Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Apr 2020

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 gel will contain 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
024.9
ICD-10 code description
Diabetes mellitus in pregnancy, unspecified

2
Description of health condition studied
Pregnancy, childbirth and the puerperium
ICD-10 code
060
ICD-10 code description
Preterm labour and delivery

3
Description of health condition studied
Pregnancy, childbirth and the puerperium
ICD-10 code
082
ICD-10 code description
Single delivery by caesarean section

4
Description of health condition studied
Pregnancy, childbirth and the puerperium
ICD-10 code
099.3
ICD-10 code description
Mental disorders and diseases of the nervous system complicating pregnancy, childbirth and the puerperium

5
Description of health condition studied
Pregnancy, childbirth and the puerperium
ICD-10 code
014
ICD-10 code description
Gestational [pregnancy-induced] hypertension with significant proteinuria

6
Description of health condition studied
Pregnancy, childbirth and the puerperium
ICD-10 code
026.9
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
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 questionnare

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
Befor intervention between 16-20 weeks; 35-37 weeks
Method of measurement
Gas chromatography

8
Description
Maternal weight gain
Timepoint
befor 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

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### 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

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### 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

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### Sponsors / Funding sources

**1**

**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

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### Person responsible for general inquiries

**Contact**

**Name of organization / entity**
- Research Center of NPMC/ Faculty of Nursing and Midwifery-Tabiz 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**
- Midwifery Department, Faculty of Nursing and Midwifery, End of South-Shariati Ave, Tabriz, Iran

**City**
- Tabriz

**Postal code**
- +98 41 1479 6770

**Phone**
- +98 41 1479 6969

**Email**
- azizeh_farshbafkhalili@yahoo.com; farshbafa@tbzmed.ac.ir

**Web page address**
- empty

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### 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
Other areas of specialty/work
Research Center of Nutrition, Faculty of Nutrition, Gholgasht Street, Tabriz, Iran
City
Tabriz
Postal code
15178
Phone
+98 41 1335 2292
Fax
Email
ostadrahimi@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
Azizeh Farshbaf Khalili
Position
PhD Student of Community Nutrition/ MS in Midwifery/ Member of Midwifery Department
Other areas of specialty/work
Faculty of Nursing and Midwifery, Research Center of NPMC, Tabriz University of Medical Sciences, Tabriz, Iran
City
Tabriz
Postal code
1479
Phone
+98 41 1479 6770
Fax
Email
azizeh_farshbafkhalili@yahoo.comfarshbafa@tbzmed.ac.ir
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