

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jul 2026

Investigating the effect of omega-3 fatty acid supplements on women's sexual function during pregnancy

Protocol summary

Study aim

Investigating the effect of omega-3 fatty acid supplements on women's sexual function during pregnancy

Design

Clinical trial with control group, double-blind, randomized

Settings and conduct

This study is performed on pregnant women in Ahvaz who are under the supervision of public health centers, and is a two-way blind study in which researchers and participants are kept blind.

Participants/Inclusion and exclusion criteria

Pregnant women in 16 to 22 weeks of pregnancy, no chronic illness and depression, Gravid one, no psychiatric medication

Intervention groups

In this study, there are two groups of intervention and control. In the control group, pregnant women in the control group have the same conditions as the intervention group, but in the control group, placebo is used.

Main outcome variables

Improving the sexual function of pregnant women

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200415047078N1**

Registration date: **2020-05-13, 1399/02/24**

Registration timing: **prospective**

Last update: **2020-05-13, 1399/02/24**

Update count: **0**

Registration date

2020-05-13, 1399/02/24

Registrant information

Name

Zeinab Khanjari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 84 3362 7885

Email address

khanjari.z@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-06-21, 1399/04/01

Expected recruitment end date

2020-12-20, 1399/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of omega-3 fatty acid supplements on women's sexual function during pregnancy

Public title

"Investigating the effect of omega-3 on the sexual function of pregnant women"

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

No anxiety Lack of chronic illness and depression Have Literacy Gestational Age Between 16_22 Week Gravid 1

Exclusion criteria:

Multiparity Having depression and chronic illness Lack of

literacy and lack of awareness Depression First and third trimesters of pregnancy

Age

From **18 years** old to **42 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **62**

Randomization (investigator's opinion)

Randomized

Randomization description

Samples are divided into two groups of pairs and individuals using a table of random numbers (manufacturing of placebo and omega 3 capsule will be done by Zahravi Company of Tabriz and placebo will be made of corn oil). Each instance is given an envelope with code (2 or 1) that the researcher and the sample do not know about the contents of the envelopes, so that code 1 is for the samples that are in the pair group and code 2 is for the sample. The ones that are individual are given. Encoding is done by a third party who is unaware of the research.

Blinding (investigator's opinion)

Double blinded

Blinding description

This study is a two-blind clinical trial study (researcher and patient). And coding is done by a third party who is unaware of the research.

Placebo

Used

Assignment

Parallel

Other design features

In this study, the anxiety disorder agent is controlled by the Wendenberg Questionnaire.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee in Biomedical Research

Street address

Golestan Blv, Nursing And Midwifery Department

City

Ahvaz

Province

Khouzestan

Postal code

6135539345

Approval date

2020-03-01, 1398/12/11

Ethics committee reference number

IR.AJUMS.REC.1398.935

Health conditions studied

1

Description of health condition studied

Sexual Dysfunction

ICD-10 code

F52

ICD-10 code description

Sexual dysfunction not due to a substance or known physiological condition

Primary outcomes

1

Description

Percentage of people with improved sexual function

Timepoint

Determining sexual dysfunction at the beginning of the study and improving sexual function at the end of the study

Method of measurement

Sexual Performance Index Questionnaire

2

Description

Sexual Performance Score in the Sexual Performance Index Questionnaire

Timepoint

Measure sexual function at the beginning and end of the study

Method of measurement

Qeistionnaire Fsfj

Secondary outcomes

empty

Intervention groups

1

Description

In this study, there are two groups of control and intervention. Intervention group: Omega 3 supplement made by Zahravi Company of Tabriz with a dose of 300 mg daily and given to pregnant women for 8 weeks.

Category

Treatment - Drugs

2

Description

Control group: There are 62 samples in the control group. In the placebo control group, manufactured by

Zahravi Company of Tabriz, it is given daily for 8 weeks
Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
University-affiliated health care centers
Full name of responsible person
Zeinab Khanjari
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Deputy Of Research And Technology
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Medical Sience Of Ahvaz
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
Ahvaz University of Medical Sciences
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Zeinab Khanjari
Position
Student
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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is 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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Demographic information of individuals and data before and after the intervention is reported without mentioning the name

When the data will become available and for how long

Access started in 1400

To whom data/document is available

Only researchers in the field of medical universities

Under which criteria data/document could be used

It can only be used in similar research

From where data/document is obtainable

Researcher's personal email

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

According to the publication of the article and the registration of the information of the responsible author, the applicant will contact the responsible author to receive the data by academic email and the information will be sent after the approval of the academic email.

Comments