

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jul 2026

The evaluation of effect of rTPA (recombinant tissue Plasminogen Activator) in clinical manifestations and prognosis of patients with ischemic stroke

Protocol summary

Study aim

The objective of this clinical trial is evaluation of the effect of rTPA (recombinant tissue Plasminogen Activator) in clinical manifestations and prognosis of patients with ischemic stroke

Design

In this study, all patients with ischemic stroke will be assigned into the study.

Settings and conduct

The National Institutes of Health Stroke Scale (NIHSS) will be used to evaluate the clinical manifestations of ischemic stroke. The patients will be followed up for 3 months. 0.9 mg/Kg intravenous rTPA will be administered for single dose. Before the intervention, the NIHSS questionnaire will be recorded then one day, three days, seven days and one month, two months, and three months after the intervention will be followed up respectively.

Participants/Inclusion and exclusion criteria

Inclusion criteria of the study is Ischemic stroke patients; Referring to the hospital less than 4.5 hours and Indication of rtPA injection. Exclusion criteria of the study is intracerebral hemorrhage (ICH); Subarachnoid hemorrhage (SAH); subdural hematoma (SDH); contraindications for rTPA; venous sinus thrombosis.

Intervention groups

0.9 mg/Kg intravenous rTPA will be administered for single dose.

Main outcome variables

The National Institutes of Health Stroke Scale (NIHSS) will be used to evaluate the clinical manifestations of ischemic stroke. Before the intervention, the NIHSS questionnaire will be recorded then one day, three days, seven days and one month, two months, and three months after the intervention will be followed up respectively.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160318027097N10**

Registration date: **2018-06-01, 1397/03/11**

Registration timing: **registered_while_recruiting**

Last update: **2018-06-01, 1397/03/11**

Update count: **0**

Registration date

2018-06-01, 1397/03/11

Registrant information

Name

Dr Faramarz Darghahi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 45 3351 2000

Email address

mj.naghizadeh@arums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-05-22, 1397/03/01

Expected recruitment end date

2018-09-23, 1397/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The evaluation of effect of rTPA (recombinant tissue Plasminogen Activator) in clinical manifestations and prognosis of patients with ischemic stroke

Public title

Effect of rTPA (recombinant tissue Plasminogen Activator) in patients with ischemic stroke

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with ischemic stroke Referring to the hospital less than 4.5 hours Indication of rtPA injection with no evidence of hemorrhage on the initial brain image

Exclusion criteria:

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Ardebil University of Medical Sciences

Street address

Ardabil University of Medical Sciences, Daneshgah Avenue, Ardabil, Iran

City

Ardebil

Province

Ardabil

Postal code

5163639888

Approval date

2017-08-13, 1396/05/22

Ethics committee reference number

IR.ARUMS.REC.1396.88

Health conditions studied

1

Description of health condition studied

Cerebellar stroke

ICD-10 code

G46.4

ICD-10 code description

Cerebellar stroke syndrome

Primary outcomes

1

Description

The stroke clinical manifestations

Timepoint

Before the intervention, 24 hours, 48 hours, 168 hours, 1 month, 2 months, 3 months after the intervention

Method of measurement

National Institutes Of Health Stroke Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Recombinant tissue Plasminogen Activator (rTPA), 0.9 mg/Kg, intravenous, Single dose

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Vice Chancellor for research of Ardebil University of Medical Sciences

Full name of responsible person

Dr Vahid Abbasi

Street address

Boali hospital, Daneshgah Avenue, Ardebil, Iran

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5163639888

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Email

naghizadeh73@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ardabil University of Medical Sciences

Full name of responsible person

Dr Vahid Abbasi

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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

Ardabil 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**

Ardabil University of Medical Sciences

Full name of responsible person

Dr Afshan Sharghi

Position

استادیار

Latest degree

Specialist

Other areas of specialty/work

Epidemiology

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Person responsible for scientific inquiries

Contact**Name of organization / entity**

Ardabil University of Medical Sciences

Full name of responsible person

Dr Vahid Abbasi

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Neurology

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Person responsible for updating data

Contact**Name of organization / entity**

Ardabil University of Medical Sciences

Full name of responsible person

Fateme Taghvatalab

Position

Medical student

Latest degree

Medical doctor

Other areas of specialty/work

Neurology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Total potential data after unidentifiable individuals

When the data will become available and for how long

Start the access period from 2021

To whom data/document is available

Researchers in academic and scientific institutions

Under which criteria data/document could be used

Data can be used for scientific and research studies.

From where data/document is obtainable

Fateme Taghvatalab; Medical student;
Naghizadeh73@yahoo.com

What processes are involved for a request to access data/document

After receiving the request email, data files will be sent in less than a week.

Comments