

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jul 2026

The effect of fish-oil supplementation on pregnancy outcomes in mother and infant: a randomized controlled trial

Protocol summary

Summary

Objective: To determine the effect of fish oil supplementation on pregnancy outcomes in mother and infant: a randomized controlled clinical trial. This is a randomized, triple blind, placebo-controlled multicenter study. 150 healthy pregnant women aged 18-35 years who are in 16-20 weeks of pregnancy will be recruited in the study. The study will be done at public health centers in Tabriz. The women will be allocated to the intervention and control groups using permuted block randomization with allocation ratio of 1:1. We will use sequentially numbered packs containing fish oil or placebo soft gels to conceal the allocation and maintain blinding. The capsules will be identical and unrecognizable for participants, and those involved in recruitment and data collection. Each fish oil soft gels will be 1000 mg containing 120 mg of DHA and 180 mg EPA. The soft gels will be taken once per day from end of the 20th week of pregnancy to 1 month after childbirth (approximately 24 weeks). Primary outcomes are the mean weight of newborns; postpartum depression; and infant neurodevelopment at the 4th and 6th months. At baseline and weeks 35-37, 3cc blood samples will be taken from the participants to examine the phospholipids.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013100914957N1**

Registration date: **2014-02-14, 1392/11/25**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2014-02-14, 1392/11/25

Registrant information

Name

Azizeh Farshbaf-khalili

Name of organization / entity

Tabriz university of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Research Deputy of Tabriz University of Medical Sciences

Expected recruitment start date

2014-02-15, 1392/11/26

Expected recruitment end date

2015-06-15, 1394/03/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of fish-oil supplementation on pregnancy outcomes in mother and infant: a randomized controlled trial

Public title

The effect of fish-oil supplementation on pregnancy outcomes in mother and infant

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria: Healthy pregnant women in 16-20 weeks of pregnancy; Aged 18-35 years; 5th pregnancy or less; Singleton pregnancy; No history of infertility and

premature birth; Not having history of depression or postpartum depression; Edinburgh depression score less than 23; Absence of known placenta previa or cerclage in this pregnancy; No adverse event occurred 6 months before the study Exclusion criteria: Smoking or drugs using ;consumption of more than two servings fish per week; Having bleeding disorders or taking anticoagulants; BMI more than 30; participating in another study; Wanting to change living area in the next 6 months; No access to call phone; Being illiterate or unable to answer questions; History of sensitivity to fish oil or other fish products; sensitivity to gelatin; participation in other intervention study; Not willingness to participate; known underlying disease including heart, kidney, stomach, lung, thyroid or autoimmune diseases, diabetes, impaired glucose tolerance in pregnancy, epilepsy, essential hypertension,hyperlipidemia

Age

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

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **150**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Triple blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Regional Ethical Committee for Medical Research

Street address

Research Deputy of Tabriz University of Medical Sciences, End of Gholgasht street, Tabriz, Iran

City

Tabriz

Postal code**Approval date**

2013-12-02, 1392/09/11

Ethics committee reference number

92141

Health conditions studied**1****Description of health condition studied**

Pregnancy, childbirth and the puerperium

ICD-10 code

O14

ICD-10 code description

Gestational [pregnancy-induced] hypertension with significant proteinuria

2**Description of health condition studied**

Pregnancy, childbirth and the puerperium

ICD-10 code

O24.9

ICD-10 code description

Diabetes mellitus in pregnancy, unspecified

3**Description of health condition studied**

Pregnancy, childbirth and the puerperium

ICD-10 code

O60

ICD-10 code description

Preterm labour and delivery

4**Description of health condition studied**

Pregnancy, childbirth and the puerperium

ICD-10 code

O82

ICD-10 code description

Single delivery by caesarean section

5**Description of health condition studied**

Pregnancy, childbirth and the puerperium

ICD-10 code

O99.3

ICD-10 code description

Mental disorders and diseases of the nervous system complicating pregnancy, childbirth and the puerperium

