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 Fsfi

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

Street address

Golestan.blv

City

Ahvaz

Province

Khouzestan

Postal code

6135539345

Phone

+98 61 3373 8333

Email

Zeinabkhanjari2019@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Deputy Of Research And Technology

Street address

Golestan Blv

City

Ahvaz

Province

Khouzestan

Postal code

6135715794

Phone

+98 61 3571 5794

Email

Zeinabkhanjari2019@yahoo.com

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

Full name of responsible person

Zeinab Khanjari

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

Street address

Golestan. Blv

City

Ahvaz

Province

Khouzestan

Postal code

6135715794

Phone

+98 61 3373 8333

Email

Zeinabkhanjari2019@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Mina iravani

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

Street address

Golestan.Blv

City

Ahvaz

Province

Khouzestan

Postal code

6135539345

Phone

+98 61 3373 8333

Email

Minairavani2004@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person
Zeinab Khanjari
Position
Student
Latest degree
Bachelor
Other areas of specialty/work
Midwifery
Street address
Golestan blv
City
Ahvaz
Province
Khouzestan
Postal code
6135715794
Phone
+98 61 3373 8333
Email
Zeinabkhanjari2019@yahoo.com

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