Clinical Trial Protocol
Iranian Registry of Clinical Trials

21 Jun 2026

Effect of Memoral on the memory dysfunction after mild traumatic brain injury , a randomize clinical trial

Protocol summary

Study aim
To assess and evaluate the efficacy of the generic medication “Memoral” on the recovery of the memory dysfunction in patients with TBI

Design
Two arm parallel group single-blind, Placebo-controlled phase 4randomized trial.

Settings and conduct
This study is performed at Shiraz University of Medical Sciences, Trauma Research Center, on patients who have memory problems after mild brain injury. Community Verified icon

Participants/Inclusion and exclusion criteria
In this study patients with the diagnosis of MTBI, who have the following criteria will be included in the study: ۱- Age between ۲۰ and ۶۰ ۲- ۶th class education; ۳- Having no previous history of trauma ۴- Having no major psychiatric and neurologic disorders according to the self-report ۵- Having no judiciary issues or any probability of economic or insurance-related sue ۶- Having no hematologic disorder

Intervention groups
intervention group: receiving memoral capsule every eight hours (8 am - 4 pm - 12 pm) for a month control group: receiving placebo every eight hours (8 am - 4 pm - 12 pm) for a month

Main outcome variables
Patient memory function based on AVLT test results

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20130310012776N8**
Registration date: **2022-02-11, 1400/11/22**
Registration timing: **registered_while_recruiting**
Last update: **2022-02-11, 1400/11/22**
Update count: **0**

Registration date
2022-02-11, 1400/11/22

Registrant information
Name
Hosseinali Khalili
Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 71 3625 4206
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khalili_h@sums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-02-04, 1400/11/15

Expected recruitment end date
2022-06-20, 1401/03/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of Memoral on the memory dysfunction after mild traumatic brain injury , a randomize clinical trial

Public title
effect of Memoral on memory after TBI

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Cases should have mild traumatic brain injury cases

should have memory dysfunction after MTBI age between 20 and 60 years at least six class of education
Exclusion criteria:
moderate or severe brain injury history of psychiatric or neurological disorders history of hematologic disorders Having previous history of trauma Having major psychiatric and neurologic disorders according to the self-report

Age
From **20 years** old to **60 years** old

Gender
Both

Phase
4

Groups that have been masked

- Participant

Sample size
Target sample size: **94**

Randomization (investigator's opinion)
Randomized

Randomization description
Included patients will be allocated randomly into the experiment and placebo groups via the blocked randomization method. A trained research assistant will use blocked randomization with block sizes of 4 with an equal probability to enroll the eligible patients to the experiment group (group A) and placebo (group B). Regarding the size of block 4, we have six possible combinations of group assignments, including AABB, ABAB, BAAB, BABA, BBAA, and ABBA. At first, the assistant will select one of these arrangements randomly, and the four eligible admitted patients would be assigned accordingly in each block. We will repeat this process many times to include the eligible patients.

Blinding (investigator's opinion)
Single blinded

Blinding description
Although the patients will be informed of our primary objectives, they won’t know which drugs/ placebo they will receive. Well-trained nurses will be recruited to give the medication/placebo to the patients. As the placebo's color, shape, and size were identical to our medications, their differentiations were only possible via a specific code imprinted on the bottles.

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
Zand Boulevard, the central building of Shiraz University of Medical Sciences

City
Shiraz

Province
Fars

Postal code
۱۴۳۳۶ - ۷۱۳۴۸

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

Ethics committee reference number
IR.SUMS.REC.1400.726

Health conditions studied

1

Description of health condition studied
Memory impairment after mild brain injury

ICD-10 code
S07.1

ICD-10 code description
Crushing injury of skull

Primary outcomes

1

Description
Patient memory function

Timepoint
Intervals of one month and three months after starting the drug

Method of measurement
Based on the auditory-verbal learning test questionnaire (AVLT)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: memoral capsules are given to patients every 8 hours at 8 am, 2 pm and 12 pm for one month.

Category
Treatment - Drugs

2

Description
Control group: placebo are given to patients every 8 hours at 8 am, 2 pm and 12 pm for one month.

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Emtiaz trauma center

Full name of responsible person
Omid Yousefi

Street address
Chamran blvd, Emtiaz trauma center Zip code: 7194815711

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Shiraz

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Email
Trauma_research_center@yahoo.com

Web page address
https://traumarc.sums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
Mahtab Memarpour

Street address
7th floor, Central building of Shiraz University of medical sciences

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vcrdep@sums.ac.ir

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
80

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
Hosseinali Khalili

Position
Associat professor

Latest degree
Specialist

Other areas of specialty/work
Neurosurgery

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Rajaee Hospital, Chamran Boulevard, Shiraz, Iran.

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Person responsible for scientific inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

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
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is 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
Yes - There is a plan to make this available

Title and more details about the data/document
The results of the memory test will be published after the completion of the necessary tests while maintaining the principle of anonymity of the patients

When the data will become available and for how long
The data will be availableafter the results are published

To whom data/document is available
Members of Trauma Research Center, Shiraz University of Medical Sciences

Under which criteria data/document could be used
For possible use in future research, it will be made available to researchers with an approved researches

From where data/document is obtainable
Emtiaz Hospital Trauma Research Center

What processes are involved for a request to access data/document
The researcher's request will be reviewed after sending an official letter to the Trauma Center Research Council

Comments