# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

22 Nov 2026

## Efficacy of Spirulina Supplementation on Glasgow Outcome ScaleExtended in Patients with Moderate to Severe Traumatic Brain Injury a double-blind, randomized controlled clinical trial

## Protocol summary

**Study aim**

Determining the Effect of Spirulina Supplementation on the Extended Glasgow Outcome Scale in Patients with Moderate to Severe Traumatic Brain Injury

**Design**

This is a randomized, double-blind, parallel-group, phase 3 clinical trial involving 130 patients. Randomizer.org is used for randomization.

**Settings and conduct**

The study is being conducted in Shiraz at Emtiaz Hospital, the trauma center for Fars Province. In this study, the person enrolling patients, the clinical staff, the person assessing the study outcomes, and the statistician are all blinded to the participants' group assignments.

**Participants/Inclusion and exclusion criteria**

Study inclusion criteria: 1) Glasgow Coma Scale (GCS) score of less than 13 upon admission 2) Abbreviated Injury Scale (AIS) score greater than 3 for the head region and less than 3 for other body regions 3) Age between 15 and 65 years. study exclusion criteria: 1) History of significant brain injuries, including stroke or prior craniotomy 2) pregnancy or breast feeding 3) Occurrence of cardiorespiratory arrest upon arrival 4) Patients with critical traumatic brain injury (TBI) with a GCS score of 3 or 4, accompanied by fixed, dilated pupils. 5) INR more than 1.4 on admission.

**Intervention groups**

The intervention group receives a 9-gram dose of Spirulina solution once daily for 14 days or until discharge. Administration begins on the first day following the initiation of enteral feeding in the ICU, delivered either orally or via nasogastric (NG) tube, depending on the patient's condition. control group receives a solution with identical color, viscosity and weight to spirulina solution, once a day for 14 days or until discharge, orally or via NG tube.

**Main outcome variables**

glascow outcome scale extended , length of ICU hospitalization , length of whole hospitalization , amount of weight gain

## General information

**Reason for update**

**Acronym**

SSS

**IRCT registration information**

IRCT registration number: **IRCT20220220054079N2**
Registration date: **2026-11-14, 1405/08/23**
Registration timing: **registered_while_recruiting**

Last update: **2026-11-14, 1405/08/23**
Update count: **0**

**Registration date**

2026-11-14, 1405/08/23

**Registrant information**

**Name**

Zahra Eghlidos

**Name of organization / entity**

**Country**

Iran (Islamic Republic of)

**Phone**

+98 71 3622 4078

**Email address**

eghlidos.zahra@gmail.com

**Recruitment status**

**recruiting**

**Funding source**

**Expected recruitment start date**

2026-10-23, 1405/08/01

**Expected recruitment end date**

2027-12-22, 1406/10/01

**Actual recruitment start date**
empty
**Actual recruitment end date**
empty
**Trial completion date**
empty

**Scientific title**
Efficacy of Spirulina Supplementation on Glasgow Outcome ScaleExtended in Patients with Moderate to Severe Traumatic Brain Injury a double-blind, randomized controlled clinical trial

**Public title**
The Effect of Spirulina Supplementation on Traumatic Brain Injury
**Purpose**
Treatment
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
age 15-65 years old GCS on admission less than 13 AIS more than 3 in head and less than 3 in other areas
**Exclusion criteria:**
GCS 3-4 with fixed dilated pupils history of significant brain damage like CVA or craniotomy history of rheumatologic and autoimmune disorders pregnancy of breast feeding cardiac arrest on admission Plt count less than 100,000 on admission INR more than 1.4 on admission drug history of current antiplatelet therapy like ASA, Clopidogrel, ticagrelor
**Age**
From **15 years** old to **65 years** old
**Gender**
Both

**Phase**
3
**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

**Sample size**
Target sample size: **130**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
Following enrollment, participants are assigned to either the intervention or control group at a 1:1 ratio using block randomization. The randomization sequence is generated and maintained by a second study coordinator—who has no role in patient assessment, data collection, or statistical analysis—using the Randomizer.org website. To ensure allocation concealment, group assignment codes (A and B) are placed in opaque, sealed, and sequentially numbered envelopes; this information is disclosed only to a designated staff member who is not involved in treatment, outcome assessment, or data analysis. This individual is responsible for preparing and administering the intervention to the patient. The Spirulina supplement and the placebo are provided in containers that are identical in shape, size, and appearance, distinguished solely by codes A and B; consequently, patients, healthcare staff, outcome assessors, and the data analyst remain unaware of group assignments, thereby fully maintaining the study's double-blind design. Ultimately, 65 patients will be enrolled in each group.
**Blinding (investigator's opinion)**
Double blinded
**Blinding description**
To maintain allocation concealment, following the generation of a randomization sequence using block randomization, group allocation codes (A and B) were placed in opaque, sealed, and numbered envelopes by an independent individual who was not involved in treatment, outcome assessment, or data analysis. The Spirulina supplement and placebo were prepared in identical containers and labeled solely with codes A and B; consequently, patients, healthcare staff, outcome assessors, and the data analyst remained unaware of the group allocations, ensuring the study's double-blind design was fully maintained.
**Placebo**
Used
**Assignment**
Parallel
**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**
**Name of ethics committee**
Ethics Committee of Shiraz University of Medical Sciences
**Street address**
Shiraz Medical School, Imam Hossein Square, Zand Street, Shiraz
**City**
Shiraz
**Province**
Fars
**Postal code**
7134845794
**Approval date**
2026-09-07, 1405/06/16
**Ethics committee reference number**
IR.SUMS.MED.REC.1405.243

