

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 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 completing 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

Name

Leila Moslemi

Name of organization / entity

Islamic Azad University Sari Branch

Country

Iran (Islamic Republic of)

Phone

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Email address

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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

Full name of responsible person

Leila Moslemi

Position

MSC Midwifery

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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