

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

Survey of the Effect of Omega-3 in the Prevention of Preeclampsia in Pregnant Women Suffering Hyperlipidemia

Protocol summary

Study aim

The aim of this study is survey of the relationship between omega-3 administrations in pregnant women suffering hyperlipidemia with prevention of preeclampsia.

Design

A clinical trial with a control group, with intervention and control groups, double-blind, randomized block, on 72 patients. A checklist was used for randomization.

Settings and conduct

This clinical trial study will be performed on pregnant women with hyperlipidemia referred to the infertility treatment center of Besat Hospital of Kurdistan University of Medical Sciences in Sanandaj city, Kurdistan Province, Iran. Pregnant women with hyperlipidemia are randomly divided into two groups and treated with omega-3. Finally, patients are evaluated for preeclampsia during childbirth.

Participants/Inclusion and exclusion criteria

Entry conditions :Pregnant women suffering hyperlipidemia with triglyceride levels above 150 milligrams per deciliter; no entry conditions: pregnant women with metabolic diseases, pregnant women with the age of less than 20 years and over the age of 40 years, pregnant women with a history of preeclampsia in a previous pregnancy or in a first-degree relative, pregnant women with a history of having twins, pregnant women with a body mass index equal to or greater than 29, pregnant women with kidney disease, high blood pressure, diabetes and hyperthyroidism, pregnant women that use of aspirin, calcium, anticoagulants and insulin, pregnant women that do not have history of omega-3 allergies.

Intervention groups

Intervention group A: 36 pregnant women aged 20 to 40 years with hypertriglyceridemia who received omega-3 daily in the form of one gram capsule. Intervention group B: 36 pregnant women aged 20 to 40 years with hypertriglyceridemia who received the placebo daily in

the form of one 100 mg gelatin capsule.

Main outcome variables

Preeclampsia

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210426051094N1**

Registration date: **2021-06-07, 1400/03/17**

Registration timing: **registered_while_recruiting**

Last update: **2021-06-07, 1400/03/17**

Update count: **0**

Registration date

2021-06-07, 1400/03/17

Registrant information

Name

Shima Mahdavian Naghash Zargar

Name of organization / entity

Kurdistan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 87 3366 0089

Email address

mnz_shima@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-05-02, 1400/02/12

Expected recruitment end date

2022-04-28, 1401/02/08

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Survey of the Effect of Omega-3 in the Prevention of Preeclampsia in Pregnant Women Suffering Hyperlipidemia

Public title

"Survey of the Effect of Omega-3 in the Prevention of Preeclampsia"

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Pregnant Women Suffering Hyperlipidemia that triglyceride levels is above 150 Milligrams per Deciliter.

Exclusion criteria:

Pregnant women that are suffering metabolic diseases. Pregnant women that have the age of less than 20 years and over the age of 40 years. Pregnant women that have a history of preeclampsia in a previous pregnancy or in a first-degree relative. Pregnant women that have a history of having twins. Pregnant women that have a body mass index equal to or greater than 29. Pregnant women that have kidney disease, high blood pressure, diabetes and hyperthyroidism. Pregnant women that use of aspirin, calcium, anticoagulants and insulin. Pregnant women that do not have history of omega-3 allergies.

Age

From **20 years** old to **40 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **72**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization of patients will do by randomization method of 4 blocks (AA, BB-AB, AB-BA, BA-AA, BB). So exactly the same numbers of participants enter the intervention and control groups in the consecutive but equal intervals. Therefore, two groups are considered. Patients in intervention group A, that received omega-3 and placebo group B, that received placebo. Intervention group A receives omega-3 in the form of one gram tablet containing Eicosapentaenoic acid and Docosahexaenoic acid daily until the end of pregnancy. The placebo group receives the placebo daily in the form of gelatin capsules until the end of pregnancy. Patients will be referred for blood pressure measurement during pregnancy and will be evaluated for triglyceride measurements. The necessary information for the study is collected using a checklist and finally the incidence of eclampsia between the intervention and placebo groups will be analyzed and

compared.

