# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

03 Jul 2026

## Comparative study of the effect of capsules "Ginger-Lavender" ,"Ginger" with "Mefenamic Acid " on the severity of primary dysmenorrhea

### Protocol summary

**Study aim**
Comparative study of the effect ofcapsules "ginger-lavender" ,"ginger"with "mefenamic "acid on the severity of primary dysmenorrhea pain in female students living in selected dormitories of Shahid Beheshti University of Medical Science-1399

**Design**
Controlled clinical trial work, with parallel groups, triple-blind, randomized, phase 3 on 90 students, Excel software is used for randomization

**Settings and conduct**
After selecting three dormitories(Zeynab, Alzahra and Somayeh) from Shahid Beheshti University of Medical Sciences, sampling will be done continuously and purposefully. The method of coding on cans is used for blinding.Researcher, samples and statistics consultants are blind

**Participants/Inclusion and exclusion criteria**
Be 1)18 to 30 years old and single. 2) Experience menstrual pain in the first 3 days of bleeding for 3 consecutive periods in the last 6 months. 3) People with primary dysmenorrhea whose pain intensity is moderate to severe according to McGill's pain ruler. The exit criteria in this study include: 1) Dissatisfaction or obedience of the person to continue participating in the study 2) Lack of proper use of medication or mefenamic acid 3) Taking any herbal medicine while studying

**Intervention groups**
Pain intensity is recorded in three groups based on the pain ruler, before the intervention (as a base) and in the first and second cycles after the intervention.Consumption of 500 mg of "ginger-lavender" , 250 mg capsules of "ginger" and 250 mg of" Mefenamic acid".During the two periods, with the help of a questionnaire, a system of several verbal dimensions and (visual analog scale) are obtained.4 times a day from the onset of pain until three days of menstruation will be use .Average pain at the end of the three days of menstruation will be relieved with the help of visual analog scale.

**Main outcome variables**
Severity of primary dysmenorrhea

### General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20200525047565N2**
Registration date: **2021-01-03, 1399/10/14**
Registration timing: **retrospective**

Last update: **2021-01-03, 1399/10/14**
Update count: **0**

**Registration date**
2021-01-03, 1399/10/14

**Registrant information**

**Name**
Sharareh Jannesari

**Name of organization / entity**

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Iran (Islamic Republic of)

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**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2020-08-09, 1399/05/19

**Expected recruitment end date**
2020-11-09, 1399/08/19

**Actual recruitment start date**
empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Comparative study of the effect of capsules "Ginger-Lavender" ,"Ginger" with "Mefenamic Acid " on the severity of primary dysmenorrhea

**Public title**

Comparative study of the effect of capsules "Ginger-Lavender", "Ginger" with "Mefenamic Acid " on the severity of primary dysmenorrhea

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

1)Be 18 to 30 years old and single. 2)Experience menstrual pain in the first 3 days of bleeding for 3 consecutive periods in the last 6 months 3)People with primary dysmenorrhea whose pain intensity is moderate to severe according to McGill's pain ruler 4)Not known to be a person with a chronic illness (diabetes, high blood pressure, cardiovascular, infectious, liver, and epilepsy) 5)Do not have a specific gynecological disease that interferes with the study process 6)Have regular cycles with intervals of 21 to 38 days and the duration of menstruation is 3-7 days 7)Their body mass index is in the normal range of 19.8 to 26 8)According to the person, there are no symptoms such as burning, itching or abnormal discharge during the study. 9)Do not take any medications or supplements. 10)No herbal medicine has been used for 3 months before the intervention.01 11)Stressful factors such as parental separation, death of first-degree relatives, etc. should not be present in the last six months

**Exclusion criteria:**

1)Dissatisfaction or obedience of the person to continue participating in the study 2)Lack of proper use of medication or mefenamic acid 3)Take any herbal medicine while studying

**Age**

From **18 years** old to **35 years** old

**Gender**

Female

**Phase**

3

**Groups that have been masked**

- Participant
- Investigator
- Data analyser

**Sample size**

Target sample size: **90**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

First, sampling is selected based on the number of targets from the single girl living in the dormitory.After introducing herself, the researcher will explain to the participants the goals and how to implement the research.Then, out of 90 students with study characteristics who have primary dysmenorrhea, they are placed in separate blocks (moderate and severe dysmenorrhea).In the next stage, people with moderate to severe pain are divided into three equal groups of capsule users"Ginger - Lavender" "Ginger" and" Mefenamic Acid " by accidental assignment using Excel software.

**Blinding (investigator's opinion)**

Triple blinded

**Blinding description**

The blinding was done in such a way that the capsule containing Ginger-Lavender and capsule containing Ginger was prepared in exactly the same way as the Mefenamic Acid capsule and coded.Only the Pharmacogenesis Consultant is aware of its contents and codes, and the researcher and participants in the research and data analyser are unaware of it.In this way, the study will be done in triple blind ways.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**

Ethics Committee In Research, School of Farmecy, Nurssing, Midwifery of Shahid Beheshti University.

