Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Jun 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

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Urmia University of Medical Sciences
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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
Ir.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
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Nutritionist
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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