Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Clinical trial comparing topical application of Black Seed Oil and placebo on primary dysmenorrheal and premenstrual syndrome

Protocol summary

Summary

Dysmenorrheal is the most commonly menstrual disorder. The common treatments have some complications, therefore in this study; the effect of topical application of Black Seed Oil on the treatment of dysmenorrheal will be assessed. This randomized study, triple-blind, placebo-control, that 140 sample were randomly selected divided into two groups; use Oil Black Seed and placebo. Oil Black Seed and placebo will be coded seperatly for sampler and data analyzer. The Demographic & history of menstrual data with researcher made questionnaire will be asked and pain intensity and premenstrual syndrome symptoms by standard questionnaire will be measured. Height and weight were measured by standard methods. one or two drops of oil rubbing at the Fontanel area during nights will be used from several days before menstruation to the 5 days after that menstrual periods, , this can be done at least three times. After intervention, the samples fill out again the questionnaires.The inclusion criteria consist of: being 15-45 years old; having regular menstrual cycle; severe or moderate menstrual pain; three days maximum duration of pain; at least 3 years of menarche; no medications or herbal pain relief not being; affected by depression or anxiety; not having an acute or chronic disease; not taking medicines or supplements and not having regular exercise The exclusion criteria consist of: pregnancy; willingness to use hormonal contraceptive methods or taking any hormonal treatment; not taking the drug or not filling out the forms regularly; and unwillingness to continue the treatment

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014033117109N1**
Registration date: **2015-11-29, 1394/09/08**
Registration timing: **retrospective**
Last update:
Update count: **0**

Registration date

2015-11-29, 1394/09/08

Registrant information

Name
Ezat Samadipour
Name of organization / entity
Sabzevar medical university
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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Sabzevar University of Medical Sciences

Expected recruitment start date

2013-12-22, 1392/10/01

Expected recruitment end date

2014-01-21, 1392/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial comparing topical application of Black Seed Oil and placebo on primary dysmenorrheal and premenstrual syndrome

Public title

Black Seed Oil effect on dysmenorrhea

Purpose

Treatment

Inclusion/Exclusion criteria

The inclusion criteria consist of: being 15-45 years old; having regular menstrual cycle; severe or moderate menstrual pain; three days maximum duration of pain; at least 3 years of menarche; no medications or herbal pain relief not being; affected by depression or anxiety; not having an acute or chronic disease; not taking medicines or supplements and not having regular exercise The exclusion criteria consist of: pregnancy; willingness to use hormonal contraceptive methods or taking any hormonal treatment; not taking the drug or not filling out the forms regularly; and unwillingness to continue the treatment

Age

From **18 years** old to **24 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **140**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Triple blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Sabzevar University of Medical Sciences

Street address

Sabzevar, University of Medical Sciences, 5KM Tehran road

City

Sabzevar

Postal code

9613873136

Approval date

2014-02-10, 1392/11/21

Ethics committee reference number

medsab.Rec.92.30

Health conditions studied

1

Description of health condition studied

Disorder-menstural

ICD-10 code

N92

ICD-10 code description

Excessive, frequent and irregular menstruation

Primary outcomes

1

Description

pain intensity

Timepoint

pre intervention and minimal three period after intervention

Method of measurement

Prospective Record of the Impact and Severity of Menstrual Symptoms (PRISM)

2

Description

Premenstural syndrom symptoms

Timepoint

Befor intervention and after three menstural periods intervention

Method of measurement

Cox Menstrual Symptom Scale questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: The topical application Baryj Essence Pharmaceutical Company Black Seed Oil contains 30 to 40 percent oil; Linolenic Acid 55%, 2-1 drops will use on the Fontanel area for 30 seconds to two minutes with gently massage. Finding Fontanel area: each person will open her hand completely and put her little finger on the tip of the nose and the other hand on the forehead and head along, the place of the thumb (in the middle line) is considered fontanel area. The massage will do in each period from the first day beginning of periods until 5 days after the end of period.

Category

Treatment - Drugs

2

Description

Intervention group 2: The topical application liquid vegetable Oil 2-1 drops on the Fontanel area about 30

seconds to two minutes with gently massage. Finding Fontanel area: each person will open her hand completely and put her little finger on the tip of the nose and the other hand on the forehead and head along, the place of the thumb (in the middle line) is considered fontanel area. The massage will do in each period from several days before menstruation until 5 days after the end of period.

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Sabzevar University of Medicine Science

Full name of responsible person
Dr Mohamad Mohamadzadeh

Street address
Vice chancellor for research, 5 KM Tehran Road, Sabzevar University of Medicine Sciences

City
Sabzevar

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for research, Sabzevar University of Medicine Sciences

Full name of responsible person
Dr Mohamad Mohamadzadeh

Street address
Vice chancellor for research, 5 KM Tehran road,Sabzevar University of Medical Sciences

City
Sabzevar

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, Sabzevar University of Medicine 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
Sabzevar University of Medicine Sciences

Full name of responsible person
Ezat Samadipour

Position
faculty member

Other areas of specialty/work

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Person responsible for scientific inquiries

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Name of organization / entity
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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