Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparisons of healthy sleep education alone and combined with pharmacotherapy in the treatment of sleep disturbances in Non-psychotic depressed patients

Protocol summary

Summary

1) Objectives: Main aim: Efficacy of healthy sleep education and pharmacotherapy alone or in combination for the treatment of sleep disorders in Non-psychotic depressed patients. Goals: A- Determine of the effect of healthy sleep education in the treatment of sleep disorders in Non-psychotic depressed patients. B- Determine of the effect of Lorazepam in the treatment of sleep disorders in Non-psychotic depressed patients. C- Determine of the effect of healthy sleep education with Lorazepam in the treatment of sleep disorders in Non-psychotic depressed patients. (2) Design: The study is a randomized clinical trial. (3) Setting and conduct: Research environment is Farshchian psychiatry hospital in Hamedan city. 90 Non-psychotic depressive disorder patients will be in three therapeutic groups with random method. A- Healthy sleep education B- Pharmacotherpay C- Combination method. Non-psychotic depressive disorder will diagnose using DSM-IV criteria. Patients will assess with the Hamilton Depression Inventory and sleep disorders questionnaire before and after treatment. (4) Participants including major eligibility criteria: Participants included Non-psychotic depressive disorder patients with inclusion middle age group (35-60)؛ No history of psychiatric disorders associated؛ No history of serious physical illness؛ Treated with SSRI antidepressants؛ The ability to read and write. Exclusion criteria included Electroconvulsive therapy؛ Having physical pain from chronic diseases؛ History of substance abuse. (5) Intervention: Group 1: Patients in group 1 will receive Lorazepam 1mg per night for 4 week. Group 2: Patients in group 2 will receive sleep hygiene education face to face training and pamphlets. Group 3: Patients in group 3 will receive sleep healthy education face to face training and pamphlets and Lorazepam 1mg per night for 4 week. (6) main outcome measures (variables): status of sleep disorders and depressive level.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012100411004N1**
Registration date: **2013-07-09, 1392/04/18**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2013-07-09, 1392/04/18

Registrant information

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Farshid Shamsaei
Name of organization / entity
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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Hamadan University of Medical SciencesAdd: Hamadan University of Medical Sciences, Shahid Fahmideh Bulv, Hamedan, Postal cod: 65178

Expected recruitment start date

2013-06-20, 1392/03/30

Expected recruitment end date

2014-03-20, 1392/12/29

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparisons of healthy sleep education alone and combined with pharmacotherapy in the treatment of sleep disturbances in Non-psychotic depressed patients

Public title
Treatment of sleep disorders in patients with non-psychotic depressed
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: Middle age group (35-60؛ No history of psychiatric disorders associated؛ No history of serious physical illness؛ Treated with SSRI antidepressants؛ The ability to read and write. Exclusion criteria included Electroconvulsive therapy؛ Having physical pain from chronic diseases؛ History of substance abuse.
Age
From **35 years** old to **65 years** old
Gender
Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **90**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Hamadan university of medical sciences
Street address
Vice chancellor for research, Hamadan University of Medical Sciences, Shahid Fahmideh Bulv.
City
Hamedan
Postal code
65178
Approval date
2013-05-20, 1392/02/30
Ethics committee reference number
709/9/35/16/P/D

Health conditions studied

1

Description of health condition studied
Depressive disorder
ICD-10 code
F30, F31,
ICD-10 code description
Mood [affective] disorders

Primary outcomes

1

Description
Sleep disorders
Timepoint
Before and 4 week after
Method of measurement
Sleep Disorders Inventory

Secondary outcomes

1

Description
Depressive level
Timepoint
Before and four weeks after
Method of measurement
Hamilton Depression Scale

Intervention groups

1

Description
Group 1: patients in group 1 will receive Lorazepam 1mg per night for 4 week.
Category
Treatment - Drugs

2

Description
Group 2: patients in group 2 will receive sleep healthy education face to face training and pamphlets.
Category
Other

3

Description
Group 3: patients in group 3 will receive sleep healthy

education face to face training and pamphlets and Lorazepam 1mg per night for 4 week.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Farshchian psychiatry hospital

Full name of responsible person

Farshid Shamsaei

Street address

Farshchian psychiatry hospital, Research center for behavioral disorders and substance abuse, Dibaj Ave

City

Hamedan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Hamadan university of medical sciences

Full name of responsible person

Hidar Tavilani

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Vice chancellor for research, Hamadan University of Medical Sciences, Shahid Fahmideh Bulv, Hamedan

City

Hamedan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, Hamadan 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

Hamadan university of medical sciences

Full name of responsible person

Farshid Shamsaei

Position

Assistan Professor

Other areas of specialty/work

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Assistan Prof.

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