

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 2026

Comparing the efficacy of Ticagrelor and Clopidogrel in patients with acute ischemic stroke or transient ischemic attack(TIA)

Protocol summary

Study aim

Comparison of efficacy and side effects between Clopidogrel and Ticagrelor in patients with Acute ischemic stroke.

Design

unblinded randomized controlled clinical trial, phase 2 and 3, Tow arm parallel groups is conducted on 424 patients and simple random assignment method with the help of random numbers table.

Settings and conduct

This randomized controlled clinical trial will be conducted to compare the efficacy of Ticagrelor compared to Clopidogrel among patients with Acute ischemic stroke referred to Golestan Hospital, Ahvaz.

Participants/Inclusion and exclusion criteria

Inclusion criteria: diagnosis of ischemic stroke or TIA based on history and neurological examination and imaging findings by a specialist. Exclusion criteria: More than 24 hours have passed since the onset of symptoms Thrombolytic therapy or thrombectomy Intracranial hemorrhage Severe or moderate ischemic stroke (NIHSS>>12)

Intervention groups

Intervention: Aspirin (a loading dose of 300 mg on the first day followed by 80 mg once daily) with Ticagrelor (loading dose 180 mg) administered on day 1 and then 90 mg twice daily until day 30. Control : Aspirin (a loading dose of 300 mg on the first day, then 80 mg once daily) plus Clopidogrel (300 mg), The loading dose is given on day 1, followed by 75 mg once daily until day 30.

Main outcome variables

Age; Gender; Body mass index; Underlying disease; Smoking; Lack of movement; Acute ischemic stroke; Type of treatment; Systolic/Diastolic blood pressure; Clinical complications

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130311012781N6**

Registration date: **2024-02-16, 1402/11/27**

Registration timing: **registered_while_recruiting**

Last update: **2024-02-16, 1402/11/27**

Update count: **0**

Registration date

2024-02-16, 1402/11/27

Registrant information

Name

Davood Kashipazha

Name of organization / entity

Ahvaz JodndiShapour University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 61 1374 3012

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-02-04, 1402/11/15

Expected recruitment end date

2024-08-05, 1403/05/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the efficacy of Ticagrelor and Clopidogrel in patients with acute ischemic stroke or transient ischemic attack(TIA)

Public title

Comparing the efficacy of Ticagrelor and Clopidogrel in patients with Acute ischemic attack or Transient ischemic attack(TIA)

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Diagnosing Ischemic Stroke or TIA based on history and neurological examination and Imaging findings by a Specialist

Exclusion criteria:

More than 24 hours have passed since the onset of symptoms
Thrombolytic therapy or Thrombectomy
Intracranial hemorrhage
Vascular malformations
The presence of contraindications to Aspirin, Clopidogrel or Ticagrelor
Severe or moderate Ischemic Stroke (NIHSS>>12)
Lack of patient consent to enter the study
The presence of acute coronary syndrome at the beginning of hospitalization
cardioembolic Stroke or TIA

Age

No age limit

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **424**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization method: Simple random allocation,
Individual randomization: unit, Randomization tool including Random numbers table

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Reserch Ethics Committees of Ahvaz Jundishapur of University of Medical Sciences

Street address

Ahvaz, Golestan region, Farvardin Street, Golestan Hospital, Department of Neurology

City

Ahvaz

Province

Khouzestan

Postal code

6441945781

Approval date

2024-01-13, 1402/10/23

Ethics committee reference number

IR.AJUMS.REC.1402.551

Health conditions studied

1

Description of health condition studied

Acute Ischemic Stroke

ICD-10 code

I63

ICD-10 code description

Cerebral infarction

Primary outcomes

1

Description

Recurrence of stroke

Timepoint

21 days, 3 months, 6 months from the beginning of the study

Method of measurement

Clinical history and in case of recurrence of stroke symptoms, imaging findings.

Secondary outcomes

1

Description

Intracranial hemorrhage, Dyspnea, Mortality

Timepoint

21 days, 3 months, 6 months from the beginning of the study.

Method of measurement

Clinical history and Imaging findings in case of Symptoms related to Intracranial hemorrhage or Dyspnea.

Intervention groups

1

Description

Intervention group: (Ticagrelor/Aspirin): Aspirin (a loading dose of 100-300 mg as one to three tablets of 100 mg on the first day and then 80 mg once a day) together with Ticagrelor (loading dose of 180 mg) is

prescribed as two tablets of 90 mg on day 1 and then 90 mg twice a day until day 30.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Department of Neurology of Golestan hospital

Full name of responsible person

Davood kashipazha

Street address

Farvardin Ave., Golestan Blvd., Ahvaz

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Mehrnoosh Zakerkish

Street address

Esfand Ave., Golestan Blvd., Ahvaz

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Fax

+98 61 3336 1544

Email

itc@ajums.ac.ir

Web page address

http://vchresearch.ajums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Ahvaz 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

Ahvaz University of Medical Sciences

Full name of responsible person

Maryam Alwanian

Position

Neurology Resident

Latest degree

Medical doctor

Other areas of specialty/work

Neurology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Position

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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

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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

The primary clinical outcome of participants will be shared by the analysis of collected data.

When the data will become available and for how long

6 months after publication of results

To whom data/document is available

available for people who working in academic institutions

Under which criteria data/document could be used

Primary clinical outcome of participants will be shared by tables and charts.

From where data/document is obtainable

Davood kashipazha _ Department of Neurology of
Golestan Hospital in Ahvaz. Email: dakashi47@gmail.com

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

Please your request will be send by email. our response will be send you by email during a month.

Comments