

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Aug 2026

### The effect of fish-oil supplementation on lipid profile of pregnant mothers: a randomized controlled trial

#### Protocol summary

##### Summary

The purpose of study is to determine the effect of fish oil supplementation on lipid profiles of pregnant. Randomized clinical trial, In this study, researcher and researcher assistance, the analyser and the participants will be Blind. Questionnaire number one for evaluation of the inclusion criteria will be given to people who would like to participate in the study. If conditions was appropriate the second questionnaire will be given to collect demographic information and complete their pregnancy occurs. Also the third questionnaire contains a tutorial on how to use capsules, recorded weekly taking capsules and possible events will be given to pregnant women. A total of 150 samples will be selected from which 75 patients will be in the intervention group and 75 patients will be in the placebo group. The study population consisted of 18-35 years old pregnant women with first to fifth parity who have family records at health centers in Tabriz .Thus healthy 18-35 years old pregnant women with gestational age of 16-20 weeks of pregnancy with first to fifth parity, who have not been used any drug will be participate in the project. Pregnant women were randomly divided into two groups, one group receiving placebo and another group receiving fish oil supplements capsules. Consumption of fish oil capsules (1,000 mg contains of 120 mg DHA and 180 mg EPA) and placebo (same shape, the same size and weight with other capsules) daily one capsule from the end of the 20th week of pregnancy until first month of postpartum period which will be about 24 weeks (168 capsules). At the beginning of the study (20-16 weeks gestation) and in the fifth care of pregnancy (weeks 35-37) 3 cc blood samples will be collected and will be sent to the laboratory for evaluation of lipid profiles level. Sampling will be carried out as quota with the order of the number of pregnancies (first, second or more pregnancy). Main outcome measure variables is the lipid profile test.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2015070523067N1**

Registration date: **2015-08-13, 1394/05/22**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2015-08-13, 1394/05/22

##### Registrant information

##### Name

Esmail Faraji

##### Name of organization / entity

Tabriz University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 1335 7850

##### Email address

farajie@tbzmed.ac.ir

##### Recruitment status

##### Recruitment complete

##### Funding source

Endocrine Research Center, Tabriz University of Medical Sciences

##### Expected recruitment start date

2014-11-27, 1393/09/06

##### Expected recruitment end date

2015-10-28, 1394/08/06

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

The effect of fish-oil supplementation on lipid profile of pregnant mothers: a randomized controlled trial

## Public title

The effect of fish-oil supplementation on lipid profile of pregnant mothers: a randomized controlled trial

## Purpose

Treatment

## Inclusion/Exclusion criteria

Inclusion criteria: willingness to participate in the study, aged 18-35 years, first to fifth pregnancy, pregnant women with 16-20weeks of gestation, single pregnancy; BMI less than 30, healthy pregnant women with no previous underlying medical condition, including heart disease, kidney, gastrointestinal, respiratory, autoimmune, diabetes, impaired glucose tolerance testing in the current pregnancy, thyroid, epilepsy, hypertension underlying psychiatric disorders, hyperlipidemia and not to use any drugs because of the above conditions .Exclusion criteria:, bleeding, placenta previa, placenta detachment in current pregnancy, infertility and premature labor history, the existence of any history of allergy to fish or fish oil or other products or allergic to gelatin, the unfortunate incident that had occurred 6 months prior to the study, smoking or drugs, bleeding disorders or taking anticoagulants, participating in another study

## 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: **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

Ethics Committee of Tabriz University of Medical Sciences

## Street address

Tabriz University of Medical Sciences, Daneshgah Square Tabriz, Tabriz

## City

Tabriz

## Postal code

## Approval date

2015-06-24, 1394/04/03

## Ethics committee reference number

TBZMED.REC.1394.276

## Health conditions studied

### 1

#### Description of health condition studied

Lipid levels in Pregnant women

#### ICD-10 code

094-095-09

#### ICD-10 code description

Other obstetric conditions, not elsewhere classified

## Primary outcomes

### 1

#### Description

Lipid Profile

#### Timepoint

beginning of study,fifth care of pregnancy

#### Method of measurement

blood analysis

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Group interventions: fish oil capsules (containing 120 mg of DHA and 180 mg, 1000 mg EPA) ,Every day 1 number

#### Category

Treatment - Drugs

### 2

#### Description

Control group: placebo (same shape, size and weight with other capsules) ,Every day 1 number

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Health facilities in Tabriz

**Full name of responsible person**

Hossein Aslani

**Street address**

Imam Reza Hospital, Tabriz Department Of Internal  
Medicine, Tabriz University of Medical Sciences,  
Daneshgah Avenue, Daneshgah Square Tabriz

**City**

Tabriz

+98 41 3382 3655

**Fax****Email**

hosseinaslani1990@gmail.com

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

Tabriz University of Medical Sciences

**Full name of responsible person**

Dr.Esamil Faraji

**Position**Assistant Professor of Endocrinology and Metabolic  
Diseases**Other areas of specialty/work****Street address**

Tabriz University of Medical Sciences, Daneshgah  
Square, Imam Reza Hospital, Tabriz Department Of  
Internal Medicine

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**Postal code****Phone**

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farajie@tbzmed.ac.ir

**Web page address****Person responsible for updating data****Contact****Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Hossein Aslani

**Position**

General Practitioner

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

Imam Reza Hospital, Tabriz University of Medical  
Sciences, Daneshgah Avenue, Daneshgah Square  
Tabriz

**City**

Tabriz

**Postal code****Phone**

+98 41 3382 3655

**Fax****Email**

hosseinaslani1990@gmail.com

**Web page address****Sharing plan****Deidentified Individual Participant Data Set (IPD)***empty***Study Protocol***empty***Sponsors / Funding sources****1****Sponsor****Name of organization / entity**Endocrine Research Center, Tabriz University of  
Medical Sciences**Full name of responsible person**

Esmail Faraji

**Street address**

Endocrine Research Center, Imam Reza Hospital,  
Tabriz University of Medical Sciences, Daneshgah  
Avenue, Daneshgah Square Tabriz

**City**

Tabriz

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor  
organization/entity?**

Yes

**Title of funding source**Endocrine Research Center, Tabriz 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**

Tabriz University of Medical Sciences

**Full name of responsible person**

Hossein Aslani

**Position**

General Practitioner

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

Imam Reza Hospital, Tabriz Department Of Internal  
Medicine

**City**

Tabriz

**Postal code****Phone**

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*