Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Jun 2026

عنوان پژوهش به انگلیسي: (حداکثر 2 خط)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

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

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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
(عنوان پژوهش به انگلیسي: (حداکثر 2 خط)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

Public title
(عنوان پژوهش به انگلیسي: (حداکثر 2 خط)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
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

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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
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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
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 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

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