Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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

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Seyyedeh Zahra Masoumi
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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 receive1 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 Tavilani
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

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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