

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 May 2026

Ticagrelor plus Aspirin vs Clopidogrel plus Aspirin in Minor Non-cardioembolic Ischemic Stroke (TACAMINIS)

Protocol summary

Study aim

To assess the efficacy of ticagrelor plus aspirin in comparison with clopidogrel plus aspirin in reduce of minor non-cardioembolic ischemic stroke or high risk TIA recurrence during first 3 months

Design

A randomized, controlled, active comparator arm, outcome assessor blind, parallel group design on 90 ischemic stroke patients with block randomization method

Settings and conduct

This is a randomized, controlled active comparator arm, outcome assessor blind on 90 patient with diagnosis of ischemic stroke admitted in Bou-Ali Sina Hospital, Sari, Iran

Participants/Inclusion and exclusion criteria

Inclusion criteria: age>40, signing inform consent, recent ischemic stroke within 24 h, diagnosed by brain CT or MRI mild stroke with NIHSS = <8, high risk TIA with ABCD >4, no cardioembolic source such as low E/F, MS, AF, ... no specific etiology such as dissection, vasculitis, ... no carotid stenosis > 50 % in side of involvement Exclusion criteria: history of hypersensitivity to consumptive drug any indication for anticoagulant therapy acute phase treatment with intravenous thrombolysis or thrombectomy any contraindication for consumptive drug history of intracranial hemorrhage history of GI bleeding during past 6 m candidate for endarterectomy history of coagulopathy active hemorrhagic diathesis during randomization

Intervention groups

comparator group will be treat with ASA 325 mg stat and clopidogrel 300 mg stat, then ASA 80 mg and clopidogrel 75 mg daily for 21 days. intervention group will be treat with ASA 325 mg stat and ticagrelor 180 mg stat, then ASA 80 mg daily and ticagrelor 90 mg BID for 21 days. Then all groups will be treat with ASA 80 mg daily after day 21.

Main outcome variables

ischemic stroke recurrence during first 3 months and major bleeding event

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200112046094N2**

Registration date: **2021-08-01, 1400/05/10**

Registration timing: **prospective**

Last update: **2021-08-01, 1400/05/10**

Update count: **0**

Registration date

2021-08-01, 1400/05/10

Registrant information

Name

Athena Sharifi-Razavi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 3334 3014

Email address

athena.sharifi@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-08-07, 1400/05/16

Expected recruitment end date

2022-08-07, 1401/05/16

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Ticagrelor plus Aspirin vs Clopidogrel plus Aspirin in Minor Non-cardioembolic Ischemic Stroke (TACAMINIS)

Public title

Ticagrelor in minor ischemic stroke

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

signing informed consent recent ischemic stroke within 24 h, diagnosed by brain CT or MRI mild stroke with NIHSS ≤ 8 high risk TIA with ABCD > 4 no cardioembolic source such as low E/F, MS, AF, ... no specific etiology such as dissection, vasculitis, ... no carotid stenosis $> 50\%$ in side of involvement

Exclusion criteria:

history of hypersensitivity to consumptive drug any indication for anticoagulant therapy acute phase treatment with intravenous thrombolysis or thrombectomy any contraindication for consumptive drug history of intracranial hemorrhage history of GI bleeding during past 6 m candidate for endarterectomy history of coagulopathy active hemorrhagic diathesis during randomization

Age

From **40 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

by using 4 block randomization method and random numbers table with 1:1 fashion

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

this protocol designed as outcome assessor blind. The comparator group is an active group and participants treated with standard drugs.

Secondary Ids

1

Registry name

مرکز ثبت کارآزمایی های بالینی ایالات متحده آمریکا
(www.clinicaltrials.gov)

Secondary trial Id

"NCT04738097 "for clinicaltrials.gov

Registration date

2021-02-04, 1399/11/16

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mazandaran University of Medical Sciences

Street address

Deputy of research and technology, Moallem Sq

City

Sari

Province

Mazandaran

Postal code

4815733971

Approval date

2021-06-23, 1400/04/02

Ethics committee reference number

IR.MAZUMS.REC.1400.304

Health conditions studied

1

Description of health condition studied

ischemic stroke

ICD-10 code

ICD-10 code description

2

Description of health condition studied

transient ischemic attack

ICD-10 code

G45

ICD-10 code description

Transient cerebral ischemic attacks and related syndromes

Primary outcomes

1

Description

ischemic stroke recurrence during first 3 months after first event

Timepoint

3 months after first stroke event

Method of measurement

recording new event based on new lesion on brain CT scan or MRI

Secondary outcomes

1

Description

ischemic stroke recurrence during first 1 month

Timepoint

1 month after first event

Method of measurement

recording recurrence based on new lesion on brain CT scan or MRI

2

Description

Major hemorrhagic event

Timepoint

during first 1 month

Method of measurement

Major bleeds were defined according to the International Society of Thrombosis and Hemostasis (ISTH)

3

Description

other cardiovascular events

Timepoint

during first 3 months

Method of measurement

recording proven cardiovascular event such as MI

Intervention groups

1

Description

Intervention group: Patients will be treated with ASA 325 mg stat and ticagrelor 180 mg stat, then ASA 80 mg daily and ticagrelor 90 mg BID for 21 days. Then ASA 80 mg daily will be continued.

Category

Prevention

2

Description

Control group: Patients will be treated with standard minor stroke treatment, ASA 325 mg stat and clopidogrel 300 mg stat, then ASA 80 mg daily and clopidogrel 75 mg daily for 21 days. Then ASA 80 mg daily will be continued.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Bou-Ali Sina Hospital

Full name of responsible person

Athena Sharifi-Razavi

Street address

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

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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

Mazandaran 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

Mazandaran University of Medical Sciences

Full name of responsible person

Athena Sharifi-Razavi

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Neurology

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Person responsible for scientific inquiries

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Position

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be 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