

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

The effect of omega3 fatty acid capsules on primi gravida during pregnancy depression that refer to health clinic in shiraz, Iran

Protocol summary

Summary

The aim of this study was to investigate the effect of omega3 fatty acid capsules during pregnancy depression in a primi gravida woman from 18 years old attending the selected health clinics of Shiraz university of medical sciences which had agreed to cooperate with the researchers. In case the study subject suffered from any illness, were not willing to continue participating in the study, and showed allergic reactions to medication, they were excluded from the study. After all, a total of 80 subjects were entered into the study and randomly divided into 2 groups receiving the drug, , and placebo, respectively for 6 weeks was evaluated with using Beck Depression inventory.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012121011717N1**

Registration date: **2013-01-08, 1391/10/19**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-01-08, 1391/10/19

Registrant information

Name

Laleh Saniee

Name of organization / entity

Fatemeh (PBUH) College of Nursing and Midwifery,
Shir

Country

Iran (Islamic Republic of)

Phone

+98 71 1235 4449

Email address

sanieel@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Research office, Shiraz University Of Medical Sciences

Expected recruitment start date

2012-07-07, 1391/04/17

Expected recruitment end date

2013-01-06, 1391/10/17

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of omega3 fatty acid capsules on primi gravida during pregnancy depression that refer to health clinic in shiraz, Iran

Public title

The effect of omega3 fatty acid capsules on primi gravida during pregnancy depression

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: willingness to participate; primi gravida woman from 18 years old; not having disease such as heart disease, hyperthyroidism, hypothyroidism, renal infection and diabetes mellitus; not taking any medication that effect depression such as anti depressent, SRII; no familial disorder; no psychotic problem and no psychotic consultation. Exclusion criteria: unwillingness to cooperate after the beginning of the study and showing allergic reaction to omega3.

Age

From **18 years** old to **44 years** old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: 80

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 Shiraz University of Medical Sciences

Street address

Central building of Shiraz University of Medical Sciences, Zand Street, Shiraz

City

Shiraz

Postal code

7188833398

Approval date

2012-07-07, 1391/04/17

Ethics committee reference number

91-611

Health conditions studied

1

Description of health condition studied

depression

ICD-10 code

F32.0

ICD-10 code description

episode-depressive-mild

Primary outcomes

1

Description

Depression

Timepoint

At the start of intervention- After intervention

Method of measurement

Beck depression inventory

Secondary outcomes

empty

Intervention groups

1

Description

Intervention with omega 3 capsules for each patient 1000 mg/day in 6 weeks.

Category

Treatment - Drugs

2

Description

placebo capsules are used 1 per day for 6 weeks

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Parseh health clinic

Full name of responsible person

Masumeh Kaviani

Street address

Sadra

City

Shiraz

2

Recruitment center

Name of recruitment center

Talegani health clinic

Full name of responsible person

Masumeh Kaviani

Street address

Modares bolvar

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Shiraz University of Medical Sciences

Full name of responsible person

Dr. Gholam Reza Hatam

Street address

7th Flat, Central building of Shiraz University of
Medical Sciences, Zand Street, Shiraz

City

Shiraz

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, Shiraz 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

Fatemeh (PBUH) College of Nursing and Midwifery
Shira

Full name of responsible person

kavianimasumeh

Position

Faculty Member, MSc in Midwifery

Other areas of specialty/work

Street address

Namazi square, Shiraz

City

shiraz

Postal code

kavianm@sums.ac.ir

Phone

+98 71 1647 4252

Fax

+98 71 1647 4252

Email

kavianm@sums.ac.ir

Web page address

**Person responsible for scientific
inquiries**

Contact

Name of organization / entity

Fatemeh (PBUH) College of Nursing and Midwifery
Shiraz University of Medical Sciences

Full name of responsible person

Masumeh Kaviani

Position

Faculty Member, MSc in Midwifery

Other areas of specialty/work

Street address

Namazi square, Shiraz

City

Shiraz

Postal code

Phone

+98 71 1647 4252

Fax

+98 71 1647 4252

Email

kavianm@sums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Fatemeh (PBUH) College of Nursing and Midwifery,
Shiraz

Full name of responsible person

saniee laleh

Position

Student, Msc in Midwifery

Other areas of specialty/work

Street address

Namazi Sq

City

shiraz

Postal code

iran

Phone

+98 71 1647 4252

Fax

+98 71164748252

Email

sanieel@sums.ac.ir

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