Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The comparison effect of Ginger and Fennel extract on severity primary Dysmenorrhea

Protocol summary

Summary

Introduction: Primary dysmenorrhea is described as pelvic pain around the time menstrual bleeding in the absence of an identifiable pathological lesion. It is a common gynecologic problem among women in reproductive age groups. Our objective was to compare the effect of Ginger and Fennel extract on primary dysmenorrhea. A randomized single blind, Placebo-controlled trial carry out among 75 single female students who inclusion criteria are including regular menstruation periods, range of age 18-30 years old, single girls with primary dysmenorrhea and exclusion criteria are including being affected by known diseases, Symptoms such as burning, itching, abnormal vaginal discharge; history of PID, tumor and fibrom; history of drug or herbal allergy and appearance of stressful events (divorce and death of parents and relatives) have joined to the study group in recent 6 month and during the treatment period. Students divided into 3 groups randomly: Fennel extract, Ginger extract and placebo. Groups use treatment four times a day from the onset of bleeding and continue through three days for two consecutive menstrual periods. Moreover, two questionnaires has given to them until comleting the intensity of pain (according VAS and verbal multidimensional scoring system) and duration of pain(number of days pain) and in the related forms after treatment during each menstruation period and to deliver to researcher after the end of period.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201212226705N2**
Registration date: **2015-05-06, 1394/02/16**
Registration timing: **retrospective**
Last update:
Update count: **0**

Registration date

2015-05-06, 1394/02/16

Registrant information

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Leila Moslemi
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Recruitment status

Recruitment complete

Funding source

Sari Branch, Islamic Azad University

Expected recruitment start date

2013-03-21, 1392/01/01

Expected recruitment end date

2013-08-23, 1392/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison effect of Ginger and Fennel extract on severity primary Dysmenorrhea

Public title

Effect of herbal drugs on menstrual pain

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria are including regular menstruation periods, range of age 18-30 years old, single girls with primary dysmenorrhea and exclusion criteria are including being affected by known diseases, Symptoms such as burning, itching, abnormal vaginal discharge; history of pelvic infection disease, tumor and fibrom; history of drug or herbal allergy and appearance of stressful events (divorce and death of parents and relatives) have joined to the study group in recent 6 month and during the treatment period.

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: **75**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

1

Registry name
-

Secondary trial Id
-

Registration date
empty

Ethics committees

1

Ethics committee

Name of ethics committee
Islamic Azad University Sari Branch

Street address
Firuzkande, Complex University of Islamic Azad Sari, Office building, The fifth flooR, Vice chancellor for research

City
Sari

Postal code

Approval date
2012-09-22, 1391/07/01

Ethics committee reference number
1391-5

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 of Primary Dysmenorrhea

Timepoint
A month before intervention and 2 months during intervention

Method of measurement
Visual analog scale and verbal multidimensional scoring system

Secondary outcomes

1

Description
Duration of Primary Dysmenorrhea

Timepoint
A month before intervention and 2 months during intervention

Method of measurement
Number of days

Intervention groups

1

Description
Fennel extract capsule 46 mg used treatment four times a day from the onset of bleeding and continued through three days for two consecutive menstrual periods.

Category
Treatment - Drugs

2

Description
Ginger extract capsule ,250 mg, four times a day from the onset of bleeding and continued through three days for two consecutive menstrual periods

Category
Treatment - Drugs

3

Description
Placebo capsule four times a day from the onset of bleeding and continued through three days for two consecutive menstrual periods

Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Medical School at Islamic Azad University Sari Branch
Full name of responsible person
Street address
City
Sari

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for Research and Technology, Islamic Azad University Sari Branch
Full name of responsible person
Leila Moslemi
Street address
Firuzkande, Complex University of Islamic Azad Sari, Office building, The fifth floor, Vice chancellor for Research
City
Sari
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 and Technology, Islamic Azad University Sari Branch
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
Midwifery group, Medical School, Islamic Azad University Sari Branch
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Person responsible for scientific inquiries

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Person responsible for updating data

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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