Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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

Country
Iran (Islamic Republic of)

Phone
+98 21 8820 2512

Email address
shararehjannesari@sbmu.ac.ir

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.
City
Tehran
Province
Tehran
Postal code
1996835119
Phone
+98 21 8842 2022
Email
info@sbmu.ac.ir

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.
City
Tehran
Province
Tehran
Postal code
1983963113
Phone
+98 21 29901
Email
info@sbmu.ac.ir

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
Reproductive Health
Street address
Schoole of Nursing and Midwifery, Opposite to Rajaee Heart Hospital, Vali-Asr Avenue, Intersection Vali-Asr and Neiaiesh Highway, Tehran, Iran .
City
Tehran
Province
Tehran
Postal code
1996835119
Phone
+98 21 8865 5366
Email
shararehjannesari@gmail.com

Person responsible for scientific 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
Reproductive Health
Street address
Schoole of Nursing and Midwifery, Valiasr Street, Intersection of Niayesh Highway,Tehran, Iran .
City
Tehran
Province
Tehran
Postal code
1996835119
Phone
0218855366
Fax
Email
shararehjannesari@gmail.com

Person responsible for updating data

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
Reproductive Health
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
Phone
0218865366
Email
shararehjannesari@gmail.com

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