Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effects of separate and concurrent supplementation of n-3 fatty acids and rosa damascena extract on primary dysmenorrhea

Protocol summary

Summary

This study is designed as a randomized, double-blind, placebo-controlled clinical trial to investigate effect of separate and concurrent supplementation of n-3 fatty acids (FAsn-3) and Rosa damascena extract (RDE) on pain severity, systemic symptoms, menstrual duration and blood loss and appetite in girls with primary dysmenorrhea. Students of Tabriz University of medical sciences in dormitories would complete questionnaires of demographic, physical activity and menstrual parameters such as pain and systematic severity symptoms of dysmenorrhea by visual analogue scale (VAS) and multi-dimensional system (MDS). Then 120 students with moderate and severe dysmenorrhea according to inclusion and exclusion criteria will be enroll in the study after signing the informed consent sheet and randomly divided into 4 groups of 30 subjects . Group1: FAsn-3 oral capsule containing 180 mg EPA & 120 mg DHA plus placebo of RDE containing starch, Group 2: RDE oral capsule containing 800 mg rosa damascena extract plus placebo of FAsn-3 containing paraffin, Group 3: FAsn-3 oral capsule containing 180 mg EPA & 120 mg DHA plus RDE oral capsule containing 800 mg rosa damascena extract, Group 4: placebo capsules of FAsn-3 and for 2 months every day. All capsules for each of the four groups will be formed in the envelopes so that the researcher and the subjects will be unaware of the contents of the envelopes. Primary outcomes is defined as the severity of pain and systematic symptoms of dysmenorrhea, menstrual duration and blood loss by valid questionnaires is measured before and 1,2 mounths after interventions and also 3 day food record in first and last of study. Also appetite questionnaire would complete by subjects before and 1,2 mounths after intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201403105670N8**
Registration date: **2014-04-12, 1393/01/23**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2014-04-12, 1393/01/23

Registrant information

Name

Ali Tarighat-Esfanjani

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 914 300 5895

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Recruitment status

Recruitment complete

Funding source

Research deputy of Tabriz University of Medical Sience

Expected recruitment start date

2014-03-06, 1392/12/15

Expected recruitment end date

2014-05-05, 1393/02/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of separate and concurrent supplementation of n-3 fatty acids and rosa damascena extract on primary dysmenorrhea

Public title
Supplementation in dysmenorrhea
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:having dysmenorrhea in menstrual cycles in most recent years; women with moderate and severe dysmenorrhea according to VAS and MDS systems; regular menstrual cycles (21-35 day); body mass index in normal range (BMI)=18.5-24.9, Exclusion criteria: being married; history of hypersensivity for fish, seafoods and rosa damascena,; stressful event (loss of one family members, parental separation,...); regular consumption of nutritional supplements and vitamins, oral contraceptives and other drugs; special diets like weight loss/gain diets; performing any surgery during the study; smoking and alcohol consumption; lack of complianc
Age
From **18 years** old to **30 years** old
Gender
Female

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **120**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research deputy of Tabriz University of Medical Sience
Street address
Central department of Tabriz University of Medical Sience, Golgasht street, Azadi street, Tabriz
City
Tabriz
Postal code
Approval date
2014-02-24, 1392/12/05
Ethics committee reference number
92212

Health conditions studied

1

Description of health condition studied
Primary dysmenorrhea
ICD-10 code
N94.4
ICD-10 code description
Primary dysmenorrhea

Primary outcomes

1

Description
Dysmenorrhea pain severity
Timepoint
befor,1,2 mounth after intervention
Method of measurement
Visual Analog Scale (VAS)- 1-10 score

2

Description
Severity of systematic symptoms of dysmenorrhea
Timepoint
befor,1,2 mounth after intervention
Method of measurement
Visual Analoge Scale (VAS)- 1-10 score

3

Description
Menstrual duration
Timepoint
before and after of intervention
Method of measurement
Complete of questionnare

4

Description
Amount of blood loss
Timepoint
before and after of intervention
Method of measurement
Complete of questionnare

5

Description
Appetite
Timepoint
befor,1,2 mounth after intervention
Method of measurement
Visual Analoge Scale (VAS)- 1-100 score

6

Description
Calorie and macronutrient intake
Timepoint

before and after of intervention

Method of measurement

Food record for 3 day

Secondary outcomes

1

Description

Body weight

Timepoint

before and after of intervention

Method of measurement

Measurment of weight by scale (kg)

2

Description

Waist circumference

Timepoint

before and after of intervention

Method of measurement

meter (cm)

Intervention groups

1

Description

Control Group: placeboes of FAsn-3 and rosa damascena extract every day for 2 mounths

Category

Placebo

2

Description

Intervention group 2: oral capsul containing of 800mg rosa damscena extract and placebo of FAsn-3 containing paraffin every day for two mounths.

Category

Other

3

Description

Intervention group 1: FAsn-3 oral capsule.1 g containing 180 mg EPA &120mg DHA and placebo of rosa damascena extract containing starch every day for two mounths

Category

Other

4

Description

Intervention group3: FAsn-3 oral capsule,1g containing 180 mg EPA and 120 mg DHA and oral capsule containing 800 mg rosa damascena extract every day for two mounths

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Dormitories of Tabriz University of Medical Sciences

Full name of responsible person

Soheila Davaneghi

Street address

Nutrition faculty of Tabriz University of Medical Sience, Golgasht street, Tabriz

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research deputy of Tabriz University of Medical Sience

Full name of responsible person

Dr Bahram Pourghasem Gagari

Street address

Central department of Tabriz University of Medical Sience, Golgasht street, Azadi street, Tabriz

City

Tabriz

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Research deputy of Tabriz University of Medical Sience

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tabriz University of Medical Science

Full name of responsible person

Dr. Ali Tarighat-Esfanjani

Position
Assistant Professor
Other areas of specialty/work
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Person responsible for updating data

Contact

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty