

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

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Email address

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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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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

Mohamadreza Naghi pour

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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

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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Person responsible for scientific inquiries

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Position

Assistant Professor

Latest degree

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Other areas of specialty/work

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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

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