Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of the Effects of Ticagrelor on the Prognosis of Percutaneous Coronary Interventions in Patients with Covid-19 and Comparing it with Clopidogrel

Protocol summary

Study aim

Investigating the effects of Ticagrelor versus Clopidogrel on the clinical outcomes of patients with covid-19 who undergo coronary angioplasty (percutaneous coronary interventions) with the diagnosis of acute myocardial infarction.

Design

The study is a single-blind, randomized clinical trial with two parallel groups, where the number of patients in each group is 100. Random function is used in Excel software for randomization.

Settings and conduct

This study will be conducted in 501 AJA hospital. Patients presenting with acute MI who are also suffering from covid will be randomly divided into two groups, one group will receive Ticagrelor and the other group will receive Clopidogrel. The rest of the standard treatments will be prescribed in the same way for all patients. During the study, the patients will be informed about the drug category used, but the project manager is not aware of the type of drug prescribed. (The type of drug prescribed will be delivered to them in the form of A, B)

Participants/Inclusion and exclusion criteria

Inclusion criteria: Over 18 years of age, diagnosed with acute myocardial infarction (with or without ST-segment elevation), concomitant Covid-19 infection Exclusion criteria: under 18 years of age, severe heart, kidney, or liver failure, pregnancy or suspicion of pregnancy, history of malignancy, simultaneous use of anticoagulants, administration of intravenous antiviral drugs in the same admission.

Intervention groups

As a P2Y12 inhibitor drug, in the intervention group, Ticagrelor drug in the dose of 180 mg as a loading dose, and then 90 mg every 12 hours will be prescribed as a daily maintenance dose. In the control group, 600 mg of Clopidogrel is prescribed as a loading dose, and then 75 mg every 24 hours as a daily maintenance dose.

Main outcome variables

Cardiovascular mortality during initial hospitalization and one month after discharge.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220813055675N1**
Registration date: **2022-08-16, 1401/05/25**
Registration timing: **prospective**

Last update: **2022-08-16, 1401/05/25**
Update count: **0**

Registration date

2022-08-16, 1401/05/25

Registrant information

Name

Reza Arefizade

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-08-20, 1401/05/29

Expected recruitment end date

2022-11-20, 1401/08/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the Effects of Ticagrelor on the Prognosis of Percutaneous Coronary Interventions in Patients with Covid-19 and Comparing it with Clopidogrel

Public title

Effects of Ticagrelor on the Clinical consequences of Angioplasty in Myocardial Infarction and Covid-19.d

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients over 18 years of age who present with acute myocardial infarction. Candidates for emergent coronary angioplasty (Percutaneous coronary intervention) Less than 24 hours have passed since the onset of chest pain symptoms. are infected with the concomitant covid-19 disease (proved by CT Scan or PCR).

Exclusion criteria:

Lack of patient consent to perform coronary interventions or enter the study Chronic and necessary use of any anti-coagulant drug by the patient severe renal failure (GFR less than 30) Severe heart failure (EF less than 30%) Age under 18 years old Pregnancy or suspected pregnancy History of intracranial or intraspinal bleeding Administration of any intravenous antiviral drug in the same admision Severe liver failure Past history of any malignancy or chemotherapy regimen

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **200**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, simple randomization method is used by Excel software, and by Random function in this software. The randomization unit in this method will be individual. Patients are divided into two groups: Ticagrelor and Clopidogrel.

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, the researcher, who is also responsible for the follow-up of patients and the evaluation of the expected outcomes, and finally analyzes the data with the cooperation of statisticians, will be unaware of the type of medicine prescribed for the groups throughout the study. The desired drugs will be prescribed to the patients by the residents, or doctors who coordinate with the research team in the emergency room.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of AJA University of Medical Sciences

Street address

Etemad Zade St., West Fatemi Ave.

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Approval date

2021-12-11, 1400/09/20

Ethics committee reference number

IR.AJAUMS.REC.1400.233

Health conditions studied

1

Description of health condition studied

Myocardial Infarction

ICD-10 code

I21

ICD-10 code description

ST elevation (STEMI) and non-ST elevation (NSTEMI) myocardial infarction

Primary outcomes

1

Description

Cardiovascular Death

Timepoint

During the index admission, and after 1 month from hospital discharge

Method of measurement

Admission file and follow-up data

Secondary outcomes

1

Description
Stent Thrombosis
Timepoint
During index admission and 1 month after discharge
Method of measurement
Coronary Angiography

2

Description
Myocardial Infarction
Timepoint
During index admission and 1 month after discharge
Method of measurement
Troponin measurement and Electrocardiography

3

Description
Arterial O2 saturation
Timepoint
During the index admission
Method of measurement
Pulse-Oxymetry

Intervention groups

1

Description
Intervention group: Ticagrelor drug ("Brilavus" from ABIDI Company) is prescribed orally at the loading dose of 180 mg at the beginning of the patient's visit and before the start of angioplasty, then will be given at the dose of 90 mg every 12 hours as a daily dose. Other prescription drugs are similar to the control group and are performed according to the guidelines.
Category
Treatment - Drugs

2

Description
Control group: Clopidogrel drug ("Plavix" from Sanofi Company) is prescribed orally at the dose of 600 mg at the beginning of the patient's visit and before the start of angioplasty, then will be given at the dose of 75 mg every 24 hours as a daily dose. Other prescription drugs are similar to the intervention group and are performed according to the guidelines.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
501 Artesh Hospital
Full name of responsible person
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Sponsors / Funding sources

1

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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
Artesh 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
Artesh University of Medical Sciences
Full name of responsible person
Reza Arefi Zade
Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Cardiology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All collected data can be published.

When the data will become available and for how long

Access starts 3 months after the results are published.

To whom data/document is available

All people.

Under which criteria data/document could be used

Any type of data and analysis is accessible. For this purpose, please call 09125752404.

From where data/document is obtainable

Dr Reza Arefi Zadeh, 501 AJA hospital

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

It is necessary to go to 501 Aja Hospital, cardiology department, or call 09125752404. E-mail: saeedtofighi69@gmail.com is also available for respected clients.

Comments