

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

The effect of aqueous extract of saffron on antioxidant defense system in stroke patients

Protocol summary

Study aim

The current study aimed at proving or rejecting the neuroprotective hypothesis of saffron in stroke patients.

Design

All patients with ischemic stroke will be randomly divided into the control and saffron groups. In this study, blindness is not performed. Finally, 60 patients will be selected.

Settings and conduct

Patients with ischemic stroke are studied, who are referred to Emergency Hospital of Imam Hossein (AS) and admitted in the department of neurology. The demographic data of all patients will be recorded in the form presented in the appendix. Neurological examinations will be carried out daily on the days of hospitalization. The NIHSS of the patients of both groups will be calculated and recorded in two times, the first and forth day. Blood samples will be also taken to measure oxidative stress biomarkers in the morning of the first day of admission before taking medication and in the morning of the forth day (discharge).

Participants/Inclusion and exclusion criteria

In this randomized clinical trial, patients with ischemic stroke in the Middle Cerebral Artery range with NIHSS: 5-20 have been referred to Emergency Hospital of Imam Hossein Hospital and admitted to the department of neurology.

Intervention groups

The case group will receive the capsules containing aqueous extract of saffron with a dose of 200 mg twice per day plus a routine regimen of cerebral ischemic stroke (including an antiplatelet or anticoagulant drug with atorvastatin) during the four days of hospitalization after the stroke. The control group will only take the mentioned routine pharmaceutical regimen.

Main outcome variables

Ischemic stroke; Saffron; NIHSS; oxidative stress

General information

Reason for update

The plan expanded to measure new oxidative stress biomarkers. Therefore, these biomarkers will be measured in serum prepared from stroke patients.

Acronym

IRCT registration information

IRCT registration number: **IRCT20180806040716N1**

Registration date: **2018-10-24, 1397/08/02**

Registration timing: **retrospective**

Last update: **2020-05-01, 1399/02/12**

Update count: **1**

Registration date

2018-10-24, 1397/08/02

Registrant information

Name

Gila Pirzad Jahromi

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-12-16, 1396/09/25

Expected recruitment end date

2018-07-16, 1397/04/25

Actual recruitment start date

2017-12-16, 1396/09/25

Actual recruitment end date

2018-07-16, 1397/04/25

Trial completion date

2018-08-16, 1397/05/25

Scientific title

The effect of aqueous extract of saffron on antioxidant defense system in stroke patients

Public title

The evaluation of saffron effect in patients with stroke

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

All patients with ischemic stroke (NIHSS Score: 5-20) who have had brain trauma for less than 24 hours, whose stroke has been defined within the range Middle Cerebral Artery (MCA) based on clinical examination and brain imaging (CT scan or MRI) and who are admitted to the Neurology or Emergency Department of Imam Hossein Hospital could be entered into the study.

Exclusion criteria:

Intolerance to the drug Hemorrhagic stroke NIHSS > 20 during hospitalization Acute and chronic renal failure (renal failure, stages 4 and 5) Acute failure or acute liver disease (Stage B and C failure) A history of disability before the current stroke Acute ischemic heart disease during the last 48 hours A history of Alzheimer's disease or other types of dementia History of receiving drugs that have neuroprotective properties for the last 6 months Thrombolysis (tPA) CNS tumor A recent trauma to the head

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 60

Actual sample size reached: 50

Randomization (investigator's opinion)

Randomized

Randomization description

Simple Randomization

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Baqiyatallah University of Medical Sciences

Street address

Baqiyatallah University of Medical Sciences, Vanak Sq., Molla-Sadra street

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Postal code

14359-16471

Approval date

2018-05-14, 1397/02/24

Ethics committee reference number

IR.BMSU.REC.1397.028

Health conditions studied

1

Description of health condition studied

Ischemic stroke

ICD-10 code

G46.3*

ICD-10 code description

Brain stem stroke syndrome

Primary outcomes

1

Description

National Institutes of Health Stroke Scale (NIHSS) is a questionnaire based on an examination to estimate the severity of stroke. Cellular enzymatic and non-enzymatic antioxidant defense system include superoxide dismutase (SOD), catalase (CAT), glutathione S-transferase (GST), glutathione peroxidase (GPx) and glutathione reductase (GR) and GSH, which act as free radical scavenger. Malondialdehyde (MDA) is an end-product of lipid peroxidation, which occurs due to the oxidation of polyunsaturated fatty acid side chains of membranes leading to a change in their functional properties level. Measurement of total antioxidant capacity (TAC) evaluates the efficiency and ability of all antioxidants present in biological fluids to protect against oxidative damage to membranes and other cellular components.

Timepoint

The first day of hospitalization and the fourth day of admission to the hospital.

Method of measurement

NIHSS scale: questionnaire, Oxidative stress biomarkers including SOD, CAT, GST, GPx and GR activities, GSH, TAC and MDA levels will be measured by biochemical methods manually or using kits.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: They will receive capsules containing aqueous extract of saffron with a dose of 200 mg twice per day in the acute stroke phase (the first 4 days in which the patient is admitted) along with a routine regimen of ischemic stroke (including antiplatelet or anti-coagulant medication plus atorvastatin). In order to prepare the capsules, Saffron stigmas were purchased from Talakaran-e-Mazraeh Co., (Torbat-Heydarieh, South Khorasan, Iran) and delivered to the Niak Darou Co., Tehran, Iran for aqueous extraction. The extract was then enrolled in the capsules containing 50 mg of saffron extract. The analysis of the extract showed that it contains 20% crocin, which was used as the base for filling capsules.

Category

Treatment - Drugs

2

Description

Control group: this group will only take the routine pharmaceutical regimen. The routine regimen of ischemic stroke is including antiplatelet or anti-coagulant medication plus atorvastatin.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

The neurology department of Imam Hussein Hospital

Full name of responsible person

Mostafa Asadollahi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

Bagheiat-allah 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

Tehran University of Medical Sciences

Full name of responsible person

Mostafa Asadollahi1

Position

Non-faculty specialist

Latest degree

Specialist

Other areas of specialty/work

Others

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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

Yes - There is a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be 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

Data can be shared after making the participants unidentifiable.

When the data will become available and for how long

Available 6 months after printing the results.

To whom data/document is available

The researchers working in the academic and scientific institutes and pharmacies.

Under which criteria data/document could be used

In order to produce medicine and write overview articles

From where data/document is obtainable

Gila Pirzad Jahromi Neuroscience Research Centre, Baqiyatallah University of Medical Sciences, Nosrati Alley, Sheikh Bahayi Ave, Mulla Sadra St, Vanak Square, POBox: 19568-37173 Telephone: 00982188620817 Email: g_pirzad_jahromi@yahoo.com Cell Phone: 98-912-509-0473

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

Request by phone or email

Comments