# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

16 Sep 2026

## The effects of Zingiber officinal R. root on primary dysmenorrhea

## Protocol summary

**Summary**

This is a randomize, double- blind, placebo-control, parallel-group study conducting on students with moderate and severe primary dysmenorrhea residing in dormitories of Shahed University. Subjects are selecting through a questionnaire which including demographic and menstrual cycle characteristics and grading of dysmenorrhea. Grading of dysmenorrhea are determine by verbal multidimensional scoring system and subjects who are grading moderate and severe dysmenorrhea are randomly allocating into two groups that receiving the Zingiber capsule and the placebo capsule. Severity of pain is determining by a visual analogue scale.

## General information

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT201105266206N3**
Registration date: **2011-07-10, 1390/04/19**
Registration timing: **retrospective**

Last update:
Update count: **0**

**Registration date**

2011-07-10, 1390/04/19

**Registrant information**

**Name**
Parvin Rahnama

**Name of organization / entity**
Shahed University

**Country**
Iran (Islamic Republic of)

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+98 21 6641 8587

**Email address**
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**Recruitment status**
**Recruitment complete**

**Funding source**
Shahed University

**Expected recruitment start date**
2008-06-21, 1387/04/01

**Expected recruitment end date**
2009-02-18, 1387/11/30

**Actual recruitment start date**
empty

**Actual recruitment end date**
empty

**Trial completion date**
empty

**Scientific title**
The effects of Zingiber officinal R. root on primary dysmenorrhea

**Public title**
effect of ginger on pain relief in primary dysmenorrhea

**Purpose**
Treatment

**Inclusion/Exclusion criteria**
Students with (aged 18 and over), primary and moderate to severe dysmenorrhea (score 2 or 3), regular period, and single are including in this study. Exclusion criteria are a pre-existing diagnose disease, history of gestation or taking oral contraceptives, body mass index (BMI)<19 or>26, and mild dysmenorrhea

**Age**
From **18 years** old to **32 years** old

**Gender**
Female

**Phase**
N/A

**Groups that have been masked**
*No information*

**Sample size**
Target sample size: **105**

**Randomization (investigator's opinion)**
Randomized

**Randomization description**
**Blinding (investigator's opinion)**
Double blinded
**Blinding description**
**Placebo**
Used
**Assignment**
Parallel
**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**
**Name of ethics committee**
Shahed University
**Street address**
Opposite to Holy Shrine of Imam Khomeini, Tehran-Qom Freeway
**City**
Tehran
**Postal code**
**Approval date**
2006-08-15, 1385/05/24
**Ethics committee reference number**
150/828

## Health conditions studied

### 1

**Description of health condition studied**
primary dysmenorrhea
**ICD-10 code**
N94.4
**ICD-10 code description**
Primary dysmenorrhoea

## Primary outcomes

### 1

**Description**
pain
**Timepoint**
After treatment
**Method of measurement**
The visual analog scale (VAS)

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**
The ginger is receiving 500 mg capsules of ginger powders three times in two different treatment protocols. Both the treatment protocols are conducting on the same patients with one month interval between the protocols. Treatment protocol 1: In this protocol ginger is giving two days before and continuing through the three days from starting menstrual period. In the second protocol ginger is giving for the first three days of the menstrual period. Treatment protocol 2: In this protocol ginger is giving for the first three days of the menstrual period.
**Category**
Treatment - Drugs

### 2

**Description**
The placebo is receiving 500 mg capsules of placebo powders three times in two different treatment protocols. Both the treatment protocols are conducting on the same patients with one month interval between the protocols. Treatment protocol 1: In this protocol placebo is giving two days before and continuing through the three days from starting menstrual period. In the second protocol placebo is giving for the first three days of the menstrual period. Treatment protocol 2: In this protocol placebo is giving for the first three days of the menstrual period.
**Category**
Treatment - Drugs

## Recruitment centers

### 1

**Recruitment center**
**Name of recruitment center**
dormitory of Shahed University
**Full name of responsible person**
**Street address**
**City**
Tehran

## Sponsors / Funding sources

### 1

**Sponsor**
**Name of organization / entity**
Herbal Research Center, Shahed University
**Full name of responsible person**
Ghlamali Naderi
**Street address**
Opposite to Holy Shrine of Imam Khomeini, Tehran-Qom Freeway
**City**
Tehran
**Grant name**
**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Herbal Research Center, Shahed University
**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**
shahed University
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Parvin Rahnama
**Position**
Ph.D
**Other areas of specialty/work**
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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**Other areas of specialty/work**
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**Email**
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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*