# 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**


**Name**

Mohammad Bagher Roozgar

**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

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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*