

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparison effect of omega-3 supplementation on postpartum depression and serum homocysteine of lactating women and growth and development of their infants

Protocol summary

Summary

The aim of this study is to test the effect of maternal supplementation of omega-3 fatty acids during first six month of lactation on postpartum depression and serum homocysteine levels of mothers and growth and development of their infants. This study is a double-blind placebo-controlled randomized trials. The inclusion criteria are lactating women who have moderate depression and term birth. The exclusion criteria are lactating women who have severe depression and preterm birth. The sample size consist of 70 lactating women that randomly divided into two groups of 35 women: the treatment group and control group. The intervention consist of maternal supplementation containing 1 gram gel capsules of omega-3 fatty acids daily for 3 months. The control group receive gel capsules of paraffin oil as placebo daily for 3 months. The maternal outcomes of serum homocysteine and postpartum depression will be evaluated before and after the intervention. The outcomes of growth and development of the infants will be evaluated before and after the intervention as well.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015100313678N6**
Registration date: **2016-03-01, 1394/12/11**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-03-01, 1394/12/11

Registrant information

Name

Saeed Ghavamzadeh

Name of organization / entity

Urmia University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 44 1278 0803

Email address

ghavamzadeh_s@umsu.ac.ir

Recruitment status

Recruitment complete

Funding source

Uremia University of Medical Sciences

Expected recruitment start date

2015-10-01, 1394/07/09

Expected recruitment end date

2015-10-22, 1394/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison effect of omega-3 supplementation on postpartum depression and serum homocysteine of lactating women and growth and development of their infants

Public title

Effect of omega3 supplementation during lactation on postpartum depression and growth and development of infant

Purpose

Supportive

Inclusion/Exclusion criteria

Including criteria: lactating women who have moderate depression; have singleton and term birth; have no complicated pregnancy and labor; have no history of depression and use antidepressants or anticoagulants; age of mother between 18-35; weight of infants above 2500 grams. Excluding criteria: lactating women who have severe depression; have preterm birth and twins; have chronic diseases such as blood pressure and diabetes; have complicated pregnancy and labor; ages of mothers under 18 years old and above 35 years old.

Age

From **18 years** old to **35 years** old

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **70**

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

Uremia University of Medical Sciences

Street address

Uremia University of Medical Sciences

City

Uremia

Postal code

57147-83734

Approval date

2015-09-02, 1394/06/11

Ethics committee reference number

lr.umsu.rec.1394.180

Health conditions studied

1

Description of health condition studied

Postpartum depression

ICD-10 code

F53

ICD-10 code description

Pregnancy; childbirth and the puerperium

Primary outcomes

1

Description

Postpartum depression

Timepoint

Before and after intervention

Method of measurement

Edinburgh Postpartum Depression Scales - Beck Depression Inventory

2

Description

Homocysteine

Timepoint

Before and after intervention

Method of measurement

Blood Samples

3

Description

Infants growth

Timepoint

Monthly

Method of measurement

Weight, height, head circumstances

4

Description

Development

Timepoint

4 and 6 month after birth

Method of measurement

Ages and Stages Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Treatment group; omega3 one gram daily for 3 months

Category

Treatment - Drugs

2

Description

Controls groups; Paraffin oil daily for 3 months

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Health Centers

Full name of responsible person

Street address

Ardebil

City

Ardebil

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Student

Full name of responsible person

Nasrin Nazeri

Street address

Uremia university of Medical Science

City

Uremia

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Student

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

Person responsible for scientific inquiries

Contact

Name of organization / entity

Uremia University of Medical Sciences

Full name of responsible person

Dr Saeiad Ghavamzadeh

Position

Nutritionist

Other areas of specialty/work

Street address

Uremia University of Medical Sciences

City

Uremia

Postal code

Phone

+98 44 3223 4897

Fax

Email

Ghavamzadeh@hotmail.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Uremia University of Medical Science

Full name of responsible person

Nasrin Nazeri

Position

MS student of nutrition

Other areas of specialty/work

Street address

Uremia University of Medical Science

City

Uremia

Postal code

5714783738

Phone

00

Fax

Email

nasrin.nazeri11@yahoo.com

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