

# 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

**City**

Qom

**Province**

Ghoush

**Postal code**

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

**Street address**

Beheshti Hospital, Beheshti Blvd, Qom, Iran

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**Phone**

+98 25 3612 2000

**Email**

somayeh.mehrpour@gmail.com

### Sponsors / Funding sources

## 1

### Sponsor

**Name of organization / entity**

Ghous University of Medical Sciences

**Full name of responsible person**

Rahim Aali

**Street address**

No. 83, Shahid Lotfi Niaser Ave, Safashehr Blvd

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rahimalii@yahoo.com

**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**

Anesthesiology

**Street address**

Beheshti Hospital

**City**

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**Province**

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**Postal code**

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### Person responsible for scientific inquiries

**Contact****Name of organization / entity**

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**Position**

Assistant professor

**Latest degree**

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**Other areas of specialty/work**

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### Person responsible for updating data

**Contact****Name of organization / entity**

Ghous University of Medical Sciences

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Assistant Professor

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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