Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Jun 2026

Comparison of the effect of achillea millefolium on disability and functional state of ischemic stroke patients, A clinical trial study

Protocol summary

Study aim
Effect of achillea supplement on disability, quality of life and performance of patients with ischemic stroke

Design
A clinical trial with a control group and an intervention group, three blind, randomized, phase 3 on 110 patients. Web-based software is used for randomization.

Settings and conduct
Eligible stroke patients referred to the emergency room of Ali Ibn Abi Talib Hospital with full consent were included in the study and randomly divided into two groups of 55 people, intervention and placebo. The routine treatment of patients by the doctor during the period of taking the supplement goes through its normal process. Our treatment continues for three months, one capsule daily. The tests are done before and after the intervention (3 months later).

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age above 18 years Informed consent of the patient or relatives 1st degree Have had an ischemic stroke for the first time do not have NIHSS above twenty-five. ability to swallow Exclusion criteria: Use of Alteplase in treatment Patients with skin allergies Patients who are pregnant or plan to become pregnant or decide to breastfeed.

Intervention groups
The first group = capsules containing 500 mg of water yarrow extract. The second group = receive placebo capsules containing cellulose.

Main outcome variables
NIHSS = score of disability in stroke patients (0-42) before and after the intervention, mRs = a functionals score for stroke patients (0-6) before and after the intervention, Stroke Specific quality of life before and after the intervention

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190129042540N2**
Registration date: **2023-04-26, 1402/02/06**
Registration timing: **registered_while_recruiting**

Last update: **2023-04-26, 1402/02/06**
Update count: **0**

Registration date
2023-04-26, 1402/02/06

Registrant information

Name
Alireza Vakilian

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 34 3428 9393

Email address
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-04-21, 1402/02/01

Expected recruitment end date
2024-04-20, 1403/02/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effect of achillea millefolium on disability and functional state of ischemic stroke patients, A clinical trial study

Public title
Effect of achillea Mellifolium in Ischemic Stroke
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
ischemic stroke for the first time satisfy to participate nihss less than 25 age more than 18
Exclusion criteria:
The use of alteplase in treatment impaired swallowing pregnancy or intend to be pregnant using other herbal medicine allergy to achillea millefolium
Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **110**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization was done using free web-based systems.
Blinding (investigator's opinion)
Triple blinded
Blinding description
Participants do not know which drug is placebo and which is the main drug. The follower of drug prescription and the examiner of the results of function and quality of life are unaware of the type of drug.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Rafsanjan University of Medical Sciences Ethics committee
Street address
Imam Ali boulevard
City
Rafsanjan
Province
Kerman
Postal code
7717937555
Approval date
2022-12-06, 1401/09/15
Ethics committee reference number
IR.RUMS.REC.1401.206

Health conditions studied

1

Description of health condition studied
Ischemic stroke
ICD-10 code
I63
ICD-10 code description
Cerebral infarction

Primary outcomes

1

Description
disability scale
Timepoint
First and 3 months later
Method of measurement
Questionnaire of NIHS

Secondary outcomes

1

Description
functional state
Timepoint
First and 3 months later
Method of measurement
Questionnaire of Modified Rankin Scale (mRS)

Intervention groups

1

Description
Treatment group: Stroke patients are randomly assigned to the treatment group. People in this group receive yarrow capsules. Capsules in a dose of 500 mg are prepared from the aqueous extract of flowering branches and yarrow leaves. First, the plant is purchased from the Isfahan herbarium after the herbarium expert confirms the species. Then it is cleaned, thoroughly washed, and dried in a cool and dark place. The capsules are extracted and prepared at Barich Essence pharmaceutical company (4 grams of plant powder is brewed in 200 ml of distilled water for 20 minutes and then the extract is separated and dried). Patients take one capsule daily, preferably with food, for 3 months. Achillea extract has anti-inflammatory and neuroprotective properties due to the presence of apigenin and luteolin and improves CNS function. So far, the effects of this medicinal plant have been studied on

MS and several other inflammatory diseases , but it has not been studied on stroke.

Category

Treatment - Drugs

2

Description

Control group: Control group: The other group of cerebral ischemia stroke patients randomly use cellulose capsules made by Barij Essan company with the same shape and weight as the drug for three months.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Ali-Ibn-Abitalib Hospital

Full name of responsible person

Alireza Vakilian

Street address

No 13. 4th Alley,Emam Ave.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rafsanjan University of Medical Sciences

Full name of responsible person

Reza Vazirinejad

Street address

Central Organization, Imam Ali Boulevard, Rafsanjan

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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

Rafsanjan 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

Rafsanjan University of Medical Sciences

Full name of responsible person

Alireza Vakilian

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Neurology

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Person responsible for scientific inquiries

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Full name of responsible person

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Latest degree

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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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All the data obtained in the study will be made available to the public after being de-identified through the writing of the article.

When the data will become available and for how long

The data will be published after the conclusion of the research plan and the statistical analysis of the findings and the preparation of the results in about two years.

To whom data/document is available

The data does not belong to specific people and the results are available to the public.

Under which criteria data/document could be used

There is no special condition for using the data and the public can use the results.

From where data/document is obtainable

The data will be published as an article, and if needed, it will be available through correspondence with the corresponding author's email.

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

The applicant can contact the corresponding author via email and send a request for access to the results

Comments