Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 May 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
۱۳۴۴۶۶۶۱۷۷_
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 eicosapentalenoic 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
۱۳۴۴۶۶۶۱۷۷-
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
City
Sanandaj
Province
Kurdistan
Postal code
۱۳۴۴۶۶۶۱۷۷-
Phone
+98 87 3366 0089
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
Sanandaj

Province
Kurdistan

Postal code
66177-13446

Phone
+98 87 3366 0089

Email
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

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
۱۳۴۴۶۶۶۱۷۷ـ

Phone
+98 87 3366 0089

Email
mnz_shima@yahoo.com

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