

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jun 2026

Effect of treatment with tissue plasminogen activator in improving clinical status of patients with acute ischemic stroke: a randomized clinical trial

Protocol summary

Summary

Objectives: To assess the effect treatment with tissue plasminogen activator in improving clinical status of patients with acute ischemic stroke. Design: A randomized clinical trial. Setting and conduct: The eligible patients with acute ischemic stroke who will refer to ... Hospital during the study period will be enrolled into the trial. Inclusion criteria: Age of 18 to 85 years; acute ischemic stroke. Exclusion criteria: A history of acute ischemic stroke in the past 3 months; using heparin or warfarin in the past 48 hours; a history of head trauma in the past 3 months; a history of intra cranial hemorrhage; a history of myocardial infarction in the past 3 months; gastric hemorrhage in the past 3 months; a history of major surgery in the past 2 weeks; a history of convulsion. Intervention group: Routine treatment plus tissue plasminogen activator 0.9 mg/kg through intravenous infusion. Control group: Just routine treatment. Primary outcome: Assessing the neurological signs every 12 hours for 72 hours using NIHSS scale. Randomization: Random assignment of the patients to the intervention and control groups through drawing of lots. Blinding: Not possible.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201709049014N182**
Registration date: **2017-09-09, 1396/06/18**
Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2017-09-09, 1396/06/18

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan
University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

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

Expected recruitment start date

2017-09-23, 1396/07/01

Expected recruitment end date

2017-12-21, 1396/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of treatment with tissue plasminogen activator in improving clinical status of patients with acute ischemic stroke: a randomized clinical trial

Public title

Effect of treatment with tissue plasminogen activator in improving clinical status of patients with acute ischemic stroke

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Age of 18 to 85 years; acute ischemic stroke. Exclusion criteria: A history of acute ischemic stroke in the past 3 months; using heparin or warfarin in the past 48 hours; a history of head trauma in the past 3 months; a history of intra cranial hemorrhage; a history of myocardial infarction in the past 3 months; gastric hemorrhage in the past 3 months; a history of major surgery in the past 2 weeks; a history of convulsion.

Age

From **18 years** old to **85 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Randomization: Random assignment of the patients to the intervention and control groups through drawing of lots. Blinding: Not possible.

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 the Technology,
Hamadan University of Medical Sciences, Shahid
Fahmideh Ave

City

Hamadan

Postal code

Approval date

2017-09-02, 1396/06/11

Ethics committee reference number

IR.UMSHA.REC.1396.408

Health conditions studied

1

Description of health condition studied

Acute ischemic stroke

ICD-10 code

I63.9

ICD-10 code description

Cerebral infarction, unspecified

Primary outcomes

1

Description

Assessing the neurological signs

Timepoint

every 12 hours for 72 hours

Method of measurement

using NIHSS scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Routine treatment plus tissue plasminogen activator 0.9 mg/kg through intravenous infusion.

Category

Treatment - Drugs

2

Description

Control group: Just routine treatment.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Sina Hospital

Full name of responsible person

Ali Ghadimi Farah

Street address

Sina Hospital, Mirzadeh Eshghi Ave.

City

Hamadan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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

Full name of responsible person

Dr Saeid Bashirian

Street address

Hamadan University of Medical Sciences, Shahid
Fahmideh Ave

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Hamadan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice-chancellor for Research and Technology, Hamadan
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

Sina Hospital

Full name of responsible person

Ali Ghadimi Farah

Position

Medical Student

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Department of Epidemiology

Full name of responsible person

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Position

Associate Professor

Other areas of specialty/work

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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