Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Investigating the effect of boswellic acid on the clinical outcomes of patients with acute ischemic stroke

Protocol summary

Study aim
Investigating the effect of boswellic acid on the clinical outcomes of patients with acute ischemic stroke

Design
An open-label clinical trial that will be conducted on 70 acute ischemic stroke patients. Patients will be assign to one of the intervention or control groups using the block randomization method, based on the generated-computer numbers by the random allocation software.

Settings and conduct
In this study, patients patients with acute ischemic stroke admitted to Urmia Imam Khomeini Hospital will be enrolled. Patients will be randomly divided into two groups. Patients in the intervention group, in addition to routine stroke treatments that include anti-ischemic drugs, will receive oral boswellic acid 360 mg tablets from Gol Daru every 6 hours for one month. Routine stroke treatments will be performed in the control group. The study will be done without blinding.

Participants/Inclusion and exclusion criteria
In this study, 70 patients with acute ischemic stroke in the age range of 18 to 80 years and having a score of 5-21 based on NIHSS will be included. Patients with reduced level of consciousness will not be included in the study.

Intervention groups
Patients in the intervention group, in addition to routine stroke treatments that include anti-ischemic drugs, will receive oral boswellic acid 360 mg tablets from Gol Daru every 6 hours for one month. Routine stroke treatments will be performed in the control group.

Main outcome variables
Function score based on NIHSS; Inflammatory factors; CBC cell count including (RBC, WBC, Hb)

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20231015059724N1**
Registration date: **2023-10-24, 1402/08/02**
Registration timing: **prospective**

Last update: **2023-10-24, 1402/08/02**
Update count: **0**

Registration date
2023-10-24, 1402/08/02

Registrant information

Name
Rezvan Norouzzadeh

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 44 3198 8003

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norouzzadeh.r@umsu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-11-22, 1402/09/01

Expected recruitment end date
2024-02-19, 1402/11/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigating the effect of boswellic acid on the clinical outcomes of patients with acute ischemic stroke

Public title

Investigating the effect of boswellic acid in acute ischemic stroke patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with acute ischemic stroke Age between 18 and 80 years Hospitalization on the first day of symptoms A score between 5-21 before treatment based on the National Institutes of Health stroke scale (NIHSS)

Exclusion criteria:

Receiving alteplase or retplase in the hospital NIHSS score above 21 and loss of consciousness The presence of gastrointestinal complications that make it impossible to take drug.

Age

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

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be randomly assigned to one of the intervention or control groups using computer-generated numbers produced by the Random allocation software. Thus, in this software, the number of groups and the total sample size will be entered, and then the "randomization" will be implemented in the block section. Then, the computer-generated number list will be given to the physician, and the physician will assign patients to groups according to the determined order by the software for entry into one of the groups. Thus, the randomization process will continue until the final sample size is reached.

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 Imam Khomeini University hospital- Urmia University of Medical Sciences

Street address

Imam Khomeini hospital, Ershad Ave, Modarres Blvd, Urmia, Iran.

City

Urmia

Province

West Azarbaijan

Postal code

57157-89397

Approval date

2023-05-14, 1402/02/24

Ethics committee reference number

IR.UMSU.HIMAM.REC.1402.032

Health conditions studied

1

Description of health condition studied

Acute ischemic stroke

ICD-10 code

8B11

ICD-10 code description

Cerebral ischemic stroke

Primary outcomes

1

Description

Function score based on NIHSS

Timepoint

The first day of hospitalization (before the intervention) and one month after the intervention

Method of measurement

NIHSS questionnaire

2

Description

Erythrocyte sedimentation rate (ESR)

Timepoint

The first day of hospitalization (before the intervention) and one month after the intervention

Method of measurement

Laboratory kit based on the Westergren test

3

Description

C-reactive protein (CRP)

Timepoint

The first day of hospitalization (before the intervention) and one month after the intervention

Method of measurement

Laboratory kit based on agglutination test

4

Description

White blood cell count (WBC)

Timepoint

The first day of hospitalization (before the intervention)

and one month after the intervention

Method of measurement

Cell counter

5

Description

Red blood cell count (RBC)

Timepoint

The first day of hospitalization (before the intervention) and one month after the intervention

Method of measurement

Cell counter

6

Description

Hemoglobin (Hb)

Timepoint

The first day of hospitalization (before the intervention) and one month after the intervention

Method of measurement

Cell counter

Secondary outcomes

1

Description

Complications

Timepoint

One month after the intervention

Method of measurement

Physical examination

Intervention groups

1

Description

Intervention group: Patients in the intervention group, in addition to routine stroke treatments that include anti-ischemic drugs, will receive oral boswellic acid 360 mg tablets from Gol Daru every 6 hours for one month.

Category

Treatment - Drugs

2

Description

Control group: In the control group, routine stroke treatments including anti-ischemic drugs will be performed.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Urmia Imam Khomeini hospital

Full name of responsible person

Dr. Rezvan Norouzzadeh

Street address

Imam Khomeini hospital, Ershad Ave, Modarres Blvd, Urmia, Iran.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Dr.Saber Gholizadeh

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Urmia University of Medical Sciences, Resalat Ave, Jahad Blvd, Urmia, Iran.

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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

Oroumia 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

Oroumia University of Medical Sciences

Full name of responsible person
Dr.Rezvan Norouzzadeh

Position
Assistant professor

Latest degree
Specialist

Other areas of specialty/work
Neuroscience

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

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
Not applicable

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
The results of the study will be published as an article.

When the data will become available and for how long
After publishing the article

To whom data/document is available
Researchers

Under which criteria data/document could be used
The results will be published as an article and the data will not be published.

From where data/document is obtainable
Corresponding author (Dr. Rezvan Norouzzadeh) and with the email address: norouzzadeh.r@umsu.ac.ir

What processes are involved for a request to access data/document
By email address of the corresponding author:norouzzadeh.r@umsu.ac.ir

Comments