## Health conditions studied

### 1

**Description of health condition studied**
Brain injury
**ICD-10 code**
S06.2

**ICD-10 code description**
Diffuse traumatic brain injury

## Primary outcomes

### 1

**Description**
Glasgow Outcome Scale Extended
**Timepoint**
1, 3, and 6 months after starting Spirulina
**Method of measurement**
Glascow outcome scale extended calculator

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**
Intervention group: 8 grams of spirulina solution is used once a day for 14 days or until discharge. drug intervention is initiated 24 to 48 hours after admission, and the rout of administration is oral if level of consciousness is adequate, or via NG tube if level of consciousness is not adequate. The raw materials used in this study are provided by the knowledge-based company "Zarkhiz Khak Persia" and the formulation, preparation of the intervention solution and placebo solution are also done by "Saaditab Sina" company. It is worth mentioning that both companies operate under the supervision of the growth center of Shiraz University of Medical Sciences. The intervention solution contains 8 hot cooked spirulina (Spirulina platensis) substances, which are prepared from dried and standardized microalgae, and microbial quality and standards are used. It is prepared as a homogenized suspension in a solvent.
**Category**
Treatment - Drugs

### 2

**Description**
Control group: placebo solution is prepared as a suspension without substances, but with the same volume, color, and viscosity as spirulina solution. placebo solution is started 24 to 48 hours after admission, just like intervention group, and is used for 14 days or until discharge. placebo solution is administered to the patients orally if level of consciousness is adequate, or via NG tube if level of consciousness is not adequate.
**Category**
Placebo

## Recruitment centers

### 1

**Recruitment center**
**Name of recruitment center**
Shahid Rajaee Surgical Emergency Center
**Full name of responsible person**
Amin Niakan
**Street address**
Shahid Rajaee Surgical Emergency Center, Before Niayesh Boulevard, Shahid Chamran Boulevard, Shiraz
**City**
Shiraz
**Province**
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**Postal code**
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**Phone**
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aminniakan@yahoo.com

## Sponsors / Funding sources

### 1

**Sponsor**
**Name of organization / entity**
Shiraz University of Medical Sciences
**Full name of responsible person**
Hamid Mohammadi
**Street address**
7th floor, central building of Shiraz university of medical sciences, besides red crescent building, Shiraz
**City**
Shiraz
**Province**
Fars
**Postal code**
7134814336
**Phone**
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**Fax**
+98 71 3212 2430
**Email**
mohammadi219@gmail.com
**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Shiraz 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**

Shiraz University of Medical Sciences

**Full name of responsible person**

Hasan Avakh

**Position**

neurosurgical resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Neurosurgery

**Street address**

Shahid Rajaee Surgical Emergency Center, Before Niayesh Boulevard, Shahid Chamran Boulevard, Shiraz

**City**

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**Postal code**

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**Email**

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## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Hasan Avakh

**Position**

neurosurgical resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

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## Person responsible for updating data

**Contact**

**Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Hasan Avakh

**Position**

neurosurgical resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

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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**

The entire dataset can be shared once the individuals have been de-identified.

**When the data will become available and for how long**

Access begins upon the conclusion of the study on December 22, 2027.

**To whom data/document is available**

It will be available solely to researchers affiliated with academic and scientific institutions, subject to identity verification and the submission of a well-founded request deemed valid by the principal investigator.

**Under which criteria data/document could be used**

The data are suitable for conducting a systematic review and meta-analysis.

**From where data/document is obtainable**

Please email Dr. Amin Niakan, the project's principal investigator, to obtain the data. His email address is

aminniakan@yahoo.com.

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

The applicant must provide full particulars, state the reason for requiring the information, and commit to using the data solely for academic and scholarly purposes—within the scope disclosed to the principal investigator—and refraining from any commercial use. It is understood that any violation of these terms is subject to legal action through university ethics committees and the judicial system.

**Comments**