

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

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Name of organization / entity

Guilan Road Trauma Research Centre

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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

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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

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Position

MD, researcher

Other areas of specialty/work

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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