

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comperssion with the combined effects of omega _3 and citalopram for depression during menopause in postmenopausal women referred to health centers in Hamadan city in 1391: A double-blind clinical trial

Protocol summary

Summary

Objective: To compare the efficacy of citalopram combined with omega _3 on depression in menopausal women Design: Double blinded randomized controlled trial Setting: The eligible menopausal women with depression who will refer to selected health centers in 2013. Inclusion criteria: a) Age range 65-45 years; b) Should last at least 12 months of amenorrhea; c) According to DSM-IV criteria for depression are known to be; d) No history of hysterectomy, oophorectomy with radiation therapy; e) Not taking antidepressant medication and hormone therapy during the last 6 months; f) Not sensitive to herbal drug; g) Absence of diabetes and cardiovascular disease; h)The Beck score (10-24). Exclusion criteria: a) Drug intolerance; b) Not complete treatment duration; c) The depression scores higher of 24 at follow-up period.Control: 42 patients will receive 20 mg citalopram with placebo daily for one month. Intervention: 42 patients will receive1 gram of omega-3 and 20 mg citalopram daily for one month. Specific outcome: Evaluation of depression with the Beck scale at the end of the first, second and fourth weeks after treatment.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013052113405N1**
Registration date: **2013-07-22, 1392/04/31**
Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2013-07-22, 1392/04/31

Registrant information

Name

Seyyedeh Zahra Masoumi

Name of organization / entity

Hamedan University of Medical Sciences, School of Nursing and Midwifery

Country

Iran (Islamic Republic of)

Phone

+98 81 1838 0150

Email address

zahra.masoomi@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice-chancellor for Research, Hamadan University of Medical Sciences

Expected recruitment start date

2013-08-22, 1392/05/31

Expected recruitment end date

2014-02-19, 1392/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comperssion with the combined effects of omega _3 and citalopram for depression during menopause in postmenopausal women referred to health centers in Hamadan city in 1391: A double-blind clinical trial

Public title

Effect of omega3 in depression in menopause

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: a) Age range 65-45 years; b) Should last at least 12 months of amenorrhea; c) According to DSM-IV criteria for depression are known to be; d) No history of hysterectomy, oophorectomy with radiation therapy; e) Not taking antidepressant medication and hormone therapy during the last 6 months; f) Not sensitive to herbal drug ; g) Absence of diabetes and cardiovascular disease; h) The Beck score (10-24).

Exclusion criteria: a) Drug intolerance; b) Not complete treatment duration; c) The depression scores higher of 24 at follow-up period.

Age

From **48 years** old to **70 years** old

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **84**

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

Ethics committee of Hamedan university of Medical Scienses

Street address

Hamedan University of Medical Sciences, Fahmideh Ave, Hamedan

City

Hamedan

Postal code

Approval date

2013-05-05, 1392/02/15

Ethics committee reference number

330/9/35/16/د/پ

Health conditions studied

1

Description of health condition studied

Depression

ICD-10 code

F32,F33

ICD-10 code description

Depressive episode, Recurrent depressive disorder

Primary outcomes

1

Description

Depression

Timepoint

Before intervention, 1 ,2 ,4 week after intervention

Method of measurement

Beck Questionnaire

Secondary outcomes

1

Description

Complication of drug

Timepoint

After intervention

Method of measurement

Questionnaire

Intervention groups

1

Description

42 patients will receive 1 gram of omega-3 and 20 mg citalopram daily for one month.

Category

Treatment - Drugs

2

Description

42 patients will receive 20 mg citalopram with placebo daily for one month

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Hussein Medical Center

Full name of responsible person

Seyyedeh Zahra Masoumi

Street address

Imam Hussein Medical Center, Khezr, Hamedan.

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

Dr Heidar Tavidani

Street address

Vice-chancellor for Research, Hamadan University of Medical Sciences, Shahid Fahmideh Ave, 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**

Hamedan University of Medical Sciences

Full name of responsible person

Seyyedeh Zahra Masoumi

Position

Instructor, PhD student

Other areas of specialty/work**Street address**

School of Nursing and Midwifery, Fahmideh Ave, Hamedan

City

Hamedan

Postal code**Phone**

+98 81 1838 0150

Fax

+98 81 1838 0447

Email

zahramid2001@yahoo.comzahra.masoomi@umsha.ac.ir

Web page address

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Hamedan University of Medical Sciences

Full name of responsible person

Seyyedeh Zahra Masoumi

Position

Instructor, PhD student

Other areas of specialty/work**Street address**

School of Nursing and Midwifery, Fahmideh Ave, Hamedan

City

Hamedan

Postal code**Phone**

+98 81 1838 0150

Fax

+98 81 1838 0447

Email

zahramid2001@yahoo.comzahra.masoomi@umsha.ac.ir

Web page address

Person responsible for updating data

Contact**Name of organization / entity**

Hamedan University of Medical Sciences

Full name of responsible person

Seyyedeh Zahra Masoumi

Position

Instructor, PhD student

Other areas of specialty/work**Street address**

School of Nursing and Midwifery, Fahmideh Ave, Hamedan.

City

Hamedan

Postal code**Phone**

+98 81 1838 0150

Fax

+98 81 1838 0447

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