Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Survey of augmentation of rivastigmine in combat post traumatic stress disorder

Protocol summary

Summary

The objective of the present study was to explore the efficacy of rivastigmine as an adjunctive medication in PTSD. A 12 weeks, double-blind, placebo-controlled clinical trial was performed on 36 treatment resistant, PTSD diagnosed subjects aged 30- to 65-year-old. All had the diagnosis for more than 5 years. They were screened to avoid having any cognitive deficits. After obtaining informed consent, usual medication was administered to all participants for a month. Then rivastigmine (up to 6 mg/day) or placebo was gradually added to the ongoing medication in 2 groups and one continued on ongoing treatment randomly. Efficacy of medication was measured by administering PCL-M at baseline and weeks 2, 4, 8, and 12. Collected data were analyzed by appropriate descriptive and analytic statistical tests including ANOVA and Repeated measurement. Reported differences were significant at the 0.05 level or less.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201211195280N10**
Registration date: **2012-12-04, 1391/09/14**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2012-12-04, 1391/09/14

Registrant information

Name

Raheleh Nejati

Name of organization / entity

Mashhad University of Medical Scinces, Ibn-e- Sina Psychiatric Hospital

Country

Iran (Islamic Republic of)

Phone

+98 51 3711 2540

Email address

nejatir2@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Mashhad university of medical sciences

Expected recruitment start date

2009-08-23, 1388/06/01

Expected recruitment end date

2011-04-21, 1390/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Survey of augmentation of rivastigmine in combat post traumatic stress disorder

Public title

Ssurvey of augmentation of rivastigmine in combat post traumatic stress disorder

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusions criteria: PTSD diagnosed based on DSM. IV-TR.military PTSD; MMSE score higher than 25. Exclusion criteria:Case refused . Rivastigmine side effects.

Age

From **30 years** old to **65 years** old

Gender

Male

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **36**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Mashhad University of Medical Sciences

Street address

Ghoreish building,Daneshgah Street.

City

Mashhad

Postal code

Approval date

2008-05-28, 1387/03/08

Ethics committee reference number

86578

Health conditions studied

1

Description of health condition studied

Post-traumatic stress disorder (PTSD)

ICD-10 code

F43.1

ICD-10 code description

Post-traumatic stress disorder

Primary outcomes

1

Description

Symptoms of PTSD

Timepoint

at baseline and weeks 2, 4, 8, and 12

Method of measurement

PCL-M

Secondary outcomes

empty

Intervention groups

1

Description

rivastigmine 1.5 mg/ day two weeks and after two weeks increased 3mg/day Twice a day .

Category

Treatment - Drugs

2

Description

control group received placebo.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Ebn-e- sina hospital

Full name of responsible person

Street address

City

Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of medical sciences

Full name of responsible person

Ardakanian Marjan

Street address

Ghoreish building, Daneshgah street

City

Mashhad

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Mashhad 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
Mashhad University of medical sciences
Full name of responsible person
Amir Rezaei Ardani
Position
assistant
Other areas of specialty/work
Street address
Ebn-e-sina hospital
City
Mashhad
Postal code
Phone
+98 51 1711 2540
Fax
Email
rezaeia@mums.ac.ir
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Mashhad University of medical sciences
Full name of responsible person
Mohammad Reza Fayyazi Bordbar
Position
Associate Professor
Other areas of specialty/work
Street address
Ibn-E- Sina Hospital
City
Mashhad
Postal code
Phone
+98 51 1711 2540
Fax
Email
fayyazimr@mums.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Mashhad University of medical sciences
Full name of responsible person
Amir Rezaei Ardani
Position
assistant
Other areas of specialty/work
Street address
Ebn-e-sina hospital.
City
mashhad
Postal code
Phone
Fax
Email
Web page address

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