

# 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

+98 912 488 7140

###### Email address

pshirooye@sbmu.ac.ir

##### 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**

**Street address**

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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****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*