

# 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 81 1838 0090

##### Email address

poorolajal@umsha.ac.ir

#### 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

**City**

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**

**Street address**

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## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Sina Hospital

**Full name of responsible person**

Dr Mojtaba Khazaei

**Position**

Neurologist

**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**

Dr Jalal Poorolajal

**Position**

Associate Professor

**Other areas of specialty/work**

**Street address**

School of Public Health, Hamadan University of  
Medical Sciences, Shahid Fahmideh Ave

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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*