Blinding (investigator's opinion)

Double blinded

Blinding description

The control group receives a placebo, which is in the form of gelatin capsules and will be used daily until the end of pregnancy.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

دانشگاه علوم پزشکی کردستان

Street address

Abidar Street, Besat Hospital, Infertility Treatment Center

City

Sanandaj

Province

Kurdistan

Postal code

۱۳۴۴۶۶۱۷۷

Approval date

2020-01-23, 1398/11/03

Ethics committee reference number

IR.MUK.REC.1398.306

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

Preeclampsia in Pregnant Women Suffering Hyperlipidemia

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Preeclampsia

Timepoint

Before the intervention in the first month of pregnancy and 9 months after the intervention in the last month of pregnancy

Method of measurement

Blood pressure above 140 to 90 mm Hg, swelling of the hands and face, overweight, based on the results of clinical trials of the patient's blood, including protein in

the urine, increased liver enzymes, decreased platelet count, increased creatine and ultrasound

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: From the first month to the end of pregnancy for 9 months, the intervention group receives omega-3 daily as one gram capsule containing eicosapentanoic acid and docosahexaenoic acid. This group includes 36 pregnant women and will take the capsules with some water. The manufacturing factory of this capsule is Zahravi Pharmaceutical Company in Iran.

Category

Treatment - Drugs

2

Description

Placebo group: From the first month to the end of pregnancy for 9 months, the intervention group receives Gelatin capsules daily as 100 mg capsule. This group includes 36 pregnant women and will take the capsules with some water. The manufacturer of this capsule is Isfahan School of Pharmacy in Iran.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Besat Hospital, Infertility Treatment Center

Full name of responsible person

Sholeh Shahgeibi

Street address

Abidar Street, Besat Hospital, Infertility Treatment Center

City

Sanandaj

Province

Kurdistan

Postal code

۱۳۴۶۶۶۱۷۷

Phone

+98 87 3366 0089

Email

shahgheibi@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kurdistan University of Medical Sciences

Full name of responsible person

Sholeh Shahgheibi

Street address

Abidar Street, Besat Hospital, Infertility Treatment Center

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۱۳۴۶۶۶۱۷۷

Phone

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Email

shahgheibi@yahoo.com

Grant name

Afshin Maleki, Professor of Environmental Health Engineering, Department of Environmental Health Engineering, School of Health, Environmental Health Research Center, Research Institute for Health Development, Kurdistan University of Medical Sciences

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Kurdistan 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

Person responsible for general inquiries

Contact

Name of organization / entity

Kurdistan University of Medical Sciences

Full name of responsible person

Shima Mahdavian Naghash Zargar

Position

دانشجوی پزشکی

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

Street address

Abidar Street, Besat Hospital, Infertility Treatment Center

City

Sanandaj

Province

Kurdistan

Postal code

66177-13446

Phone

+98 87 3366 0089

Email

mnz_shima@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Kurdistan University of Medical Sciences

Full name of responsible person

Shima Mahdavian Naghash Zargar

Position

Medical student

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

Street address

Abidar Street, Besat Hospital, Infertility Treatment Center

City

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66177-13446

Phone

+98 87 3366 0089

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mnz_shima@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Kurdistan University of Medical Sciences

Full name of responsible person

Shima Mahdavian Naghash Zargar

Position

دانشجوی پزشکی

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

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

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Part of the data, such as information about the main outcome or the like that has been analyzed, can be shared as an article published in the journal.

When the data will become available and for how long

"Start of access period from 2022"

To whom data/document is available

The data will be available to researchers working in academic and scientific institutions, people working in industry.

Under which criteria data/document could be used

The use of data for scientific applications and treatment of patients can be used by mentioning the name and permission of researchers.

From where data/document is obtainable

Kurdistan Province, Sanandaj, Abidar Street, Besat Hospital, Infertility Treatment Center, Email: shahgheibi@yahoo.com, Phone Number: 09181710443, Name and Family: Sholeh Shah Gheibi

What processes are involved for a request to access data/document

Send the request to the e-mail of the responsible author, mentioning the reason for the request, if it is appropriate, will be sent after a week to a month.

Comments