

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jun 2026

Investigating the effectiveness of saffron medicine on the prognosis of ischemic CVA patients with NIHSS less than 15

Protocol summary

Study aim

Determining the effect of saffron medicine on prognosis in patients with ischemic stroke for timely treatment and reducing side effects caused by stroke.

Design

A clinical trial with a control group, with parallel groups. No blinding. Phase 3 was randomized on 72 patients and a balanced block was used for randomization

Settings and conduct

It is an intervention and randomized controlled clinical trial study. The sample size is 72 people. Patients with acute cerebral stroke in the special care department of Shahid Beheshti Hospital, Qom and after obtaining written consent, were divided into two groups by randomization using the block randomization method: The first group includes 37 patients who, in addition to the usual treatment in the intensive care unit, will receive 30 mg of saffron capsules daily (15 mg twice a day) for 30 days. The second group of 37 patients will receive only routine care

Participants/Inclusion and exclusion criteria

Inclusion: Age over 18 years - GCS less than equal to ten Patients without coagulation disorders and absence of coagulation or platelet disorders at the time of admission NIHSS less than 15, Not allergic to saffron! Exclusion: Liver disorder, kidney disorder, fever, convulsions

Intervention groups

Intervention group: including 37 patients who will receive 30 mg of saffron capsules (15 mg twice a day) for 30 days in addition to the usual treatment in the intensive care unit. Control group: 37 patients who will receive only usual care

Main outcome variables

level of consciousness

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230715058781N1**

Registration date: **2023-07-17, 1402/04/26**

Registration timing: **prospective**

Last update: **2023-07-17, 1402/04/26**

Update count: **0**

Registration date

2023-07-17, 1402/04/26

Registrant information

Name

somayeh mehrpour

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 25 3612 2000

Email address

somayeh.mehrpour@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-09-23, 1402/07/01

Expected recruitment end date

2024-02-20, 1402/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effectiveness of saffron medicine on the prognosis of ischemic CVA patients with NIHSS less than 15

Public title

Investigating the effect of saffron on the consciousness of stroke patients

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients with ischemic stroke

Exclusion criteria:

Coagulation disorders

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **74**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are divided into two groups using the randomized balanced block method with block sizes of 4 and 6. The random sequence is generated by an epidemiologist by running an online program on the website (<https://www.sealedenvelope.com>). Allocation concealment is also guaranteed due to the use of special codes generated by the website

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**

Research Ethics Committees of Qom University of Medical Sciences

Street address

No. 83, Shahid Lotfi Niaser Ave, Safashehr Blvd

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Province

Ghoum

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3719964797

Approval date

2023-05-15, 1402/02/25

Ethics committee reference number

IR.MUQ.REC.1402.074

Health conditions studied**1****Description of health condition studied**

cerebrovascular accident

ICD-10 code

G46.4

ICD-10 code description

Cerebellar stroke syndrome

Primary outcomes**1****Description**

level of consciousness

Timepoint

arrival; hospitalization time; while receiving medication

Method of measurement

Glasgow coma scale

Secondary outcomes**1****Description**

Length of hospitalization

Timepoint

The time of the patient's discharge from the hospital

Method of measurement

National Institutes Of Health Stroke Scale

Intervention groups**1****Description**

Intervention group: Including 37 patients who will receive 30 mg of saffron capsules from Duralife -Faran Chemi Pharmaceutical Company (15 mg twice a day) for 30 days orally in addition to the usual treatment(including anti platelet, statin, blood sugar and blood pressure control) in the intensive care unit.

Category

Treatment - Drugs

2**Description**

Control group: 37 patients who will receive only routine care(including anti platelet, statin, blood sugar, and blood pressure control.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Beheshti Hospital

Full name of responsible person

Somayeh Mehrpour

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ghous University of Medical Sciences

Full name of responsible person

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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

Ghous 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**

Ghous University of Medical Sciences

Full name of responsible person

Somayeh Mehrpour

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

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Latest degree

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Latest degree

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Other areas of specialty/work

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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

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

Statistical Analysis Plan

Not applicable

Informed Consent Form

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

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable