

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jul 2026

Comparison the therapeutic effects of thiamine plus fluoxetine and fluoxetine alone in the patients with major depressive disorder

Protocol summary

Summary

This is a randomized, double-blind clinical trial to evaluate the efficacy of thiamine in treating major depressive disorder. In this study 50 patients, referred to psychiatry ward of Farshchian Hospital will be enrolled in the study with consent inform ,who have been diagnosed as MDD based on DSM-V and their age is between 18 to 50 years. Overall objective: Determine the efficacy of thiamine in treatment major depressive disorder. Applicable objective: If thiamine has positive effect on the amount or rate of depression improvement in patients, it can be applied as an effective treatment along with other treatments for depression. Exclusion criteria: Other psychiatric disorders, along with major depression; Debilitating somatic illness, along with major depression; History of Alcohol or Substances abuse in the last year; Magnesium deficiency; Thiamine deficiency in laboratory evaluation; Hyperthyroidism. The patients will be divided into two groups based on randomized blocks. Intervention and control groups will be matched about demographic and disease related indicators such as age, sex, disease severity. Patients in the intervention group will receive 20 mg fluoxetine with 300 mg thiamine per day and the control group will receive 20 mg fluoxetine with placebo, for 3 months. Before the treatment and the intervals of 3, 6 and 12 weeks after the treatment, the patients' depression will be assessed through Hamilton Depression Rating Scale and finally the improvement rate of the both groups compared to each other.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013070913929N1**

Registration date: **2013-08-12, 1392/05/21**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2013-08-12, 1392/05/21

Registrant information

Name

Hassan Davari

Name of organization / entity

Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for Research and Technology of Hamadan University of Medical Sciences

Expected recruitment start date

2013-08-23, 1392/06/01

Expected recruitment end date

2014-06-22, 1393/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the therapeutic effects of thiamine plus fluoxetine and fluoxetine alone in the patients with major depressive disorder

Public title

Effectiveness of thiamine in treatment of depression

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: - Diagnosis of major depressive disorder (MDD), according to DSM-V -Age between 18 to 50 years. Exclusion criteria: - Patients with other psychiatric disorders, along with major depression - Debilitating somatic illness, along with major depression -Suffering from Wernicke Syndrome -History of alcohol or substances abuse in the last year -Known gastrointestinal disease -History of long-term dialysis - Suffering from congestive heart failure with long-term use of diuretics -Magnesium deficiency -Suffering from anorexia nervosa -Allergy and sensitivity to thiamine - Thiamine deficiency in laboratory evaluation - Hyperthyroidism

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **50**

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

Vice chancellor for Research and Technology of
Hamadan University of Medical Sciences

Street address

Hamadan University of Medical Sciences, Hamadan

City

Hamadan

Postal code

65178

Approval date

2013-06-08, 1392/03/18

Ethics committee reference number

16/35/9/710/د/پ

Health conditions studied

1

Description of health condition studied

Major Depressive Disorder

ICD-10 code

F32

ICD-10 code description

Depressive episode

Primary outcomes

1

Description

Severity of symptoms of Depression

Timepoint

Baseline and 3weeks, 6weeks ,12weeks after treatment

Method of measurement

Hamilton Depression Rating Scale

Secondary outcomes

empty

Intervention groups

1

Description

Administration of fluoxetine +placebo

Category

Treatment - Drugs

2

Description

Administration of fluoxetine+thiamine

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Farshchian Hospital in Hamadan

Full name of responsible person

Street address

Farshchian Hospital, Hamadan

City

Hamadan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for Research and Technology of
Hamadan University of Medical Sciences

Full name of responsible person

Dr. Heydar Tavailani

Street address

Hamadan University of Medical Sciences, Hamadan

City

Hamadan

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 and Technology of
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

Dr. Hassan Davari

Position

Resident of Psychiatry

Other areas of specialty/work

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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