Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Determining the effect of saffron extract on the level of consciousness, cognitive function, and serum antioxidant capacity in patients with traumatic brain injury: A double-blind controlled randomized clinical trial

Protocol summary

Study aim

Determining the effect of Saffron Extract on the level of consciousness, cognitive function and serum antioxidant capacity in patients with traumatic brain injury

Design

This study is a double-blind controlled randomized clinical trial that is conducted in parallel mode. The number of samples was calculated at 21 people in each group.

Settings and conduct

The research setting is the Intensive Care Unit and Neurosurgery Center of Imam Reza Hospital affiliated with Tabriz University of Medical Sciences.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Hospitalization for fewer than 3 days, age range between 18 and 65 years, patients with moderate to sever traumatic brain injury based on GCS index (9-15), no record of delirium, dementia, and hospitalization in psychiatric hospitals or centers, There is no record of active bleeding or coagulation disorders or allergies to saffron. Exclusion criteria: Children and elderly with traumatic brain injury, patients with severe traumatic brain injury, any record of non-traumatic cerebral hemorrhage, and decreased level of consciousness due to metabolic disorders.

Intervention groups

Patients in the first intervention group are given saffron hydroalcoholic extract syrup (100 mg per day) for 10 days. Patients in the second intervention group receive a hydroalcoholic extract of saffron along with rose water and sugar, at a dose of 100 milligrams of saffron per day, for 10 days.

Main outcome variables

Consciousness level and cognitive function of patients with traumatic brain injury

General information

Reason for update

Because patients with mild traumatic brain injury have a short hospital stay and it was not possible to perform the intervention for 10 days, these patients were excluded from the inclusion criteria of the study and patients with moderate to severe injury according to the Glasgow Coma Scale (GCS = 3-12) were included in the study. Also, due to the low prevalence of patients with traumatic brain injury in Torbat Heydariyeh, the location of the study was changed to Tabriz due to the larger number of patients and greater cooperation in the research environment.

Acronym

IRCT registration information

IRCT registration number: **IRCT20131204015649N5**
Registration date: **2023-05-18, 1402/02/28**
Registration timing: **prospective**

Last update: **2025-09-05, 1404/06/14**
Update count: **1**

Registration date

2023-05-18, 1402/02/28

Registrant information

Name
Mohammad Eghbali
Name of organization / entity
Torbat Heydariyeh University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 51 5242 1257
Email address
m-eghbali@alumnus.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date
2024-02-01, 1402/11/12
Expected recruitment end date
2024-11-01, 1403/08/11
Actual recruitment start date
2024-02-01, 1402/11/12
Actual recruitment end date
2024-11-01, 1403/08/11
Trial completion date
2025-11-22, 1404/09/01

Scientific title
Determining the effect of saffron extract on the level of consciousness, cognitive function, and serum antioxidant capacity in patients with traumatic brain injury: A double-blind controlled randomized clinical trial

Public title
Effectiveness of saffron extract on the level of consciousness, cognitive function, and serum antioxidant capacity in patients with traumatic brain injury
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Hospitalization for fewer than 3 days Age range between 18 and 65 years Patients with moderate to sever traumatic brain injury based on GCS index (3-12) No record of delirium, dementia, and hospitalization in psychiatric hospitals or centers No record of active bleeding or coagulation disorders, No record of allergies to saffron.
Exclusion criteria:
Children and elderly with traumatic brain injury Patients with severe traumatic brain injury Any record of non-traumatic cerebral hemorrhage Decreased level of consciousness due to metabolic disorders
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size
Target sample size: **63**
Actual sample size reached: **63**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomized block design (based on triple block size) was used for randomization. The random sequence was proposed by a statistical expert; then, appropriate software was employed accordingly. Overall, 21 blocks of three were prepared, and then the samples were assigned to three groups
Blinding (investigator's opinion)
Double blinded
Blinding description
In this study, the corresponding researcher produces syrups containing saffron extract and identical placebo in similar cans. These cans are labeled as 1, 2, and 3. Thus, none of the participants, university researchers, hospital personnel, data collectors, or data analysts was informed whether the cans contain saffron or the placebo
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committees of School of Medicine-Tehran University of Medical Sciences
Street address
Secretariat of Ethics Committee in Biomedical Research, University of Tehran, Keshavarz Blvd., Intersection of Quds St., Central Building, Tehran University of Medical Sciences, 6th Floor
City
Tehran
Province
Tehran
Postal code
1417653761
Approval date
2023-04-11, 1402/01/22
Ethics committee reference number
IR.TUMS.MEDICINE.REC.1402.036

