

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jul 2026

Investigating the Effect of Fish Oil Supplement on Pregnancy Outcome in Women with a History of High-risk Pregnancy

Protocol summary

Study aim

Determining the effect of fish oil supplementation on pregnancy outcomes in women with a history of high-risk pregnancies

Design

Clinical trial with control group, with parallel groups, double-blind, randomized, phase 2 in 200 patients, Block randomization was used for randomization.

Settings and conduct

In this double-blind study, pregnant women referred to health centers with a history of high-risk pregnancies were divided into intervention and control groups using block randomization, and members of the intervention group from 16 weeks of gestation to the end of pregnancy, In addition to routine pregnancy care, they received a daily capsule of 1000 mg salmon oil containing essential fatty acids (fish oil and flax seed oil), and control group members received only routine care.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age between 18 and 40 years Second pregnancy and after that History of problems such as preterm delivery; intrauterine growth retardation; preeclampsia; induced gestational hypertension in previous pregnancy Exit criteria: Threat of miscarriage and placental previa in the current pregnancy

Intervention groups

From the 16th week of pregnancy, the intervention group was given one 1000 mg capsule of omega-3 fish oil daily until the end of the pregnancy, and routine pregnancy care was performed. The control group received only routine pregnancy care.

Main outcome variables

Baby weight, Apgar score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100701004281N3**

Registration date: **2020-07-13, 1399/04/23**

Registration timing: **retrospective**

Last update: **2020-07-13, 1399/04/23**

Update count: **0**

Registration date

2020-07-13, 1399/04/23

Registrant information

Name

Azam Hamidzadeh

Name of organization / entity

Shahroud University of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 23 3239 5054

Email address

azhamidzadeh@shmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2015-03-30, 1394/01/10

Expected recruitment end date

2015-12-21, 1394/09/30

Actual recruitment start date

2015-03-31, 1394/01/11

Actual recruitment end date

2016-02-15, 1394/11/26

Trial completion date

2016-02-15, 1394/11/26

Scientific title

Investigating the Effect of Fish Oil Supplement on Pregnancy Outcome in Women with a History of High-risk Pregnancy

Public title

Effect of Fish Oil Supplement on Pregnancy Outcome in Women with a History of High-risk Pregnancy

Purpose

Health service research

Inclusion/Exclusion criteria**Inclusion criteria:**

Iranian race Age between 18 and 40 years Second pregnancy and after that History of problems such as preterm delivery; intrauterine growth retardation; preeclampsia; induced gestational hypertension in previous pregnancy The first visit to a medical center before the 16th week of pregnancy

Exclusion criteria:

Threat of miscarriage and placental abruption (bleeding) in the current pregnancy Cervical cerclage Having cardiovascular disease; kidney disease and lack of urinary tract infections; polyhydramnios; chronic lung disease; liver disease; hepatitis of any type; hyper and hypothyroidism; overt diabetes or gestational diabetes in previous pregnancies; diagnosis or suspicion of severe fetal abnormalities or hydrops in the current pregnancy Substance abuse, alcohol and smoking; regular consumption of fish oil or nonsteroidal anti-inflammatory agents or other medications Allergy to fish products Lack of desire to take pill and irregular visit

Age

From **18 years** old to **40 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **200**

Actual sample size reached: **200**

Randomization (investigator's opinion)

Randomized

Randomization description

In order to assign patients to two groups of intervention and control, block randomization method with the size of four random blocks was used and randomization sequence was performed in the central committee. The sequence of randomization using web-based randomization is done through the following site: <https://www.Randomization.com>

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, participants were unaware of the study group they were in (intervention or control). Also, the evaluation of the study results (pregnancy outcomes) was performed by a person outside the research team.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics Committee of Shahid Beheshti University of Medical Sciences

Street address

Shahid Chamran Highway, Yemen St., Shahid Arabi St., next to Ayatollah Taleghani Hospital

City

Tehran

Province

Tehran

Postal code

1983535511

Approval date

2015-09-06, 1394/06/15

Ethics committee reference number

IR.SBMU.RAM.REC.1394.201

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

Increase of blood pressure during current pregnancy

ICD-10 code

O10

ICD-10 code description

Pre-existing hypertension complicating pregnancy, childbirth and the puerperium

Primary outcomes**1****Description**

Newborn Weight

Timepoint

At birth time

Method of measurement

By means of newborns scale into gram

2**Description**

Apgar score in the first and fifth minutes

Timepoint

At birth time

Method of measurement

Observation and physical examination

Secondary outcomes

1

Description

Childbirth before 37 weeks

Timepoint

At the time of hospitalization

Method of measurement

Estimation of gestational age

2

Description

Increase of blood pressure

Timepoint

From the 16th week of pregnancy on prenatal visits

Method of measurement

By Blood pressure control device

3

Description

mode of delivery

Timepoint

at birth time

Method of measurement

observation

Intervention groups

1

Description

Intervention group: Soft capsule of 1000 mg salmon oil (Omega 3), without mercury, containing essential fatty acids (fish oil and flaxseed oil) made in Iran, Zahravi Pharmaceutical Company, each capsule of which contains 180 mg of eicosapentaenoic acid and 120 mg Docosahexaenoic acid, and from the 16th week to the end of pregnancy, one capsule a day was given and it was recommended to be taken orally with food and water; Routine pregnancy care was also provided for this group

Category

Treatment - Drugs

2

Description

Control group: No intervention was performed and they only received routine pregnancy care.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Ghalehmir health center

Full name of responsible person

Leila Khorasani

Street address

The main street of Ghalemir, next to the telecommunication

City

Tehran

Province

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Phone

+98 21 5686 6722

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2

Recruitment center

Name of recruitment center

Salehabad health center

Full name of responsible person

Leila Khorasani

Street address

Next to Noor Al-Zahra school, end of the first 15 meters, Negarestan 18, Salehabad

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+98 21 4055 8917

Email

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3

Recruitment center

Name of recruitment center

Fesharghavi health center

Full name of responsible person

Leila Khorasani

Street address

After Fathipour alley, corner of the first 10 meters, Shahid Sattari 30-meter street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

Street address

Next to Taleghani Hospital, Yemen Street, Shahid Chamran Highway

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

Yes

Title of funding source

Shahid Beheshti University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Academic

kiani.m89@gmail.com

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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Robabeh Taheripanah

Position

Faculty member of university

Latest degree

Subspecialist

Other areas of specialty/work

Gynecology and Obstetrics

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

Shahroud University of Medical Sciences

Full name of responsible person

Mahdieh Kiani

Position

Faculty member of Shahroud University of Medical Sciences

Latest degree

Master

Other areas of specialty/work

Midwifery

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Email**Person responsible for updating data****Contact****Name of organization / entity**

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Faculty member of Shahroud University of Medical Sciences

Latest degree

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Other areas of specialty/work

Midwifery

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Email

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is not further information

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available