Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 2026

Evaluation of omega-3 supplementation intake on the risk of preeclampsia in nulliparous pregnant women

Protocol summary

Study aim
Determination of the effect of supplementation of omega-3 on the risk of preeclampsia in Nulliparous pregnant mothers

Design
Clinical trials with intervention and control group ,parallel, double blind, randomized, with placebo , with 144 cases

Settings and conduct
The study is a double-blind, so that the patient and the person distributing the medications and the person who measures the patient's pressure are not aware of the type of treatment and drug. The medications are placed inside the two envelopes A and B, which are same shape. Given to the individual distributor of medications.This study will be conducted at Shahid Sayyid Shirazi Hospital in Gorgan

Participants/Inclusion and exclusion criteria
inclusion criteria: Nulliparous Pregnant women with 18 - 20 gestational age 20 to 40 yeas old Women with high risk of preeclampsia (age below 20 years of age and over 40 years , history of pre-eclampsia in the previous pregnancy or in the first-degree family , twin pregnancy , BMI equal to or greater than 29, kidney disease and hypertension) Do not use calcium, aspirin, anticoagulants and insulin No history of allergy to omega-3 exclusion criteria: Unwilling to participate in the study Forced to use aspirin, calcium and heparin during the study Not being able to continue taking medication due to digestive problems or due to an allergic reaction

Intervention groups
The first intervention group uses an omega-3 pearl containing Eicosapentalenoic acid (EPA) and Duxa hexaenoic acid (DHA)(Omega-3 capsule without mercuric) daily until the end of pregnancy. The control group received the drug that is in the form of pearl containing gelatin , which is used daily until the end of pregnancy.

Main outcome variables
Preeclampsia

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180103038196N4**
Registration date: **2018-07-29, 1397/05/07**
Registration timing: **retrospective**

Last update: **2018-07-29, 1397/05/07**
Update count: **0**

Registration date
2018-07-29, 1397/05/07

Registrant information

Name
Amir Hossein Salimi Kordasiabi

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-05-21, 1397/02/31

Expected recruitment end date
2018-07-22, 1397/04/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Evaluation of omega-3 supplementation intake on the risk of preeclampsia in nulliparous pregnant women

Public title
Evaluation of omega-3 supplementation intake on the risk of preeclampsia

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
nulliparous Pregnant women with 14 to 18 weeks gestational age Satisfaction to participate in the study Women without a high risk of preeclampsia (age under 20 and over 40 years, history of preeclampsia in a previous pregnancy or in the family, twins pregnancy, body mass index equal or greater than 29, kidney disease and hypertension) Do not use calcium, aspirin, anticoagulants and insulin No history of allergy to omega-3 20 to 40 years old

Exclusion criteria:
Unwillingness to cooperate Forced to use aspirin, calcium and heparin during the study Not being able to continue taking medication due to digestive problems or because of an allergic reaction Women with a high risk of preeclampsia

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

Gender
Female

Phase
3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size
Target sample size: **122**

Randomization (investigator's opinion)
Randomized

Randomization description
Using SAS statistical software and block randomization. patients will be divided into two groups: Group 1: Omega-3 and Group 2: Placebo.

Blinding (investigator's opinion)
Double blinded

Blinding description
The study is a double-blind, so that the patient and the person distributing the medications and the person who measures the patient's pressure are not aware of the type of treatment and drug. The medications are placed inside the two envelopes A and B, which are same shape and will Give to the person distributing the medications.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of gorgan University of Medical Sciences

Street address
Golestan university of medical science ,Beginin of Shastkola Street, 5th Kilometers of Gorgan Sari Road, Gorgan

City
Gorgan

Province
Golestan

Postal code
1234567890

Approval date
2018-05-20, 1397/02/30

Ethics committee reference number
IR.Goums.REC.1397.029

Health conditions studied

1

Description of health condition studied
Pre-eclampsia

ICD-10 code
O14

ICD-10 code description
Pre-eclampsia

Primary outcomes

1

Description
Pre-eclampsia Prevalence in Nulliparous Pregnant Women

Timepoint
From the beginning of the study to the end of pregnancy

Method of measurement
Pressure gauge and criteria for diagnosis of pre-eclampsia

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The first group uses a gram of an EPA with DHA as an omega-3 pearl until the end of

pregnancy.

Category

Prevention

2

Description

Control group: The control group received the placebo, which is in the form of pearl containing gelatin

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Sayyad Shirazi Hospital

Full name of responsible person

Dr Sara Shafiee

Street address

Sayyad Shirazi Hospital - Sayyad Shirazi Blv, Gorgan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Gorgan University of Medical Sciences

Full name of responsible person

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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

Gorgan 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

Gorgan University of Medical Sciences

Full name of responsible person

Dr Sara Shafiee

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for scientific inquiries

Contact

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Position

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Latest degree

Medical doctor

Other areas of specialty/work

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Person responsible for updating data

Contact
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
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
Title and more details about the data/document
Data are obtainable after individuals were unidentified
When the data will become available and for how long
Start the access after 6 months after establishing the results
To whom data/document is available
Professors and medical students
Under which criteria data/document could be used
It does not matter
From where data/document is obtainable
Send email to salimia92@gmail.com
What processes are involved for a request to access data/document
Using email
Comments
no