Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Survey the effect of Elaeagnus Angustifolia supplementation on the symptoms of primary dysmenorrhea in female students of Ahvaz Jundishapur university

Protocol summary

Study aim

1- Determination of pain severity and duration of pain in female students with dysmenorrhea of Ahvaz Jundishapur University of Medical Sciences 2- Determination of the amount and duration of bleeding in girls with dysmenorrhea of Ahvaz Jundishapur University of Medical Sciences

Design

A randomized controlled clinical trial with parallel, double-blind, randomized groups

Settings and conduct

88 college students are randomly divided into two groups: (1) a group receiving 15 grams of sesame seeds; (2) a group receiving 15 grams of corn starch . Each participant is monitored over 3 periods. During the first period (menstrual cycle), participants record the severity of dysmenorrhea and its symptoms without any intervention. During the second and third menstrual cycles (for 2 months) one group will receive 15 grams of sesame and the other group will receive 15 grams of corn starch.

Participants/Inclusion and exclusion criteria

Sample acceptance criteria: being single; age 18-26 years; having regular menstrual period between 26-30 days; developing pain several hours before or concurrently with menstruation; menstrual pain less than 3 days; primary menstrual pain in recent years without pathologic Note: having moderate to severe dysmenorrhea according to VAS visual acuity questionnaire; body mass index (BMI) = 18.5 - 24.9 kg / m 2; number of hypertensive strips consumed more than 14; Sample exclusion criteria: taking oral contraceptives or other steroid hormones; any genital disease; history of any kidney or kidney problems; any diagnosed mental or physical illness.

Intervention groups

- The group receiving 15 grams of sesame seeds 2. The group receiving 15 grams of corn starch .

Main outcome variables

Severity of pain, duration of pain, duration of bleeding, duration of bleeding

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190603043807N1**
Registration date: **2020-02-10, 1398/11/21**
Registration timing: **prospective**

Last update: **2020-02-10, 1398/11/21**
Update count: **0**

Registration date

2020-02-10, 1398/11/21

Registrant information

Name

Rezvan Amiri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3373 8330

Email address

amiri.r@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-02-19, 1398/11/30

Expected recruitment end date

2020-04-18, 1399/01/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Survey the effect of Elaeagnus Angustifolia supplementation on the symptoms of primary dysmenorrhea in female students of Ahvaz Jundishapur university

Public title

Survey the effect of Elaeagnus Angustifolia supplementation on the symptoms of primary dysmenorrhea in female students of Ahvaz Jundishapur university

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Single; Age 18-26 years; Literacy; Having regular menstrual period between 26-30 days Premenstrual syncope several hours ago; Menstrual pain less than 3 days primary menstrual pain in recent years Moderate to severe dysmenorrhea according to visual analogue scale (VAS) body mass index (BMI) = 18.5-24.9 kg / m2; duration of menstrual bleeding more than 7 days; No more than 14 healthbars consumed no known medical illness A special diet such as weight loss obesity No vegetarianism or water treatment no tobacco or alcohol use no regular exercise

Exclusion criteria:

Use of oral contraceptives or other steroid hormones so any genital tract disease, a history of any problems or kidney stones, any physical mental illness has been diagnosed

Age

From **18 years** old to **26 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **88**

Randomization (investigator's opinion)

Randomized

Randomization description

The block randomization method is divided into two groups of receiving placebo and placebo based on 6 blocks of individuals.

Blinding (investigator's opinion)

Double blinded

Blinding description

Both participants in the intervention and control groups and the clinical caregivers associated with the patients were unaware of the type of received sorghum and the received sorghum and corn starch syrups were similar in appearance. The carcasses will be supplemented with placebo and placebo labeled A and B, and before starting the study, the carcasses will be coded by a person other than the researcher as group A containing powdered powder and group B containing corn starch to Lack of researcher information on the type of capsules received by each group.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Ahvaz University of Medical Sciences

Street address

GolestanBlv, Jundishapur University of Medical Sciences

City

ahvaz

Province

Khouzestan

Postal code

15794 – 61357

Approval date

2020-01-18, 1398/10/28

Ethics committee reference number

IR.AJUMS.REC.1398.770

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

Intensity of pain

Timepoint

Before the beginning of intervention - the first and the second month after the intervention

Method of measurement

VISUAL ANALOG SCALE

2

Description
Duration of pain
Timepoint
Before the beginning of intervention - the first and the second month after the intervention
Method of measurement
Table of Specifications of Control and Tracking Cycles

3

Description
Duration of bleeding
Timepoint
Before the beginning of intervention - the first and the second month after the intervention
Method of measurement
Higam chart

4

Description
The severity of the bleeding
Timepoint
Before the beginning of intervention - the first and the second month after the intervention
Method of measurement
Higam chart

Secondary outcomes

1

Description
Body Mass Index
Timepoint
Before the intervention, the first month and the second after the intervention
Method of measurement
Weight (kg) to square (m)

Intervention groups

1

Description
Intervention group: Group receiving sachet 15 g. Each participant is monitored over 3 periods. During the first period (menstrual cycle), participants record the severity of dysmenorrhea and its symptoms without any intervention. During the second and third menstrual cycles (for 2 months) they will receive a 15 gram sachet daily. Then, the severity of pain and bleeding are assessed. Demographic characteristics including age, height, weight, waist circumference, girth, physical activity level (PAL) are measured by the Metabolic Equivalent Physical Activity Questionnaire (MET), The Higg chart will assess the visual acuity questionnaire (VAS) to measure the severity and duration of bleeding.
Category
Treatment - Drugs

2

Description
Control group: The group receiving sachets containing 15 grams of corn starch. Each participant is monitored over 3 periods. During the first period (menstrual cycle), participants record the severity of dysmenorrhea and its symptoms without any intervention. During the second and third menstrual cycles (for 2 months) they will receive 15 grams of corn starch daily. They are then assessed for severity of pain and bleeding. Questionnaires on demographic characteristics including age, height, weight, waist circumference, girth, physical activity level (PAL) by Metabolic Physical Activity Questionnaire (MET), Higg chart for severity and bleeding period, pain assessment questionnaire The vas will be reviewed.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Dormitory of Ahvaz University of Medical Sciences
Full name of responsible person
Marzie Zilae
Street address
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Marziezilae67@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
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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

Vice chancellor for research, 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

Ahvaz University of Medical Sciences

Full name of responsible person

Marzie Zilae

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be 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