

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

07 Jul 2026

### The Comparative study about effect of Donepezil with and without Memantine on recovery of cognitive, linguistic dysfunctions and disability rating in traumatic brain injury patients during the subacute phase

#### Protocol summary

##### Summary

Regarding to advantage effect of combination of Memantine and Donepezil on the induction of central cholinergic level in animal models, one double blind randomized controlled clinical trial study as consecutive sampling is designed with aim of effect of treatment of combination of Memantine and donepezil on recovery of cognitive and linguistic disorders and disability rate is designed. 162 patients with moderate and severe traumatic brain injury aged 18-60 years having post-traumatic aphasia and cognitive deficit take part in the project contently written. In the first all demographic and para-clinical information are entered in especial form. Subjects are examined with respect to disability rate, cognitive function and aphasia quotient before pharmacotherapy. Intervention is started 4 weeks after discharge. In first 4 weeks, Donepezil group receive 5 mg Donepezil and Memantine placebo, combined group use 5mg Donepezil and 5 mg Memantine, placebo group is given Donepezil and Memantine placebo. Participants are examined by physician in the end of first 4 weeks. Then interventional approach for groups that receive drugs is continued whereas drug dose increase to 10 mg for each of them. Patients are evaluated respecting to disability rate, cognitive function and aphasia quotient 12 weeks post of intervention onset again.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2013041613027N1**

Registration date: **2013-05-07, 1392/02/17**

Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2013-05-07, 1392/02/17

##### 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

Guilan university of medical sciences

##### Expected recruitment start date

2013-09-22, 1392/06/31

##### Expected recruitment end date

2015-09-22, 1394/06/31

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The Comparative study about effect of Donepezil with and without Memantine on recovery of cognitive, linguistic dysfunctions and disability rating in traumatic brain injury patients during the subacute phase

##### Public title

The effect of Donepezil and Memantine combination on treatment of traumatic brain injury

## Purpose

Treatment

## Inclusion/Exclusion criteria

Inclusion criteria: aphasia patients having post-traumatic cognitive deficit; moderate & severe traumatic brain injury according to GCS at first 24 h; age range between 18-60 years; GOS score 4 & 5; at least 4 years formal education; maximum of aphasia quotient 75 based on P.AD; moderate and severe cognitive deficit(MMSE score<17); post onset discharge time 2-4 weeks(sub-acute phase). Exclusion criteria: history of neurological disease including CVA, brain tumor, epilepsy, seizure, Parkinson and dementia...; previous brain trauma; history of psychiatric disorder and using of antipsychotic & antidepressant drugs; history of drug abuse and pre-existing verbal and cognitive deficit; exist of deafness and blindness; appearance of drug's side effects; exist of renal disease, heart disease, hypertension and unwillingness for continue of the study.

## Age

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

## Gender

Both

## Phase

N/A

## Groups that have been masked

*No information*

## Sample size

Target sample size: **162**

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Double blinded

## Blinding description

## Placebo

Used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Research Guilan university of medical sciences

##### Street address

Rasht, Namjou avenue, Research Guilan university of medical sciences

##### City

Rasht

##### Postal code

#### Approval date

2013-02-09, 1391/11/21

#### Ethics committee reference number

1910396410

## Health conditions studied

### 1

#### Description of health condition studied

Traumatic brain injury

#### ICD-10 code

G94\*

#### ICD-10 code description

other disorders of brain in diseases classified elsewhere

## Primary outcomes

### 1

#### Description

disability rate

#### Timepoint

before of intervention and 3 months after intervention onset

#### Method of measurement

disability rate scale (DRS)

### 2

#### Description

aphasia quotient

#### Timepoint

before of intervention and 3 months after intervention onset

#### Method of measurement

Persian. aphasia diagnosis (P.AD)

### 3

#### Description

Cognitive function

#### Timepoint

before of intervention and 3 month after intervention onset

#### Method of measurement

mini-mental state examination(MMSE)

## Secondary outcomes

### 1

#### Description

side effects of drugs

#### Timepoint

1 month and 3 months after intervention onset

#### Method of measurement

observation and examination

## Intervention groups

### 1

#### Description

Drug intervention of Donepezil without Memantine in dosage of 5 mg during 1 month then induction of drug dosage to 10 mg for 2 months . in first 1 month for

Donepezil group one tablet of 5 mg Donepezil and half tablet Memantin placebo at evening, whereas, next 2 months for Donepezil group one tablet of Donepezil 10 mg and half tablet of Memantine placebo at evening and half tablet of Memantin placebo at morning,

#### Category

Treatment - Drugs

### 2

#### Description

Drug intervention of Donepezil with Memantine carries out in dosage of 5 mg for each of them during 1 month then will be continued by induction of drug dosage to 10 mg for 2 months. In combined group (Donepezil+Memantine) is offered one tablet of Donepezil 5 mg and half tablet of Memantine 10 mg at evening in first 1 month. Whereas, next 2 months this group is used one tablet of Donepezil 10 mg and half tablet of Memantine 10 mg at evening and half tablet of Memantine 10 mg at morning.

#### Category

Treatment - Drugs

### 3

#### Description

Control group receive placebo similar to Memantin and Donepezil. in first 1 month one and half tablet of placebo is used daily (one tablet of Donepezil placebo and half tablet of Memantine placebo at evening) in next 2 month 2 tablet of placebo is used daily (one tablet of Donepezil placebo at evening and half tablet of Memantin placebo at morning and half other at evening) .

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Poursina educational & therapeutical center

##### Full name of responsible person

Dr. Sara Ramezani

##### Street address

, Poursina educational & therapeutical center, Namjou avenue

##### City

Rasht

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Research adjutancy ,Guilan university of medical sciences

##### Full name of responsible person

Dr. Rasoul Tabari

#### Street address

Rasht, Namjou avenue, Research adgutancy, class2

#### City

Rasht

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Research adjutancy ,Guilan university of medical sciences

#### Proportion provided by this source

100

#### Public or private sector

empty

#### Domestic or foreign origin

empty

#### Category of foreign source of funding

empty

#### Country of origin

#### Type of organization providing the funding

empty

## Person responsible for general inquiries

#### Contact

##### Name of organization / entity

Guilan Road trauma research center, Rasht, Guilan university of medical sciences

##### Full name of responsible person

Dr. Sara Ramezani

##### Position

MD, researcher

##### Other areas of specialty/work

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## Person responsible for scientific inquiries

#### Contact

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## Person responsible for updating data

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*