Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jun 2026

Investigating the effectiveness of Rosuvastatin in patients with moderate brain trauma

Protocol summary

Study aim
Effect on the level of alertness after taking the medicine (Glasgow Coma Scale (GCS))

Design
This study is a one-blind clinical trial that will be conducted with random assignment to case and control groups.

Settings and conduct
This study is a one-blind clinical trial that will be conducted by randomly assigning intervention and control groups in Al-Zahra Hospital. The sample size will be equal to 110 patients. For the case group, rosuvastatin with a dose of 20 mg (which is equivalent to 40 mg of atorvastatin and 80 mg of simvastatin) will be prescribed to patients daily for ten days, and the control group will receive a placebo (an ineffective substance made from the Faculty of Pharmacy similar to rosuvastatin daily). period of 3 months is used) they will receive the same as the case group.

Participants/Inclusion and exclusion criteria
Criteria for entering the study: patients with a level of consciousness between 8-12 and patients whose first-degree companions consent to their patient's entry into the study. Exclusion criteria: patients with a history of any brain disorders, and patients with normal liver tests.

Intervention groups
For the case group, Rosuvastatin with a dose of 20 mg (which is equivalent to 40 mg of Atorvastatin and 80 mg of Simvastatin) (21, 20) will be prescribed to patients daily for ten days. The control group will also receive a placebo (inert substance made from the Faculty of Pharmacy similar to Rosuvastatin used daily for 3 months) just like the case group. During this period, patients are also examined with weekly tests for possible drug side effects.

Main outcome variables
Improve the level of alertness (Glasgow Coma Scale (GCS))

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230627058603N2**
Registration date: **2024-01-04, 1402/10/14**
Registration timing: **registered_while_recruiting**

Last update: **2024-01-04, 1402/10/14**
Update count: **0**

Registration date
2024-01-04, 1402/10/14

Registrant information

Name
Mehdi Shafiei

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 31 3670 0666

Email address
neurosurgery_resident@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-12-22, 1402/10/01

Expected recruitment end date
2024-04-20, 1403/02/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Investigating the effectiveness of Rosuvastatin in patients with moderate brain trauma

Public title
Rosuvastatin in patients with moderate brain trauma
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with a level of consciousness between 8-12 Informed consent of first-degree companions to enter the study
Exclusion criteria:
History of any brain disorders Normal Liver function tests
Age
No age limit
Gender
Both

Phase
2
Groups that have been masked

- Participant

Sample size
Target sample size: **200**
Randomization (investigator's opinion)
Randomized
Randomization description
People are placed in 2 groups by random block method. In this way, the first 2 eligible people are selected and after obtaining consent, they enter to participate in the study. These 2 people are considered as a block of 2 and are sorted according to the last digit of the national code. The treatment methods are specified as A, B, and all combinations of 2 are specified, and after the last surgery, decoding is done for the last block.
Blinding (investigator's opinion)
Single blinded
Blinding description
The researcher does not know which patient received which medicine. In this study, the placebo is just like the original drug and the patient is unaware of which drug he is taking.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethical Committee of Faculty of Medicine, Isfahan University of Medical Sciences
Street address
Hazar Jarib Street, Azadi Square
City
Isfahan
Province
Isfehan
Postal code
8174673461
Approval date
2022-06-15, 1401/03/25
Ethics committee reference number
IR.MUI.MED.REC.1401.125

Health conditions studied

1

Description of health condition studied
Moderate traumatic brain injury
ICD-10 code
S06.2
ICD-10 code description
Diffuse traumatic brain injury

Primary outcomes

1

Description
Improve the state of Glasgow Coma Scale (GCS)
Timepoint
One, three and 6 months after the injury
Method of measurement
Glasgow coma scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Rosuvastatin with a dose of 20 mg (which is equivalent to 40 mg of Atorvastatin and 80 mg of Simvastatin) (21, 20) will be prescribed to patients daily for ten days.
Category
Treatment - Drugs

2

Description
Control group: They will receive a placebo (an ineffective substance made from the Faculty of Pharmacy, similar to Rosuvastatin , used daily for ten days) in the same way as the case group.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Al-zahra Hospital
Full name of responsible person
Mehdi Shafiei
Street address
Al-Zahra Hospital, Safa Street
City
Isfahan
Province
Isfehan
Postal code
8174675731
Phone
+98 913 310 1971
Email
Mehdishafiei82@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Gholamreza Asgari
Street address
Hazar Jarib Street, Azadi Square
City
Isfahan
Province
Isfehan
Postal code
81746-73461
Phone
+98 31 3668 0048
Email
mui@mui.ac.ir

Grant name

Grant code / Reference number

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

Title of funding source
Esfahan University of Medical Sciences

Proportion provided by this source
1

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
Esfahan University of Medical Sciences
Full name of responsible person
Mehdi Shafiei
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Neurosurgery
Street address
Hazar Jarib Street, Azadi Square
City
Isfahan
Province
Isfehan
Postal code
8174673461
Phone
+98 31 3668 0048
Email
mui@mui.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Mehdi Shafiei
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Neurosurgery
Street address
Hazar Jarib Street, Azadi Square
City
Isfahan
Province
Isfehan
Postal code
8174673461
Phone
+98 31 3668 0048
Email
mui@mui.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Mehdi Shafiei
Position
Associate professor

Latest degree
Specialist
Other areas of specialty/work
Neurosurgery
Street address
Hazar Jarib Street, Azadi Square
City
Esfahan
Province
Isfehan
Postal code
8174673461
Phone
+98 31 3668 0048
Email
mui@mui.ac.ir

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