Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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 sever 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 sensitize to medication or personal desire, they will exclude. 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 sever) 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 consequent cycles. 12 mefenamic acid capsules were given to students in each cycles 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
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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 ≤ 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 asid 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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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