Clinical Trial Protocol
Iranian Registry of Clinical Trials

21 Nov 2026

Effect of deferoxamine injection on the Glasgow Outcome Scale in patients with severe traumatic brain injury: a double-blind, randomized controlled clinical trial

Protocol summary

Study aim
To determine the effect of deferoxamine on the Glasgow Outcome Scale in severe traumatic brain injury patients

Design
A single-center, concealed, randomized, blinded, controlled clinical trial with a parallel group design of 68 patients

Settings and conduct
This study will be conducted on 68 severe traumatic brain injury patients, admitted in the intensive care units of Emtiyaz (Rajaei) hospital (Shiraz University of Medical Sciences). Patients will be randomized into two groups and receive deferoxamine (intervention group: 20 mg/kg daily for seven consecutive days) and placebo (control group: same dose). All patients and physicians will be blinded to the patient groups.

Participants/Inclusion and exclusion criteria
Inclusion criteria: severe traumatic brain injury, and the age range of 18-65 years Exclusion criteria: Glasgow Coma Scale score 3 or 4 upon admission; the presence of bilateral fixed dilated pupils; history of significant brain damage; anti-platelet and/or anti-clotting drugs use; history of blood and/or coagulation disorders; history of heart, kidney, liver, and hearing disorders; iron and /or prochlorperazine use; pregnant or breastfeeding individuals; history of cardiopulmonary arrest and resuscitation upon hospital arrival

Intervention groups
The intervention group will receive deferoxamine injection for 7 consecutive days as a 24-hour intravenous infusion. The control group will receive placebo drug for 7 consecutive days as a 24-hour intravenous infusion.

Main outcome variables
Assessment of Glasgow Outcome Scale scale

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20220220054079N1**
Registration date: **2022-12-07, 1401/09/16**
Registration timing: **prospective**

Last update: **2022-12-07, 1401/09/16**
Update count: **0**

Registration date
2022-12-07, 1401/09/16

Registrant information
Name
Zahra Eghlidos
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2022-12-22, 1401/10/01
Expected recruitment end date
2023-08-21, 1402/05/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effect of deferoxamine injection on the Glasgow Outcome Scale in patients with severe traumatic brain injury: a double-blind, randomized controlled clinical trial

Public title
Deferoxamine in severe traumatic brain injury

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients with severe traumatic brain injury Patients with pure traumatic brain injury: having a score of less and equal to 3 on the Brain Abbreviated Injury scale; and a score of less than 3 on the Extracranial Abbreviated Injury scale

Exclusion criteria:
Allergy to deferoxamine mesylate Serum creatinine more than 2 mg/dL Hemoglobin less than 7 g/L, or patients requiring transfusion therapy A Glasgow Coma Scale score of 3 or 4 with bilateral fixed and dilated pupils A known history of intracranial diseases A known history of thrombocytopenia (platelet count less than 50×109/L) Concurrent use of anti-coagulant or anti-platelet agents or history of coagulation disorders (international normalized ratio more than 1.4) Concurrent use of iron supplements or prochlorperazine Impaired hearing Pregnant or lactating women History of cardiopulmonary arrest and resuscitation Blood disorders (e.g. thalassemia, iron deficiency anemia) GFR less than 50 ml/min History of heart failure History of liver disease

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **68**

Randomization (investigator's opinion)
Randomized

Randomization description
We will randomly divide eligible patients into two groups in a 1:1 ratio: intervention (group A) and control (group B). Block randomization will be performed with four patients in each block using an online randomization tool, and block sequences will be ABBA, AABB, BBAA, BABA, ABAB, and BAAB. The principal researcher -who is not involved in patient evaluation and data analysis- will perform the randomization and conceal the allocation sequence from other investigators and patients.

Blinding (investigator's opinion)
Double blinded

Blinding description
The faculty of Pharmacy, Shiraz university of medical sciences, will prepare the placebo drug according to the intervention drug (same color, amount, and packaging). The study will be double-blind. For this purpose, the study drugs (deferoxamine and placebo) will be identically packed; the principal researcher will put number codes on the packages and he will keep these codes confidential. He will also perform the randomization but has no role in prescribing the drugs, as well as recording and analyzing the patients' information. Patients will be informed about the study's details and purpose, but they do not know which medication they will receive. So, patients, physicians, and analysts are blinded to treatment groups.

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
Emtiyaz hospital, Chamran Blvd, Shiraz

City
Shiraz

Province
Fars

Postal code
7194815711

Approval date
2022-01-10, 1400/10/20

Ethics committee reference number
IR.SUMS.REC.1400.760

Health conditions studied

1

Description of health condition studied
Severe traumatic brain injury

ICD-10 code
S06.2

ICD-10 code description
Diffuse traumatic brain injury

Primary outcomes

1

Description
Glasgow Outcome Scale

Timepoint

At the time of discharge, three and six months after the intervention

Method of measurement

Glasgow Outcome Scale

Secondary outcomes

1

Description

Duration of intensive care unit admission

Timepoint

From the admission date to discharge date from the intensive care unit

Method of measurement

Number of days

2

Description

Duration of hospital admission

Timepoint

From the admission date to discharge date from the hospital

Method of measurement

Number of days

Intervention groups

1

Description

Intervention group: severe traumatic brain injury patients receiving 20 mg/kg per day deferoxamine for 7 consecutive days and as a 24-hour intravenous infusion

Category

Treatment - Drugs

2

Description

Control group: receiving 20 mg/kg per day placebo drug for 7 consecutive days as and as a 24-hour intravenous infusion. The placebo is prepared by the faculty of Pharmacy, Shiraz university of medical sciences; it will be identical to the intervention drug in amount, shape, color, and packaging

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Emtiyaz hospital, Chamran Blvd

Full name of responsible person

Hosseinali Khalili

Street address

Emtiyaz hospital, Chamran Blvd, Shiraz

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Sponsors / Funding sources

1

Sponsor

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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

Shiraz University of Medical Sciences

Proportion provided by this source

40

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

2

Sponsor

Name of organization / entity

Afa Chemi Pharmaceutical Company

Full name of responsible person

Afsaneh Pasebani

Street address

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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
Afa Chemi Pharmaceutical Company
Proportion provided by this source
60
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Industry

Person responsible for general inquiries

Contact
Name of organization / entity
Shiraz University of Medical Sciences
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Position
General Practitioner
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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
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code

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

Data Dictionary

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