6**Description of health condition studied**

Pregnancy, childbirth and the puerperium

ICD-10 code

O26.9

ICD-10 code description

Pregnancy-related condition, unspecified

7**Description of health condition studied**

Certain conditions originating in the perinatal period

ICD-10 code

P00.4

ICD-10 code description

Fetus and newborn affected by maternal nutritional disorders

8

Description of health condition studied

Certain conditions originating in the perinatal period

ICD-10 code

P07

ICD-10 code description

Disorders related to short gestation and low birth weight, not elsewhere classified

Primary outcomes

1

Description

Postpartum Depression

Timepoint

6-8 weeks after childbirth

Method of measurement

Edinburgh Depression Scale

2

Description

Newborn Weight

Timepoint

Childbirth

Method of measurement

By means of newborns scale into gram

3

Description

Infant Neurodevelopment

Timepoint

4 and 6 month

Method of measurement

ASQ Questionnaire

Secondary outcomes

1

Description

Height and head circumference at birth

Timepoint

Postpartum

Method of measurement

Centimeter

2

Description

Low birth weight

Timepoint

postpartum

Method of measurement

by means of newborns scale into gram

3

Description

Depression in pregnancy

Timepoint

16-20; 26-28; 35-37 weeks of pregnancy

Method of measurement

Edinburgh depression questionnaire

4

Description

Preterm labor

Timepoint

childbirth

Method of measurement

weeks of pregnancy

5

Description

Preeclampsia

Timepoint

after 20th week of pregnancy until childbirth

Method of measurement

by use of measuring blood pressure and proteinuria

6

Description

Result of One-step, 2-h 75-g OGTT

Timepoint

26-28 weeks

Method of measurement

glucose oxidase

7

Description

Serum level of eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA)

Timepoint

Before intervention between 16-20 weeks; 35-37 weeks

Method of measurement

Gas chromatography

8

Description

Maternal weight gain

Timepoint

before childbirth

Method of measurement

kilogram

9

Description

Length of pregnancy

Timepoint

delivery

Method of measurement

pregnancy duration from the first day of last menstrual period to childbirth; early sonography

Intervention groups

1

Description

Intervention: Fish oil soft gels (1000 mg contains 120 mg of DHA and 180 mg EPA) will be taken once per day from the end of 20th week of pregnancy to 1 month after childbirth (approximately 24 weeks equal to 168 capsules)

Category

Treatment - Drugs

2

Description

Control: Placebo soft gels identical with the fish oils soft gels regarding shape, size and weight, will be taken once per day from the end of 20th week of pregnancy to 1 month after childbirth (approximately 24 weeks equal to 168 capsules)

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Public health centers of Tabriz

Full name of responsible person

Dr Mitra Yeghaneh

Street address

Tabriz Health Center

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

National Public-Health Management Center (NPMC)

Full name of responsible person

Mrs Jabbari

Street address

National Public-Health Management Center, Shahid Shafizadeh 24m Ave, Valiamr Square, Tavanir Outlet, Pasdaran Highway, Tabriz, Iran

City

Tabriz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

National Public-Health Management Center (NPMC)

Proportion provided by this source

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

2

Sponsor

Name of organization / entity

Faculty of Nursing and Midwifery

Full name of responsible person

Miss Abbaszadeh

Street address

Faculty of Nursing and Midwifery, End of South-Shariati, Tabriz, Iran

City

Tabriz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Faculty of Nursing and Midwifery

Proportion provided by this source

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

Research Center of NPMC/ Faculty of Nursing and Midwifery-Tabriz University of Medical Science

Full name of responsible person

Azizeh Farshbaf-Khalili

Position

PhD Student of community Nutrition/ Midwifery educator

Other areas of specialty/work

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Tabriz University of Medical Sciences

Full name of responsible person

Dr Alireza Ostad-Rahimi

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PhD Student of Community Nutrition/ MS in Midwifery/
Member of Midwifery Department

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

Faculty of Nursing and Midwifery, Research Center of
NPMC, Tabriz University of Medical Sciences, Tabriz,
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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