Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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
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Iran (Islamic Republic of)
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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

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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
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Person responsible for updating data

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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