

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

Treatment effect of aspirin with and without Clopidogrel on prevention of transient ischemic attack or acute minor stroke in patients with transient ischemic attack: a randomized clinical trial

Protocol summary

Study aim

To assess the treatment effect of aspirin with and without Clopidogrel on prevention of transient ischemic attack or acute minor stroke in patients with transient ischemic attack

Design

This is a randomized clinical trial, phase II, in which 54 eligible patients will be randomly assigned to the intervention and control groups

Settings and conduct

The eligible patients with transient ischemic attack who will refer to Sina Hospital during the study period will be enrolled in the trial

Participants/Inclusion and exclusion criteria

Inclusion criteria: age between 18 to 80 years old; transient ischemic attack; severity of stroke score less than 15. Exclusion criteria: gastric disorders; cardiac arrhythmia; sensitivity of aspirin; candidate for carotid introversion.

Intervention groups

Intervention group: Aspirin tablet 81 mg/day for 3 months plus Clopidogrel tablet 75 mg/day for 3 months
Control group: Aspirin tablet 81 mg/day for 3 months

Main outcome variables

Primary outcome: transient ischemic attack; acute minor stroke

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120215009014N232**
Registration date: **2018-08-27, 1397/06/05**
Registration timing: **registered_while_recruiting**

Last update: **2018-08-27, 1397/06/05**

Update count: **0**

Registration date

2018-08-27, 1397/06/05

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan
University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-07-23, 1397/05/01

Expected recruitment end date

2018-09-06, 1397/06/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Treatment effect of aspirin with and without Clopidogrel on prevention of transient ischemic attack or acute minor stroke in patients with transient ischemic attack: a randomized clinical trial

Public title

Treatment effect of aspirin with and without Clopidogrel

on prevention of transient ischemic attack or acute minor stroke in patients with transient ischemic attack

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Age of 18 to 80 years; Transient ischemic attack;
Severity of stroke score less than 15

Exclusion criteria:

Gastric disorders; Cardiac arrhythmia; Sensitivity of aspirin; Candidate for Carotid introversion

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **54**

Randomization (investigator's opinion)

Randomized

Randomization description

The patients will be randomly assigned to intervention and control groups using block randomization

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

Ethics Committee of Hamadan University of Medical Sciences

Street address

Vice-chancellor for Research and Technology,
Hamadan University of Medical Sciences, Shahid Fahmideh Ave

City

Hamadan

Province

Hamadan

Postal code

6517838695

Approval date

2018-07-21, 1397/04/30

Ethics committee reference number

IR.UMSHA.REC.1397.301

Health conditions studied

1

Description of health condition studied

Transient ischemic attack

ICD-10 code

G45.9

ICD-10 code description

Transient cerebral ischemic attack, unspecified

Primary outcomes

1

Description

Transient ischemic attack

Timepoint

3 months after intervention

Method of measurement

With physical examination and history taking

2

Description

Acute minor stroke

Timepoint

3 months after intervention

Method of measurement

With physical examination and history taking

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Aspirin tablet 81 mg/day for 3 months plus Clopidogrel tablet 75 mg/day for 3 months

Category

Treatment - Drugs

2

Description

Control group: Aspirin tablet 81 mg/day for 3 months

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Sina Hospital

Full name of responsible person

Fatemeh Ghasemian

Street address

Sina Hospital, Mirzadeh Eshghi Ave.

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6517838695

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dr.sahel.72@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr Saeid Bashirian

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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

Hamedan 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

Hamedan University of Medical Sciences

Full name of responsible person

Fatemeh Ghasemian

Position

Medical Student

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Mojtaba Khazaei

Position

Neurologist

Latest degree

Medical doctor

Other areas of specialty/work

Neurology

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Person responsible for updating data

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr Jalal Poorolajal

Position

Professor of Epidemiology

Latest degree

Ph.D.

Other areas of specialty/work

Epidemiology

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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