# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

17 Sep 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)

**Phone**
+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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## 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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**Phone**
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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

**Street address**
Dr. Heshmat Hospital; Bayani St; Mosala Square; Rasht.

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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**Latest degree**
Master

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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**