

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 May 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)

##### Phone

+98 41 1333 9151

##### Email address

farshbafa@tbzmed.ac.ir

#### 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

##### Street address

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

##### City

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##### Phone

+98 41 1479 6770

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**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Dr Alireza Ostad-Rahimi

**Position**

PhD of Nutrition/Associate Professor

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Gholgasht Street, Tabriz, Iran

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Tabriz University of Medical Sciences

**Full name of responsible person**

Azizeh Farshbaf Khalili

**Position**

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  
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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*