# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

17 Sep 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)
**Phone**
+98 71 3625 4206
**Email address**
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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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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**Province**
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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**