Health conditions studied

1

Description of health condition studied
Patients with traumatic brain injury
ICD-10 code
S06.9
ICD-10 code description
Unspecified intracranial injury

Primary outcomes

1

Description
Level of consciousness
Timepoint

Daily for 10 consecutive days

Method of measurement

Glasgow Coma Scale

2

Description

Cognitive Function

Timepoint

Daily for 10 consecutive days

Method of measurement

Rancho Los Amigos Level of Cognitive Functioning Scale

Secondary outcomes

1

Description

Total activities of serum antioxidant

Timepoint

Before the intervention and after 10 days

Method of measurement

The superoxide dismutase (SOD) serum activity was measured based on controlling the reduction of nitro-blue tetrazolium by the superoxide at 560 nm. The catalase (CAT) activity was determined by monitoring the initial rate of disappearance of H2O2 at 240 nm. Glutathione S-transferase (GST) activity was assayed based on monitoring the formation of the thioether product of the reaction between glutathione (GSH) and 1-chloro-2, 4-dinitrobenzene at 340 nm. GSH level was performed at 412 nm by the use of 5, 5’-dithiobis 2-nitrobenzoic acid. Serum glutathione peroxidase (GPx) and glutathione reductase (GR) activities were determined based on the decrease in absorbance of NADPH at 340 nm. The total antioxidant capacity (TAC) was measured by ferric reducing/antioxidant power (FRAP) method using commercially available kit. Malondialdehyde (MDA) level, as an indicator of lipid peroxidation, was measured as a result of condensation with thiobarbituric acid at 532 nm.

Intervention groups

1

Description

Patients in the first intervention group are given saffron hydroalcoholic extract syrup (100 mg per day) for 10 days.This product will be produced by the School of Persian Medicine, Department of Traditional Pharmacy.

Category

Treatment - Other

2

Description

Patients in the second intervention group receive a hydroalcoholic extract of saffron along with rose water and sugar, at a dose of 100 milligrams of saffron per day, for 10 days. This product will be produced by the School of Persian Medicine, Department of Traditional Pharmacy.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Intensive Care Unit and Neurosurgery departments of Imam Hossein hospital

Full name of responsible person

Mohammad Eghbali

Street address

Imam Hossein Hospital, Torbat-e-Heydariyeh, Torbat-e-Heydariyeh-Mashhad Road, 5th kilometer

City

Torbat-e Heydarieh

Province

Razavi Khorasan

Postal code

9519140001

Phone

+98 51 5242 0000

Fax

+98 51 5242 0244

Email

Eghbali.msn@gmail.com

Web page address

https://ihh.thums.ac.ir/

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Akbar Fotouhi

Street address

6th floor, Central Building of Tehran University of Medical Sciences, Qods St., Keshavarz St., Tehran

City

Tehtan

Province

Tehran

Postal code

1417653761

Phone

+98 21 8163 3658

Email

vcr@sina.tums.ac.ir

Web page address

https://vcr.tums.ac.ir/

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tehran 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

Torbate-Heidaria University of Medical Sciences

Full name of responsible person

Mohammad Eghbali

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Razi St, Torbat-e-Heydariyeh University of Medical Sciences, Torbat-e-Heydariyeh

City

Torbat-e Heydariyeh

Province

Razavi Khorasan

Postal code

9619633787

Phone

+98 51 5222 9202

Email

eghbali.msn@gmail.com

Web page address

https://snm.thums.ac.ir/

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Roja Rahimi

Position

Professor of Traditional Pharmacy

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

Street address

No. 67, corner of West Jamali Alley, Vafamanesh Street, Heravi Square

City

Tehran

Province

Tehran

Postal code

1416663361

Phone

+98 21 8897 4535

Fax

+98 21 8899 1829

Email

rojarahimi@gmail.com

Web page address

http://spm.tums.ac.ir/contact-us.html

Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Roja Rahimi

Position

Professor of Traditional Pharmacy

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

Street address

No. 67, Harvi Square, vafamanesh Street, corner of West Jamali Street

City

Tehran

Province

Tehran

Postal code

1416663361

Phone

+98 21 8897 4535

Email

rojarahimi@gmail.com

Web page address

http://spm.tums.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Currently, no decision has been made in this regard by the team

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available