Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jun 2026

Survey of Pregabalin augmentation in patients with chronic post traumatic stress disorder

Protocol summary

Summary

Objective: The aim of this study was to evaluate the effectiveness of Pregabalin augmentation to antidepressant treatment (Selective Serotonin Reuptake Inhibitors and Sodium valproate) in patients with chronic posttraumatic stress disorder (PTSD). Methods: This was a double-blinded placebo-controlled clinical trial conducted at Ibn-E-Sina Hospital (Mashhad, Iran) at 2013. 37 male patients diagnosed with PTSD based on DSM-IV-TR criteria were randomly allocated to two groups. The case group (18 patients) received Pregabalin (300 mg/day) and stable doses of antidepressants and the control group (19 patients) received placebo and routine treatment for 6 weeks. Assessments were done at baseline; two, four and six weeks based on PTSD Check List–Military version (PCL-M), Hamilton Depression Rating Scale, Hamilton Anxiety Rating Scale and Spitzer quality of life index. Inclusion criteria: diagnose with PTSD based on DSM-IV-TR criteria and sensitivity to Pregabalin and active medical disease were Exclusion criteria.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201302145280N12**
Registration date: **2013-08-30, 1392/06/08**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2013-08-30, 1392/06/08

Registrant information

Name

Raheleh Nejati

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Mashhad University of Medical Sciences

Expected recruitment start date

2012-09-22, 1391/07/01

Expected recruitment end date

2013-09-23, 1392/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Survey of Pregabalin augmentation in patients with chronic post traumatic stress disorder

Public title

Survey of Pregabalin augmentation in patients with chronic post traumatic stress disorder

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: diagnose with PTSD based on DSM-IV-TR criteria, age between 30 and 65 years, had no significant cognitive disorder and no history of drug abuse except for nicotine. Exclusion criteria: were unwillingness of patients to continue the trial; active medical disease, other diseases in axis one or two except

for PTSD and sensitivity to Pregabalin.

Age
From **35 years** old to **60 years** old

Gender
Male

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **38**

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
Mashhad University of Medical Sciences

Street address
Ghoreish building, Daneshgah Street.

City
Mashhad

Postal code

Approval date
2011-11-26, 1390/09/05

Ethics committee reference number
900441

Health conditions studied

1

Description of health condition studied
chronic Post-traumatic stress disorder(PTSD)

ICD-10 code
F43.1

ICD-10 code description
Post-traumatic stress disorder

Primary outcomes

1

Description
Post traumatic stress disorder

Timepoint
0, 2, 4 and 6th weeks

Method of measurement
PCL test

Secondary outcomes

1

Description
Quality of life

Timepoint
0, 2, 4 and 6th weeks

Method of measurement
Spitzer Quality of Life index(SQL)

2

Description
Depression

Timepoint
0, 2, 4 and 6th weeks

Method of measurement
Hamilton Depression Rating Scale

3

Description
Anxiety

Timepoint
0, 2, 4 and 6th weeks

Method of measurement
Hamilton Anxiety Rating Scale

Intervention groups

1

Description
The case group received SSRI(Serteraline 50-200 mg or citalopram 20-40 mg) daily for 6 weeks. received Pregabalin (75 mg/day for the first week then 75 mg twice daily for the second week and continued with 150 mg twice daily from the third week to the sixth week) .

Category
Treatment - Drugs

2

Description
control group received placebo and routine treatment daily for 6 weeks.

Category
Treatment - Drugs

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
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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