Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jul 2026

Effect of Chlorella supplementation on systematic symptoms and serum levels of prostaglandins, inflammatory and oxidative markers in women with primary dysmenorrhea

Protocol summary

Summary

This study is a double blind clinical trial on 44 young girls aged 18 to 35 years in Ahvaz. In order to collect information questionnaire will be used . After obtaining informed consent, the subjects will be divided into two groups (n = 22) and control (n = 22).The intervention group will receive 5 chlorella soft gel daily one week before the start of the menstrual cycle for 2 months, the control group will receive 5 placebo soft gell. Dysmenorrhea severity will be measured using a visual analog index (Visual Analog Scale). the length of dysmenorrhea pain will be recorded as well as the number of days and number of hours per day during the cycle. The verbal multidimensional system questionnaire of dysmenorrhea will be used to search systematic symptoms. For Laboratory evaluation, blood samples will be obtained after 8-12 hours fasting, at the baseline and the end of the second cycle. Blood samples, after the 0.5 to one hour, will be centrifuged at 2000 rpm and serum will be separated and will be kept at - 70 ° C for laboratory tests .The hs-CRP PGE2, PGF2a will be measured by ELISA. MDA is measured by TBARS test.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017060610181N11**
Registration date: **2017-07-07, 1396/04/16**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-07-07, 1396/04/16

Registrant information

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Fatemeh Heidari
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Ahvaz Jundishapur University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source
Ahwaz University of Medical Sciences

Expected recruitment start date

2017-06-22, 1396/04/01

Expected recruitment end date

2017-08-23, 1396/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Chlorella supplementation on systematic symptoms and serum levels of prostaglandins, inflammatory and oxidative markers in women with primary dysmenorrhea

Public title

Effect of Chlorella supplementation on Dysmenorrhea

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: having regular menstrual periods, moderate or severe dysmenorrheal and being single

Exclusion criteria: pain throughout the menstrual cycle, sensitivity to non-steroidal anti-inflammatory drugs, use of any antioxidant supplements in the past three months, taking oral contraceptives, reproductive disorders and a history of any abdominal or pelvic surgery

Age
From **18 years** old to **35 years** old

Gender
Female

Phase
1-2

Groups that have been masked
No information

Sample size
Target sample size: **44**

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
Ahvaz University of Medical Sciences

Street address
Khuzestan-Ahwaz

City
Ahvwaz

Postal code
61357-15794

Approval date
2017-05-22, 1396/03/01

Ethics committee reference number
IR.AJUMS.REC.1396.159

Health conditions studied

1

Description of health condition studied
primary Dysmenorrhea

ICD-10 code
N94.4

ICD-10 code description
Primary dysmenorrhoea

Primary outcomes

1

Description
PGE2

Timepoint
Before and after the intervention.

Method of measurement
Pg/ ml by ELISA.

2

Description
PGF2a

Timepoint
Before and after the intervention

Method of measurement
Pg/ ml by ELISA

3

Description
hs-CRP

Timepoint
Before and after the intervention

Method of measurement
µg/ml by ELISA

4

Description
MDA

Timepoint
Before and after the intervention

Method of measurement
µmol/l by TBARS

5

Description
severity of pain

Timepoint
Before and after the intervention

Method of measurement
Using Visual Analog Scale

6

Description
duration of pain

Timepoint
Before and after the intervention

Method of measurement
namber of Days and hours of pain in cycle

7

Description
Systemic symptoms

Timepoint
Before and after the intervention

Method of measurement

verbal multidimensional system questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: soft gel Chlorella , 300 mg, 5 per day for 2 months
Category
Treatment - Drugs

2

Description
Control group: placebo Soft gel , 5 per day for 2 months
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Ahwaz University of Medical Sciences
Full name of responsible person
Dr. Fatemeh haidari
Street address
Jundishapur University of Medical Sciences, Ahvaz, Khuzestan
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research of Ahvaz University of Medical sciences
Full name of responsible person
Dr.Makhmalzadeh
Street address
Ahvaz Golestan St., Ahwaz University of Medical Sciences
City
Ahwaz
Grant name
-
Grant code / Reference number
-
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research of Ahvaz University of Medical sciences
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
Name of organization / entity
Ahwaz University of Medical Sciences
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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