

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation of the Edaravan Effect on the outcomes and oxidative stress parameters in patients with acute ischemic stroke: a clinical trial study

Protocol summary

Study aim

Determining the effect of Adaravan on clinical symptoms and oxidative factors of the disease in patients with acute ischemic stroke

Design

A clinical trial with the control group, with parallel groups, double-blind, randomized, phase 2 on 60 patients

Settings and conduct

This study is a randomized, double-blind clinical trial that will be performed on patients over 18 years of age with acute ischemic stroke admitted to Farshchian Sina Hospital in Hamadan.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Having focal neurological symptoms; Age over 18 years; Stroke approved by CT or MRI; Stroke severity by NIHSS criteria greater than 4 & etc. Exclude criteria: Brain tumor; Hemorrhagic and transient stroke; Breastfeeding and pregnancy conditions

Intervention groups

The dose of the drug and the duration of use in the study groups are as follows: In the intervention group: In addition to the standard treatment, a dose of Adaravan starts with a dose of 16 / ml per weight and continues with a dose of 4.4 ml per hour and lasts up to three The day goes on. In the standard treatment group: This group receives standard drug treatment and care plus placebo at the same time as the intervention group. Standard treatment refers to any treatment used in the acute phase of stroke, including thrombolytic or thrombectomy drugs or other antiplatelet or anticoagulant drugs.

Main outcome variables

Determining the effect of Adaravan on clinical symptoms and oxidative factors of the disease in patients with acute ischemic stroke

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210602051472N1**

Registration date: **2021-06-20, 1400/03/30**

Registration timing: **prospective**

Last update: **2021-06-20, 1400/03/30**

Update count: **0**

Registration date

2021-06-20, 1400/03/30

Registrant information

Name

Fatemeh saadatipour

Name of organization / entity

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-07-23, 1400/05/01

Expected recruitment end date

2021-11-22, 1400/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the Edaravan Effect on the outcomes and oxidative stress parameters in patients with acute ischemic stroke: a clinical trial study

Public title

Evaluation of the Edaravan Effect on the outcomes in patients with acute ischemic stroke

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Focal neurological symptoms due to cerebrovascular involvement in less than 24 hours Older age 18 years Stroke is approved by CT or MRI. The severity of the stroke should be greater than 4 by the NIHSS criteria and the patient's ability scale before the stroke should be less than 2. It should be noted that it is also injected at intensities higher than 24. The patient is inclined to enter the study

Exclusion criteria:

Hemorrhagic stroke Transient stroke Brain Tumor Inflammatory diseases and demyelinating brain History of craniotomy Previous severe brain trauma Liver and kidney failure Pregnancy and lactation Acute heart attack Allergy to the drug Adaravan

Age

From **18 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

For this purpose, we will use the quadruple block method (Block Randomization). For this purpose, we prepare four sheets of paper. On the two sheets we write the letter I meaning "Intervention" and on the two sheets the letter S means "Standard treatment". Mix the sheets together and place them in the desk drawer. With the referral of each eligible patient, one of the sheets will be randomly taken out and based on this extracted sheet will be assigned to one of the two intervention groups. It should be noted that the pulled out sheets will not be returned to the drawer until all four sheets have been pulled out. After randomly pulling out all four sheets, all sheets are returned to the drawer and the above procedure will be continued for the next four patients until the desired sample size is reached.

Blinding (investigator's opinion)

Double blinded

Blinding description

Given that the patient and the researcher will be unaware of the type of drug used. Therefore, the study will be conducted in a double-blind manner.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

دانشگاه علوم پزشکی همدان

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Fahmideh Blvd, Pajooohesh Square, Hamadan
University of Medical Sciences, Hamadan Town

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همدان

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Postal code

6516618697

Approval date

2021-04-10, 1400/01/21

Ethics committee reference number

IR.UMSHA.REC.1400.070

Health conditions studied

1

Description of health condition studied

acute ischemic stroke

ICD-10 code

I63

ICD-10 code description

Cerebral infarction

Primary outcomes

1

Description

Modified Rankin Score (MRS)

Timepoint

At the time of discharge and three months after the intervention

Method of measurement

The ability of patients, which is mainly assessed after 90 days by checklist.

2

Description

NIH Stroke Scale/Score (NIHSS)

Timepoint

At the time of discharge and three months after the intervention

Method of measurement

check list

3

Description

ESR measurement

Timepoint

At the time of discharge and three months after the intervention

Method of measurement

Blood Samples, Green Blot Method

4

Description

CRP Measurement

Timepoint

At the time of discharge and three months after the intervention

Method of measurement

Blood Samples, Immuno-agglutination Assay

Secondary outcomes

1

Description

Side effects of treatment

Timepoint

After discharge and three months after intervention

Method of measurement

checklist

Intervention groups

1

Description

Intervention group: In this group, in addition to standard treatment, a dose of Edaravan (Zist daroo danesh Company) starts with a dose of 0.16 ml per weight and continues with a dose of 4.4 ml per hour per hour and continues for three days. The method of choice is to inject 360 mg of Edaravan into the intervention group over three days, which is 120 mg daily, and the injection method is by infusion.

Category

Other

2

Description

Standard treatment group: This group receives pharmacological treatment (anti-platelet including aspirin 80 mg daily and thrombolysis including alteplase at a dose of 0.9 mg per body weight) and standard care plus placebo at the same time as the intervention group.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center**Name of recruitment center**

Farshchian Sina Hospital in Hamadan

Full name of responsible person

Dr. Fatemeh Saadatipour

Street address

Mirzadeh Eshghi Street, Jahad Sq, Hamadan Town,

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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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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
Fatemeh Saadatipour
Position
Resident
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Person responsible for updating data

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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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Individual data of study participants can be shared after identifying individuals

When the data will become available and for how long

Access period starts 6 months after the results are published

To whom data/document is available

For all researchers who send an email request to the author of the article.

Under which criteria data/document could be used

In addition to the above conditions, researchers who intend to study clinically in addition to the drug mentioned are allowed to submit a request for unidentified individual data.

From where data/document is obtainable

Responsible people including the corresponding author of the article or the scientific person in charge of the intervention: Dr.Mojtaba Khazaei; Neurologist and Assistant Professor. To the address of Hamadan city - Shahid Fahmideh Blvd- Hamadan University of Medical Sciences Postal code 6516618697 Phone +98 81 3838 0030 Mobile +98 918 150 1628 email khazaeimajtaba@yahoo.com.

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

After obtaining the necessary permits from the Deputy Minister of Research and Technology, it will take about a month.

Comments

Vice-Chancellor for Research and Technology of
Hamadan University of Medical Sciences Postal code

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