

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 Jun 2026

### The effect of donepezil on the persistent cognitive executive function deficit in traumatic brain injury patients

#### Protocol summary

##### Study aim

The effect of donepezil on the persistent cognitive executive function deficit in traumatic brain injury patients

##### Design

The Phase 2 clinical trial consists of a group of 17 patients with traumatic brain injury

##### Settings and conduct

. Consecutive sampling will be done from all patients referred to the clinics of Guilan University of Medical Sciences who meet the inclusion criteria. Before the intervention, the patients' cognitive level is determined by the physician using the Persian version of MMSE. The Digital Signal-Stop Executive Function . In this experiment, the response time and accuracy of the response are measured. Digital tests such as Tower of London test , Cambridge gambling test , continues performance test , lawton daily life activity test are performed at the baseline and end of the last treatment session.

##### Participants/Inclusion and exclusion criteria

Inclusion :Patients with all TBI intensities , age 18 to 60 years, , at least 4 years of study with formal education, MMSE score 17-23, 3 months after traumatic brain injury,. Exclusion : history of neurological diseases , previous stroke, history of mental disorder and use of antipsychotic and antidepressant drugs, drug abuse while studying Or a few months ago, cognitive and verbal impairment before TBI and sensory deprivation such as deafness and blindness, , patient dissatisfaction with continuing to participate in the study

##### Intervention groups

An intervention group consisted of 17 patients receiving medication for 1 month

##### Main outcome variables

Cognitive dimensions and speed of information processing and executive functions

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20130416013027N4**

Registration date: **2020-08-17, 1399/05/27**

Registration timing: **retrospective**

Last update: **2020-08-17, 1399/05/27**

Update count: **0**

##### Registration date

2020-08-17, 1399/05/27

##### Registrant information

##### Name

Sara Ramezani Kapourchali

##### Name of organization / entity

Guilan Road Trauma Research Centre

##### Country

Iran (Islamic Republic of)

##### Phone

+98 13 1323 8373

##### Email address

s.ramezani@p@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-08-06, 1399/05/16

##### Expected recruitment end date

2020-08-16, 1399/05/26

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

The effect of donepezil on the persistent cognitive executive function deficit in traumatic brain injury patients

## Public title

The effect of donepezil on the persistent cognitive executive function deficit in traumatic brain injury patients

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Patients with all severities of TBI Patients aged 18 to 60 years Patients with GOS 4 and 5 Consciousness level of 10 to 15 At least 4 years of formal education MMSE score between 17-23 At least 3 months after discharge from hospital due to TBI

### Exclusion criteria:

History of neurological diseases History of mental disorder and use of antipsychotic and antidepressant drugs, drug abuse while studying or last few months Cognitive and verbal disorders before TBI and sensory deprivations such as deafness and blindness, clinical instability or behavioral problems that prevent the subject from participating in the intervention Patient dissatisfaction with continuing to participate in the study

## Age

From **18 years** old to **60 years** old

## Gender

Both

## Phase

2

## Groups that have been masked

*No information*

## Sample size

Target sample size: **17**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Due to the fact that only one group of 17 people are included in the study, randomization is not performed

## Blinding (investigator's opinion)

Not blinded

## Blinding description

## Placebo

Not used

## Assignment

Single

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Guilan University of Medical Sciences

## Street address

Trauma research center, Poursina hospital, Namjoo ave

## City

Rasht

## Province

Guilan

## Postal code

4193713194

## Approval date

2020-07-29, 1399/05/08

## Ethics committee reference number

IR.GUMS.REC.1399.217

## Health conditions studied

### 1

#### Description of health condition studied

persistent cognitive executive function deficit in traumatic brain injury patients

#### ICD-10 code

S06

#### ICD-10 code description

Intracranial injury

## Primary outcomes

### 1

#### Description

Cognitive executive function deficit

#### Timepoint

Before starting study and one month after starting study

#### Method of measurement

Before the intervention, the patients' cognitive level is determined by the physician using the Persian version of MMSE. The Digital Signal-Stop Executive Function Test Form is used to assess inhibitory control and executive function and information processing speed. In this test, the response time and accuracy of the response are measured. Digital tests to measure cognitive dimensions and information processing speed and performance, such as the Tower of London test (TLT), Cambridge gambling test (CGT), continuing performance test (CPT), lawton daily life activity test (IADL) are performed at the beginning and the end of the last treatment session.

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: It consists of 17 people who, after performing baseline examinations and recording their results, are prescribed Donepezil 5 mg daily for the first week, 10 mg daily for the next 3 weeks.

#### Category

## Recruitment centers

### 1

#### Recruitment center

**Name of recruitment center**

Neurosurgery Clinic of Poursina Hospital

**Full name of responsible person**

Zohair Reihanian

**Street address**

Parastar Ave, Poursina Hospital, Imam Reza Clinic

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ali.shams@hotmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Rasht University of Medical Sciences

**Full name of responsible person**

Mohamadreza Naghi pour

**Street address**

Namjoo Ave, Shahid Siadati Street

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naghi@gums.ac.ir

**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Rasht 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**

## Person responsible for general inquiries

### Contact

**Name of organization / entity**

Rasht University of Medical Sciences

**Full name of responsible person**

Zohair Reihanian

**Position**

Assistant professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Neurosurgery

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Trauma research center, PourSina Hospital, Parastar Ave

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Rasht University of Medical Sciences

**Full name of responsible person**

Sara Ramezani

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Neuroscience

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## Person responsible for updating data

### Contact

**Name of organization / entity**

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**Full name of responsible person**

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**Position**

Assistant Professor

**Latest degree**

Ph.D.

**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**

Some information related to main outcome are provided

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

6 months after summary data published

**To whom data/document is available**

Only academic researchers

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

For the therapeutic decision making in clinic

**From where data/document is obtainable**

s.ramezanisl@gmail.com

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

Between 1 to 2 month after request

**Comments**