Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Clinical trial to evaluate the effect of fish oil supplementation on pregnancy outcomes in pregnant women

Protocol summary

Summary

This study was designed as a clinical trial to evaluate the effect of fish oil supplementation on pregnancy outcomes. The study population were 360 women referred to Kosar hospital in Qazvin. They were non randomly divided into two intervention and control groups. Patients in intervention group received fish oil, 1000 mg capsules, once a day, since 20th gestational week until the end of their pregnancy. The control group did not receive any medication. Pregnancy care was the same for both groups. The main inclusion criteria included: pregnant women aged between 18-35 years old; singleton pregnancy. The main exclusion criteria included: sensitivity to the fish and fish oil. The outcomes of interest were pre eclampsia; eclampsia; preterm labo; GDM; birth weight and Gestational age at the time of pregnancy termination.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015072123269N1**
Registration date: **2017-06-11, 1396/03/21**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2017-06-11, 1396/03/21

Registrant information

Name

Seyede Nazanin Gholami

Name of organization / entity

Qazvin University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice-Chancellor for Research of Qazvin University of Medical Sciences

Expected recruitment start date

2015-12-22, 1394/10/01

Expected recruitment end date

2016-08-22, 1395/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial to evaluate the effect of fish oil supplementation on pregnancy outcomes in pregnant women

Public title

Effect of fish oil on pregnancy outcomes

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: pregnant women aged between 18-35 years old; singleton pregnancy; being in 16th -20th weeks of gestational age; lack of preterm labor history; lack of infertility history. Exclusion criteria: BMI>30; sensivity to fish and fish oil; being smoker or addict.

Age

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

Gender

Female

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **360**
Randomization (investigator's opinion)
Not randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Qazvin University of Medical Sciences
Street address
Bahonar Blvd , Qazvin
City
Qazvin
Postal code
Approval date
2015-12-09, 1394/09/18
Ethics committee reference number
IR.QUMS.REC.1394.234 , 28/20/11316

Health conditions studied

1

Description of health condition studied
pre-eclampsia
ICD-10 code
O14.9
ICD-10 code description
Pre-eclampsia, unspecified

2

Description of health condition studied
eclampsia
ICD-10 code
O15.0
ICD-10 code description
Eclampsia in pregnancy

3

Description of health condition studied
gestational diabets mellitus
ICD-10 code
O24.4
ICD-10 code description
Diabetes mellitus in pregnancy, unspecified

4

Description of health condition studied
preterm laber
ICD-10 code
O60.1
ICD-10 code description
Preterm spontaneous labour with preterm delivery

Primary outcomes

1

Description
lenght of pregnancy
Timepoint
delivery
Method of measurement
week

2

Description
preterm laber
Timepoint
child brith
Method of measurement
week

3

Description
gestational diabets mellitus
Timepoint
24-28 week
Method of measurement
laboratory test

4

Description
newborn weight
Timepoint
child birth
Method of measurement
by means of newborn scale / gram

5

Description
pre-eclampsia
Timepoint
after 20 week of pregnancy until child birth
Method of measurement

Blood pressure measurment and evaluation of proteinuria

6

Description
eclampsia
Timepoint
seizure
Method of measurement
clinical signs

Secondary outcomes

1

Description
BMI
Timepoint
before pregnancy
Method of measurement
using measurement of height and weight

2

Description
age
Timepoint
at initiation of the study
Method of measurement
year

3

Description
education
Timepoint
at initiation of the study
Method of measurement
question and answer

4

Description
parity
Timepoint
at initiation of the study
Method of measurement
the number of pregnancy

Intervention groups

1

Description
Intervention group: they will receive Fish oil 1000 mg capsules, one daily since 16-20 gestational weeks until the end of pregnancy
Category
Treatment - Drugs

2

Description
Control group: they don't receive any medication
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Kosar Hospital
Full name of responsible person
Seyede Nazanin Gholami
Street address
Kosar Hospital, Taleghani St., Qazvin
City
Qazvin

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for Research of Qazvin University of Medical Sciences
Full name of responsible person
Dr.Taghi Naserpour
Street address
Bahonar Blvd, Qazvin
City
Qazvin
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice Chancellor for Research of Qazvin 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
Qazvin University of Medical Sciences
Full name of responsible person
Seyede Nazanin Gholami

Position
Gynecology and Obstetrics resident
Other areas of specialty/work
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Person responsible for scientific inquiries

Contact
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Qazvin University of Medical Sciences
Full name of responsible person
Shokoh Alsadat Hajseyed Abotorabi
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Other areas of specialty/work
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Person responsible for updating data

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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