thrombosis
Timepoint
3 months later
Method of measurement
Clinical signs and laboratory tests

2

Description
Stroke

Timepoint
3 months later
Method of measurement
CT scan

3

Description
Myocardial Infarction
Timepoint
3 months later
Method of measurement
Electrocardiography, Echocardiography

Secondary outcomes

1

Description
Death
Timepoint
3 months later
Method of measurement
Phone call with the patient

Intervention groups

1

Description
Control group: Clopidogrel group: patients will receive 600 mg of clopidogrel as a loading dose and then in addition to aspirin 81 mg daily, clopidogrel 75 mg daily tablet will be prescribed for 3 months.
Category
Treatment - Drugs

2

Description
Intervention group: Ticagllor group: for patients, 180 mg of ticaglor loading dose and then in addition to aspirin 81 mg daily, 90 mg ticaglor tablet twice a day and one tablet every 12 hours will be prescribed for 3 months.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Dr. Heshmat Rasht Hospital
Full name of responsible person
Zahra Ahmadnia
Street address
Dr. Heshmat Hospital, Bayani St., Mosala Square
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Rasht
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4193955588
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Rasht University of Medical Sciences
Full name of responsible person
Mohammadreza Naghipour
Street address
Technology & Research Vice-chancellor of University, Shahid Siadati St., Namjoo St., Rasht
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naghi@gums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Actover pharmaceutical company
Proportion provided by this source
100
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Industry

Person responsible for general inquiries

Contact
Name of organization / entity
Rasht University of Medical Sciences
Full name of responsible person
Zahra Ahmadnia
Position
Nurse
Latest degree
Master
Other areas of specialty/work

Nursery

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Dr. Heshmat Hospital; Bayani St; Mosala Square; Rasht.

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Person responsible for scientific inquiries

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Position
Nurse

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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
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be 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
Information on the main outcome

When the data will become available and for how long
Access period starts 6 months after the results are published

To whom data/document is available
Researchers working in academic institutions

Under which criteria data/document could be used
Request to receive unidentifiable personal data or other documents

From where data/document is obtainable
Dr. Salman Nikfarjam

What processes are involved for a request to access data/document
By email to Dr. Salman Nikfarjam

Comments