

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 2026

Comparison of the influence nigella sativa with mefenamic acid on primary dysmenorrhea

Protocol summary

Summary

This study aimed to compare the effects of Nigella sativa with mefenamic acid randomized, double-blind will be the main criteria for inclusion aged between 30-18 years, female students are being educated and having regular menstrual periods, having dysmenorrhea the initial degree of moderate to severe based on a visual scale, the main criteria Exclusion history of abdominal surgery or pelvic, an ultrasound abnormal uterine or pelvic, obesity (BMI greater than 30) that the 70 students living in dormitories of Tehran University of Medical Sciences, Mashhad with random assignment of subjects assigned to one of two groups. To measure pain intensity on a visual scale, form the sample run is that the lines are long mm100 (cm10) drawn by zero is specified on the line as there is no pain and 100 as pain it is very intense.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014040117111N1**

Registration date: **2015-01-26, 1393/11/06**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-01-26, 1393/11/06

Registrant information

Name

Fatemeh Mohanazadeh flaheieh

Name of organization / entity

School of Nursing and Midwifery, Mashhad

Country

Iran (Islamic Republic of)

Phone

+98 51 1859 1511

Email address

mohanazadehf911@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Mashhad University of Medical Sciences

Expected recruitment start date

2014-11-01, 1393/08/10

Expected recruitment end date

2014-12-31, 1393/10/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the influence nigella sativa with mefenamic acid on primary dysmenorrhea

Public title

Comparison of the influence nigella sativa with mefenamic acid on primary dysmenorrhea

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: age range between 30-18 years of being single and female students studying in Iran Mashhad university dormitories having regular menstrual periods of moderate to severe primary dysmenorrhea grade based on a visual scale Exclusion criteria: history abdominal or pelvic surgery, history of sexual problems of mishaps during study coagulation disorders or abnormal uterine pelvic ultrasound consumption hormonal drugs (eg contraception), NSAIDs, opioids or any ban the sensitivity to drugs obesity (BMI greater than 30)

Age

From **18 years** old to **30 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Mashhad University of Medical Sciences

Street address

doctora Intersection Ibn Sina Street

City

mashhad

Postal code

Approval date

2014-11-01, 1393/08/10

Ethics committee reference number

930413

Health conditions studied

1

Description of health condition studied

Primary dysmenorrhoea

ICD-10 code

N94.4

ICD-10 code description

Primary dysmenorrhoea

Primary outcomes

1

Description

Intensity and duration of menstrual pain

Timepoint

1) two cycles before the intervention, 2) the first and

second cycles of the intervention

Method of measurement

Visual analog scale and the scale Cox

Secondary outcomes

empty

Intervention groups

1

Description

one intervention group: consumption of oral nigella sativa 3 grams daily (two capsules of 500 mg every 8 hours) during the first three days of menstruation

Category

Treatment - Drugs

2

Description

Two intervention groups: consumption Mefenamic Acid 250 mg (two 500 mg capsules with 125 milligrams of active ingredient Mefenamic acid every 8 hours during the first three days of menstruation

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Residences Mashhad University of Medical Sciences

Full name of responsible person

Farzaneh Jafarnejad

Street address

Doctora intersection. Ibn Sina Street

City

Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen tafaghodiy

Street address

University Avenue. Central Organization of Mashhad

University of Medical Sciences

City

Mashhad

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Mashhad 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**

Mashhad University of Medical Sciences

Full name of responsible person

Fatemeh mohanazadeh falaheieh

Position

Graduate Student Midwives

Other areas of specialty/work**Street address**

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Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

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Full name of responsible person

Farzaneh jafaarnejad

Position

Master of Midwifery

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Web page address**Person responsible for updating data****Contact****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Fatemeh mohanazadeh flaheieh

Position

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Web page address**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