

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparing the effect of topical ginger oil with oral ginger on primary dysmenorrhea

Protocol summary

Summary

Study purpose is comparing the effect of topical ginger oil with oral ginger on moderate and severe primary dysmenorrhea. Patients include grade 2,3 primary dysmenorrhea (based on Multidimensional Verbal Scoring System) according to history and pelvic sonography. And if they become pregnant or sensitized to medication or personal desire, they will be excluded. Study population is Shahid Beheshti University female students living in dormitory with dysmenorrhea. Sample size is 34 patients in each group and recalculated after the pilot on the 10 patients in each group. At the first it was evaluated severity and duration of pain without intervention. Then patients are divided stratified randomization (according to moderate and severe) between two groups: ginger capsule and ginger oil. Intervention in both groups is from two days before the onset of the menstrual period until the first three days every 6 hours that in capsule group: one 250 mg oral and in oil group: 5 drops on the abdomen under umbilicus for 3 consecutive cycles. 12 mefenamic acid capsules were given to students in each cycle and it recorded and compared the number of mefenamic acid's consumption. Intensity of pain based on VAS and duration of pain based on hour were evaluated the day before until the first three days of menstruation in every four cycles.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014090219012N1**
Registration date: **2015-05-16, 1394/02/26**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-05-16, 1394/02/26

Registrant information

Name

Pantea Shirooye

Name of organization / entity

School of Traditional Medicine, Shahid Beheshti University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

School of Traditional Medicine, Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2014-09-23, 1393/07/01

Expected recruitment end date

2016-03-19, 1394/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effect of topical ginger oil with oral ginger on primary dysmenorrhea

Public title

Comparing the effect of topical ginger oil with oral ginger on primary dysmenorrhea

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: 18-45 years; BMI \leq 35; regular menstrual cycles (21-35day) and Regular bleeding (3-10days) in the latest three menses; moderate and severe dysmenorrhea (grade 2,3) based on Multidimensional Verbal Scoring System; rejection of Secondary dysmenorrhea by history and pelvic ultrasound; no History of pelvic or abdominal surgery; not taking other medications; no history of allergy to ginger; no history of bleeding disease; no history of gallstone. Exclusion Criteria: pregnancy; sensitivity to medication during the study; avoiding the correct use of medication; taking another drug that is not defined in the study; patients with Possible serious side effects; patients who need additional interventions and surgery; patients who decide to be excluded.

Age

From **18 years** old to **45 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **34**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shahid Beheshti University of Medical Sciences

Street address

next to Taleghani hospital, Shahid Chamran Highway

City

Tehran

Postal code

Approval date

2015-01-04, 1393/10/14

Ethics committee reference number

163

Health conditions studied

1

Description of health condition studied

primary dysmenorrhea

ICD-10 code

N94.4

ICD-10 code description

primary dysmenorrha

Primary outcomes

1

Description

pain intensity

Timepoint

cycle before intervention, every cycles during intervention (3 cycles)

Method of measurement

VAS = visual analog scale

2

Description

pain duration

Timepoint

cycle before intervention, every cycles during intervention (3 cycles)

Method of measurement

hour

Secondary outcomes

1

Description

side effect: Stomachache, nasea, vomiting, hematemesis, belch, fatigue, itching, acne, heartburn, diarrhea, constipation, melena,headache, drowsiness, redness, assessment of bleeding with PBAC

Timepoint

cycle before intervention, every cycle during intervention (3 cycles)

Method of measurement

questionnaire

2

Description

Mefenamic acid use

Timepoint

cycle before intervention, every cycle during intervention (3 cycles)

Method of measurement

number

Intervention groups

1

Description

250 mg capsule of ginger every 6 hours from two days

before the onset of the menstrual period until the first three days of the menstrual period for 3 consequent cycles

Category

Treatment - Drugs

2

Description

Ointment 5 drops ginger oil on the abdomen under umbilicus every 6 hours, from two days before the onset of the menstrual period until the first three days of the menstrual period for 3 consequent cycles.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Hazrate Zeinab dormitory

Full name of responsible person

Mrs Zaeem

Street address

zafar street

City

Tehran

2

Recruitment center

Name of recruitment center

Goleyas dormitory

Full name of responsible person

Mrs Zaeem

Street address

Vanak square

City

Tehran

3

Recruitment center

Name of recruitment center

Golenarges dormitory

Full name of responsible person

Mrs Zaeem

Street address

Abshar alley, Valiasr street

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

School of Traditional Medicine, Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr. Somayeh Esmaeli

Street address

Shams Alley, Vali-e Asr Ave, Tehran, Iran

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

School of Traditional Medicine, Shahid Beheshti 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

School of Traditional Medicine, Shahid Beheshti University of Medical Sciences

Full name of responsible person

Pantea Shirooye

Position

Traditional medicine PHD student

Other areas of specialty/work

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Pantea Shirooye

Position

Traditional medicine PHD student

Other areas of specialty/work**Street 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