

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Jun 2026

### Aspirin versus dual antiplatelet therapy-aspirin and clopidogrel- in patients with minor acute ischemic stroke receiving intravenous thrombolytic therapy: a double blind randomized clinical trial (عنوان پژوهش به انگلیسی: (حداکثر 2 خط

#### Protocol summary

##### Study aim

Is double antiplatelet therapy (aspirin and clopidogrel) more effective than standard antiplatelet therapy (aspirin alone) in patients receiving intravenous thrombolysis without increasing possible complications?

##### Design

This clinical trial was designed with 2 intervention groups, which are parallel, double-blind, randomized, phase 3 groups on 180 patients. The randomization site was used for randomization.

##### Settings and conduct

This study will be conducted in Ghaem Hospital of Mashhad on 180 patients who were treated with venous thrombolysis due to ischemic stroke, and people in the intervention group and the control group will receive two drugs for 21 days. Multiple evaluation of the patient up to 90 days will be done based on the modified ranking scale and finally the results will be checked. Except for the pharmacist, none of the participants, researchers and analysts will know about the drug or placebo until the end of the study, and the study is two-sided. will be blind

##### Participants/Inclusion and exclusion criteria

Individuals over 18 years old with acute ischemic disabling stroke symptoms with NIHSS less than 5 that are not prohibited for receiving intravenous thrombolysis and double antiplatelet (aspirin and clopidogrel combination) will be included in the study. Patients with atrial fibrillation rhythm, a patient who is already on double antiplatelet therapy, causing symptomatic intracranial hemorrhage after receiving intravenous thrombolysis, will not be included in the study.

##### Intervention groups

The first intervention group received aspirin 80 mg daily and placebo a daily dose for 21 days. The second intervention group in our study is the dual therapy group,

which receives 80 mg of aspirin daily and 75 mg of clopidogrel daily for 21 days.

##### Main outcome variables

Reduction of ischemic stroke recurrence Reducing the disabilities of stroke patients

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20230729058953N1**

Registration date: **2023-08-06, 1402/05/15**

Registration timing: **registered\_while\_recruiting**

Last update: **2023-08-06, 1402/05/15**

Update count: **0**

##### Registration date

2023-08-06, 1402/05/15

##### Registrant information

##### Name

maryam panahi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 3852 5312

##### Email address

panahim@mums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-08-01, 1402/05/10

**Expected recruitment end date**

2024-01-30, 1402/11/10

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Aspirin versus dual antiplatelet therapy-aspirin and clopidogrel- in patients with minor acute ischemic stroke receiving intravenous thrombolytic therapy: a double blind randomized clinical trial (عنوان پژوهش به انگلیسی: (حداکثر 2 خط

**Public title**

Aspirin versus dual antiplatelet therapy-aspirin and clopidogrel- in patients with minor acute ischemic stroke receiving intravenous thrombolytic therapy: a double blind randomized clinical trial (عنوان پژوهش به انگلیسی: (حداکثر 2 خط

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Over the age of 18 years individuals with acute ischemic stroke symptoms of disabling with NIHSS less than 5 which are not prohibited for receiving venous thrombolysis and double antiplatelet (aspirin and clopidogrel combination) according to the protocol.

**Exclusion criteria:**

Patients with atrial fibrillation(AF) rhythm A patient who is already on dual antiplatelet therapy ICH (intracranial hemorrhage) symptomatic after receiving intravenous thrombolysis.

**Age**From **18 years** old**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Investigator
- Outcome assessor
- Data analyser

**Sample size**Target sample size: **180****Randomization (investigator's opinion)**

Randomized

**Randomization description**

According to two intervention groups, the volume of each block will be four. Then the list of blocks is written, and the numbers are assigned to them. For example, (AABB(1)- ABAB (2)-ABBA (3)- BBAA(4)- BABA(5)- BAAB(6)) - depending on the sample size of 180 people, 45 blocks will collect. The random numbers between one and 6 are then selected according to the Randomaize.com randomization site. Finally, the treatment assignment list is written based on random

numbers on envelopes containing each block.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Due to the use of placebo similar to interventional therapy, the physician associated with the participants and the participants will not be informed of the allocated treatment. The analyst will also be unaware of the treatment allocated to the two groups. Finally, after analyzing the data, the researcher who prepared the packaging reveals the A and B codes. Apart from the pharmacist, none of the participants, researchers, and analysts will know about the drug or placebo until the end of the study. Use of SNOSE sealed non-transparent letters (sequentially numbered, opaque, sealed envelopes) In this way, the envelopes will be prepared and printed by a team member and random numbers and placed inside the envelope. The envelopes will be closed and the contents will not be visible from the outside. Then, first, the purpose of the study is explained to the person who has the mentioned conditions and if the person wishes to sign the informed consent form and remove an envelope, then open it and enter the intervention or control group based on the contents of the envelope.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethic committee of Mashhad University of Medical sciences

**Street address**

Ahmadabad Blvd, Ghaem Hospital

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9176755535

**Approval date**

2023-07-04, 1402/04/13

**Ethics committee reference number**

IR.MUMS.IRH.REC.1402.090

**Health conditions studied****1****Description of health condition studied**

ischemic cerebrovascular attack

**ICD-10 code**  
**ICD-10 code description**

maryampanahi1367@gmail.com

## Primary outcomes

### 1

#### Description

Comparison of the treatment effect of aspirin and clopidogrel and aspirin alone in ischemic stroke patients after intravenous thrombolytic therapy

#### Timepoint

24 hours later, 3, 7 and 90 days after the stroke, evaluations are done.

#### Method of measurement

Brain CT scan, modified ranking scale (mRS), neurology specialist visit

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

"Intervention group 1": patients entering the study who are treated with aspirin 80 mg once a day and placebo once a day for 21 days.

#### Category

Treatment - Drugs

### 2

#### Description

"Intervention group 2": patients entering the study who are treated with aspirin 80 mg once a day and clopidogrel 75 mg once a day for 21 days.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Ghaem hospital

##### Full name of responsible person

Bahram Zarmehri

##### Street address

Ahmadabad blvd,Ghaem Hospital

##### City

Mashhad

##### Province

Razavi Khorasan

##### Postal code

9176755535

##### Phone

+98 51 3852 5312

##### Email

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Mashhad University of Medical Sciences

##### Full name of responsible person

Bahram Zarmehri

##### Street address

Ahmadabad Blvd,Ghaem Hosoitai

##### City

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##### Province

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##### Postal code

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##### Phone

+98 51 3852 5312

##### Email

zarmehrib@mums.ac.ir

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Mashhad 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

Mashhad University of Medical Sciences

##### Full name of responsible person

Bahram Zarmehri

##### Position

Assistant professor

##### Latest degree

Specialist

##### Other areas of specialty/work

Emergency Medicine

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**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

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**Position**

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

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**Position**

Assistant professor

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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**

Part of the data, such as information on the main outcome, can be shared.

**When the data will become available and for how long**

Access to the data is possible 6 months after the results are published.

**To whom data/document is available**

The data will be available for use by researchers.

**Under which criteria data/document could be used**

If used as clinical research, it will be available.

**From where data/document is obtainable**

Bahram Zarmehri Zarmehrib@mums.ac.ir

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

The request will be reviewed within 30 days

**Comments**