

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jul 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)

Phone

+98 28 3333 6005

Email address

sn.gholami@qums.ac.ir

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; sensitivity 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 labor

ICD-10 code

O60.1

ICD-10 code description

Preterm spontaneous labour with preterm delivery

Primary outcomes

1

Description

length of pregnancy

Timepoint

delivery

Method of measurement

week

2

Description

preterm labor

Timepoint

child birth

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 measurement 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**Street address**

Bahonar Blvd , Qazvin

City

Qazvin

Postal code**Phone**

+98 28 3333 6001

Fax**Email**

researchdpt@qums.ac.ir

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

Qazvin University of Medical Sciences

Full name of responsible person

Shokoh Alsadat Hajseyed Abotorabi

Position

Assistant Professor

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

Bahonar Blvd, Qazvin

City

Qazvin

Postal code**Phone**

+98 28 3333 6001

Fax**Email**

researchdpt@qums.ac.ir

Web page address**Person responsible for updating data****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**Street address**

Bahonar Blvd , Qazvin

City

Qazvin

Postal code**Phone**

+98 28 3333 6001

Fax**Email****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