Clinical Trial Protocol
Iranian Registry of Clinical Trials

14 Jun 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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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 ain 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
Street address
Fahmideh Blvd, Pajoohesh Square, Hamadan University of Medical Sciences, Hamadan Town
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Province
Hamadan
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 altplase 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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Fahmideh Blvd, Pajoohesh Ave, Hamadan
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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

Latest degree
Medical doctor

Other areas of specialty/work
Neurology

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Person responsible for scientific inquiries

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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

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