

# 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 altplasia (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)

##### Phone

+98 81 3838 0320

##### Email address

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

**City**

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**Province**

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**Postal code**

6517838689

**Phone**

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**Email**

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

**Street address**

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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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**Contact**

**Name of organization / entity**

Hamedan University of Medical Sciences

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**Person responsible for updating data****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

**Street address**

Hamadan University of Medical Sciences., Shahid

Fahmideh Blvd

**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