**Street address**

Schoole of Nursing and Midwifery, Opposite to Rajaee Heart Hospital, Valiasr Street, Intersection of Niayesh Highway, Tehran, Iran.

**City**

Tehran

**Province**

Tehran

**Postal code**

1996835119

**Approval date**

2019-12-09, 1398/09/18

**Ethics committee reference number**

IR.SBMU.PHARMACY.REC.1398.239

## 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**
Severity of primary dysmenorrhea
**Timepoint**
End of the third day of the cycle before the intervention, end of the third day of the first cycle and second cycle after the intervention
**Method of measurement**
Visual analog scale

## Secondary outcomes

### 1

**Description**
Systematic symptoms
**Timepoint**
End of the third day of the cycle before the intervention, end of the third day of the first cycle and second cycle after the intervention
**Method of measurement**
Verbal rating scale

## Intervention groups

### 1

**Description**
Intervention group: "Ginger-Lavender" group500 mg capsules containing 250 mg of ginger and 250 mg of lavender prepared in Shahid Beheshti School of Traditional Medicine will be used 4 times a day (once every 6 hours) from the beginning of menstruation until the third day. Basic pain (before the intervention) is measured with the help of a pain ruler, then during the two intervention periods, the relevant questionnaire (pain ruler) will be given to the sample, and at the end, the average pain at the end of every three days will be estimated.
**Category**
Treatment - Drugs

### 2

**Description**
Intervention group: "Ginger" group will use 250 mg "Ginger" capsule prepared in Shahid Beheshti School of Traditional Medicine 4 times (once every 6 hours) from the beginning of menstruation until the third day. The pain reliever is measured, then during the two intervention periods, the relevant questionnaire (pain reliever) will be given to the sample, and at the end, the average pain at the end of every three days will be estimated.
**Category**
Treatment - Drugs

### 3

**Description**
"Mefenamic Acid" group will use Amin Company's 250 mg "Mefenamic Acid" capsule 4 times a day (every 6 hours) from the beginning of menstruation until the third day. Basic pain (before intervention) is measured with the help of a pain ruler. Then, during the two intervention periods, the relevant questionnaire (pain ruler) will be given to the sample and at the end, the average pain at the end of every three days will be estimated.
**Category**
Treatment - Drugs

## Recruitment centers

### 1

**Recruitment center**
**Name of recruitment center**
Selected Dormitories of Shahid Beheshti University of Medical Sciences.
**Full name of responsible person**
Tahereh kalate
**Street address**
Schoole of Nursing and Midwifery, Opposite to Rajaee Heart Hospital, Valiasr Street, Intersection of Niayesh Highway, Tehran, Iran.
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## Sponsors / Funding sources

### 1

**Sponsor**
**Name of organization / entity**
Shahid Beheshti University of Medical Sciences
**Full name of responsible person**
Afshin Zarghi
**Street address**
Shahid Arabi St, Yemen St, next to Ayatollah Taleghani Hospital, Shahid Chamran Highway,Tehran.
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1983963113
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**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Shahid Beheshti University of Medical Sciences
**Proportion provided by this source**
1
**Public or private sector**
Public
**Domestic or foreign origin**
Domestic
**Category of foreign source of funding**
*empty*
**Country of origin**
**Type of organization providing the funding**
Academic

## Person responsible for general inquiries

**Contact**
**Name of organization / entity**
Shahid Beheshti University of Medical Sciences
**Full name of responsible person**
Sharareh Jannesari
**Position**
Midwifery Instructor
**Latest degree**
Master
**Other areas of specialty/work**
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Schoole of Nursing and Midwifery, Opposite to Rajaee Heart Hospital, Vali-Asr Avenue, Intersection Vali-Asr and Neiaiesh Highway, Tehran, Iran .
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**
No - There is not a plan to make this available
**Justification/reason for indecision/not sharing IPD**
The data remains confidential to the researcher at first
**Study Protocol**
Yes - There is a plan to make this available
**Statistical Analysis Plan**
Not applicable
**Informed Consent Form**
Yes - There is a plan to make this available
**Clinical Study Report**
Not applicable
**Analytic Code**
Not applicable
**Data Dictionary**
Not applicable
**Title and more details about the data/document**
This research is to see the effect of ginger-lavender and

ginger capsule on the severity of primary dysmenorrhea.

**When the data will become available and for how long**

After the article is published in the desired journal is available

**To whom data/document is available**

Everyone who is interested in the article

**Under which criteria data/document could be used**

To increase women's health and use more herbal medicines

**From where data/document is obtainable**

Email the corresponding author

**What processes are involved for a request to access data/document**

Explain the reasons for requesting an article in the email.

**Comments**