Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Jun 2026

A comparative study of the effects of tissue plasminogen activator and dual antiplatelet therapy on improvement of the score of the National Institutes of Health Stroke Scale in acute ischemic stroke treatment

Protocol summary

Summary

This study compares the effects of tissue plasminogen activator and dual antiplatelet therapy on improvement of National Institutes of Health Stroke Scale (NIHSS) scores in acute ischemic stroke treatment. A total of 60 patients with inclusion criteria will be recruited via convenience sampling method. Major inclusion criteria: proved ischemic stroke; initiation of stroke symptoms within 4.5 hours from admission; clinical NIHSS score between four and 18. Major exclusion criterion: age 80 years old, brain hemorrhage on initial computerized tomography scan, and current treatment with oral anticoagulants. The study is double-blind, one-centered, and prospective. The patients will be allocated into case (30 patients) and control group (30 patients) via randomized blocked allocation method (i.e., 1:1). The cases will receive tissue plasminogen activator (Retavase®) 0.9 milligram per kilogram (maximum doses: 90 milligram) where 10 percent of the total dose is administered as a 10 U bolus dose followed by a 60-minute infusion of the remaining doses. The controls will receive dual antiplatelet therapy by daily aspirin 80 milligrams and clopidogrel 75 milligrams for three months. Then, the clopidogrel will be discontinued. Clinical response in both groups will be assessed using NIHSS at the initial presentation, after 24 and 48 hours, and at discharge from hospital.

General information

Acronym

-

IRCT registration information

IRCT registration number: **IRCT2017082117756N24**
Registration date: **2017-09-10, 1396/06/19**
Registration timing: **registered_while_recruiting**
Last update:
Update count: **0**

Registration date

2017-09-10, 1396/06/19

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Vice-chancellor for Research of Birjand University of Medical Sciences

Expected recruitment start date

2017-03-21, 1396/01/01

Expected recruitment end date

2018-03-20, 1396/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparative study of the effects of tissue plasminogen activator and dual antiplatelet therapy on improvement of the score of the National Institutes of Health Stroke Scale in acute ischemic stroke treatment

Public title
Effects of tissue plasminogen activator and dual antiplatelet therapy in acute ischemic stroke treatment
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: Proved ischemic stroke; informed consent for participation; stroke symptoms initiated within 4.5 hours before admission; no brain hemorrhage on initial computerized tomography scan; clinical national institutes of health stroke scale between 4 and 18. Exclusion criteria: Age 80 years or above; brain hemorrhage in initial computerized tomography scan; history of stroke; history of diabetes mellitus; patients currently receiving oral anticoagulant treatment without considering the international normalized ratio; clinical national institutes of health stroke scale above 25; large ischemic changes of brain or involvement of more than one-third of middle cerebral artery supplying zone in the initial computerized tomography scan.
Age
To **80 years** old
Gender
Both

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
This is a double-blind study and both the physician and the patient are unaware of the study groups. Moreover, the participants will be selected via convenience sampling method and assigned into intervention and control groups via randomized blocked allocation method (i.e., 1:1).

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Birjand University of Medical Sciences
Street address
Vice-chancellery of Research, Birjand University of Medical Sciences, Ghaffari St.,
City
Birjand,
Postal code
Approval date
2016-08-18, 1395/05/28
Ethics committee reference number
Ir.bums.REC.1395.171

Health conditions studied

1

Description of health condition studied
acute ischemic stroke
ICD-10 code
I63.9
ICD-10 code description
cerebrovascular (embolic) (ischemic) (thrombotic)

Primary outcomes

1

Description
National Institutes of Health Stroke Scale score
Timepoint
at the initial presentation, after 24 and 48 hours, and at discharge from hospital
Method of measurement
Physical examination

Secondary outcomes

1

Description
Complications of tissue plasminogen activator treatment
Timepoint
after 24 and 48 hours from the initiation of treatment and at discharge from hospital
Method of measurement
brain computerized tomography scan

Intervention groups

1

Description
Intervention Group (tissue plasminogen activator): The cases receive tissue plasminogen activator (Retavase®) 0.9 milligram per kilogram (maximum doses: 90 milligram) where 10 percent of the total dose is administered as a 10 U bolus dose followed by a 60-minute infusion of the remaining doses. Clinical response will be assessed at the initial presentation, after 24 and 48 hours, and at discharge from hospital by national institutes of health stroke scale. Decrease in score of national institutes of health stroke scale will be considered as the sign of improvement.
Category

Treatment - Drugs

2

Description
Control Group (dual antiplatelet therapy): The controls receive dual antiplatelet therapy by daily aspirin 80 milligram and clopidogrel 75 milligram for three months. After three months, the clopidogrel will be discontinued. Clinical response will be assessed at the first presentation, after 24 and 48 hours and at discharge from hospital by national institutes of health stroke scale. Decrease in score of national institutes of health stroke scale will be considered as the sign of improvement.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Valiasr Hospital
Full name of responsible person
Dr. Elham Zarei
Street address
Neurology Ward, Valiasr Hospital, Ghaffari St.,
City
Birjand,

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice-chancellery of Research, Birjand University of Medical Sciences
Full name of responsible person
Dr. Tooba Kazemi
Street address
Vice-chancellery of Reasearch and Technology, Birjand University of Medical Sciences, Ghaffari St.,
City
Birjand,
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice-chancellery of Research, Birjand University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Birjand University of Medical Sciences
Full name of responsible person
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Person responsible for scientific inquiries

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Name of organization / entity
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty