

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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+98 912 361 5549

Email address

hosseininejad.s.mohsen@goums.ac.ir

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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infosayyad@goums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Gorgan University of Medical Sciences
Full name of responsible person
Dr. Gholamreza Roshandel
Street address
Golestan university of medical science ,Beginin of Shastkola Street, 5th Kilometers of Gorgan Sari Road, Gorgan
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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

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Person responsible for updating data**Contact****Name of organization / entity**

Gorgan University of Medical Sciences

Full name of responsible person

Dr Amir Hossein Salimi kord asiabi

Position

پزشک عمومی

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

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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