

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jun 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- Pharmacotherapy 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

Name

Farshid Shamsaei

Name of organization / entity

Hamadan University of Medical Sciences

Country

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Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Hamadan University of Medical Sciences
Add: 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.

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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

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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

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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

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Other areas of specialty/work

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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