

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jun 2026

Study of the therapeutic effect of the combination of altplas and ibtifibatide (integrilin) in comparison with altplas (r-TPA) alone, in the treatment of acute ischemic stroke

Protocol summary

Study aim

Therapeutic effect of the combination of altplas and ibtifibatide (integrilin) in comparison with altplas (r-TPA) alone, in the treatment of acute ischemic stroke

Design

Clinical trial with control group, with parallel groups, randomized, phase 2 on 50 patients. Random blocks were used for randomization.

Settings and conduct

A clinical trial study on patients with symptoms of acute ischemic stroke in the first three hours that will be performed from the beginning to the end of 1400 in Beheshti Hospital in Hamadan. In patients receiving combination drug (intervention group) and altplas (control group) at the time of arrival and discharge, the severity of stroke is assessed by the NIHSS criterion and three months later by the MRS criterion the patients' mobility is assessed.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients should have a serious measurable neurological defect on the NIHSS stroke scale due to focal ischemia of the brain (NIHSS score > 5), Intravenous therapy should be started within 3 hours of the onset of stroke symptoms. Exclusion criteria: Suspect subarachnoid hemorrhage, even if the brain CT scan is normal.

Intervention groups

The intervention group consisted of patients receiving a combination of altplasa and ibtifibatide (integrillin) and the comparison group consisted of patients receiving altoplasia (r-TPA) alone. Next month, patients' mobility will be assessed by the MRS criterion.

Main outcome variables

Stroke severity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170117032025N9**

Registration date: **2021-04-07, 1400/01/18**

Registration timing: **prospective**

Last update: **2021-04-07, 1400/01/18**

Update count: **0**

Registration date

2021-04-07, 1400/01/18

Registrant information

Name

Arash Khalili

Name of organization / entity

Hamadan University Of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 81 3838 0320

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a.khalili@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-04-21, 1400/02/01

Expected recruitment end date

2022-03-20, 1400/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study of the therapeutic effect of the combination of altplas and ibtifibatide (integrilin) in comparison with altplas (r-TPA) alone, in the treatment of acute ischemic stroke

Public title

The therapeutic effect of the combination of altplas and ibtifibatide (integrilin) in comparison with altplas (r-TPA) alone, in the treatment of acute ischemic stroke

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients should have a serious measurable neurological defect on the NIHSS stroke scale due to focal ischemia of the brain (NIHSS score > 5). Intravenous therapy should be started within 3 hours of the onset of stroke symptoms.

Exclusion criteria:

Suspect subarachnoid hemorrhage, even if the brain CT scan is normal

Age

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

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

For randomization, we use the method of block randomization with blocks with size of 4 and for this purpose, we prepare four sheets of paper. On the two sheets we write the letter I meaning "Intervention" and on the other two sheets we write the letter S meaning "Standard treatment". Mix the sheets together and place them in the desk drawer. Upon referral to any of the eligible patients, one of the sheets will be randomly pulled out and based on this sheet being drawn I or S will be assigned to one of the two intervention or comparison groups.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Hamadan University of Medical Sciences

Street address

Hamadan University of Medical Sciences., Shahid Fahmideh Blvd

City

Hamadan

Province

Hamadan

Postal code

6517838689

Approval date

2021-03-10, 1399/12/20

Ethics committee reference number

IR.UMSHA.REC.1399.923

Health conditions studied

1

Description of health condition studied

Acute Ischemic Stroke

ICD-10 code

G46.4

ICD-10 code description

Cerebellar stroke syndrome

Primary outcomes

1

Description

Cerebral hemorrhage

Timepoint

Admission, discharge and three months later.

Method of measurement

By NIHSS(National Institutes of Health Stroke Scale) criteria

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In the group receiving the combination drug Altplase and Iftifibatide (Integrilin), Altplase ampoule is used only once and the dose of Altplase is 9 tenths of a milligram per kilogram, of which ten percent is bolus and the rest is injected within one hour. . Optifibatide ampoules are used only once, with a dose of optifibatid (integrilin) of 135 micrograms per kilogram, a bolus dose of 75 percent micrograms per

kilogram per minute, and a maintenance dose for two hours.

Category

Treatment - Drugs

2

Description

Control group: In the group receiving Altplase drug, Altplase ampoule is used only once and the dose of Altplase is 9 tenths of a milligram per kilogram, of which ten percent is bolus and the rest is injected within one hour.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti Hospital, Hamadan

Full name of responsible person

Dr Mahmood Behroozi

Street address

Hamadan University of Medical Sciences., Shahid Fahmideh Blvd

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6517838689

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+98 81 3838 0535

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behrouzi2012@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr Saeed Bashirian

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Hamadan University of Medical Sciences., Shahid Fahmideh Blvd

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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

Hamedan 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

Hamedan University of Medical Sciences

Full name of responsible person

Dr Mahmood Behroozi

Position

Neurology Resident

Latest degree

Medical doctor

Other areas of specialty/work

Neuroscience

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Person responsible for scientific inquiries

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Full name of responsible person

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Position

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Latest degree

Medical doctor

Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

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Full name of responsible person

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Position

Neurology Resident

Latest degree

Medical doctor

Other areas of specialty/work

Neuroscience

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City

Hamadan

Province**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available