

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jul 2026

Comparison of the Efficacy of Ginger-Chamomile Mixed Sachet and Honey with Mefenamic Acid in The Treatment of Primary Dysmenorrhea and Associated Symptoms of Female Students that Living in the Arak University of Medical Sciences Dormitory: Randomized Controlled Clinical Trial

Protocol summary

Study aim

Effect of Ginger and Chamomile Mixed Sachet with Honey in The Treatment of Primary Dysmenorrhea and Associated Symptoms and Also Detection of Uterine Humor

Design

This study is a clinical trial and patients will divide randomly by block random sampling. 400 patients will divide to four groups by block random sampling, so that 100 people randomly will assign to each group.

Settings and conduct

During the menstrual cycle, patients of three groups will must dissolve the sachet in a glass of water and after heating, consume that with a teaspoonful of honey. For the mefenamic acid group, will provide 250 mg mefenamic acid capsules. Prescribing instruction is similar in all groups, patients will must start consuming sachets and capsules, 2 day before menstrual cycle and continue that to 3 day after the beginning of menstrual cycle, 3 time a day for 2 menstrual cycles. After the first and second cycle, the questionnaires will be filling to measure the amount of pain, bleeding severity, duration of bleeding and other symptoms of dysmenorrhea.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Between 18 to 30 years old; Unmarried; Lack of chronic diseases; Without peptic ulcer or duodenal ulcer; Do not consume anticoagulant drugs; Do not consume oral contraceptives; Avoiding to use alcohol; Exclusion criteria: Patient's refusal to participate in the study; Consume drugs irregularly; Marriage; Do not fill out the questionnaire;

Intervention groups

For the ginger and chamomile mixed group, will provide sachets containing 1000 mg of ginger root powder and

5000 mg of chamomile, for the ginger group, will provide sachets that contain 1000 mg of ginger root powder and for the chamomile group, will provide sachets that contain 5000 mg of chamomile.

Main outcome variables

The severity of bleeding, Duration of bleeding, The severity of pain, Symptoms of dysmenorrhea

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT2016100825031N5**

Registration date: **2016-11-08, 1395/08/18**

Registration timing: **registered_while_recruiting**

Last update: **2018-04-19, 1397/01/30**

Update count: **1**

Registration date

2016-11-08, 1395/08/18

Registrant information

Name

Fatemeh Rafiei

Name of organization / entity

Arak University of Medical Science

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Arak University of Medical Sciences

Expected recruitment start date

2016-10-22, 1395/08/01

Expected recruitment end date

2017-10-21, 1396/07/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the Efficacy of Ginger-Chamomile Mixed Sachet and Honey with Mefenamic Acid in The Treatment of Primary Dysmenorrhea and Associated Symptoms of Female Students that Living in the Arak University of Medical Sciences Dormitory: Randomized Controlled Clinical Trial

Public title

Effect of Ginger (Zingiber Officinale) and Chamomile Mixed Sachet with Honey in The Treatment of Primary Dysmenorrhea

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Between 18 to 30 years old Unmarried The menstruation pain is started before 20 years old Regular menstrual cycles between 21 to 35 days Menstrual bleeding without passing clots Menstrual pain start a few hours before menstrual bleeding and to continue for 5 days Lack of chronic diseases Without peptic ulcer or duodenal ulcer Do not consume anticoagulant drugs Lack of burning, itching and abnormal vaginal discharge Without history of allergy to medicinal plants Lack of stress in the past two months Do not have to take medicine or special diet and smoking Without history of pelvic inflammatory disease Without history of gynecologic surgery Do not transfer or relocation during the next 6 months Do not have pain in all the time of menstrual bleeding Do not consume oral contraceptives Do not consume drugs class of benzodiazepines, barbiturates, narcotics and some antidepressants, such as fluoxetine Avoiding to use alcohol, aspirin, warfarin and heparin Without having specific diseases of liver, kidney and diagnosed depression

Exclusion criteria:

Patient's refusal to participate in the study Consume drugs irregularly The incidence of significant stress factors during the study The incidence of any disease that requires to consume drugs, nutritional supplements or vitamins for long-term Doing any type of surgery during the study Marriage or change location Do not fill out the questionnaire Unwillingness to continue consume their medication by patients Avoiding the consume of medication as a single dose

Age

From 18 years old to 30 years old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: 280

Randomization (investigator's opinion)

Randomized

Randomization description

For Blindness and randomization will be used from numbered closed envelopes and block sampling

Blinding (investigator's opinion)

Double blinded

Blinding description

For Blindness will be used from numbered closed envelopes. Patients, researcher, physicians and statistical adviser do not know about the type of drug and groupings.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Arak University of Medical Sciences

Street address

Arak University of Medical Sciences, Basij Square, Sardasht, Arak, Iran

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Markazi

Postal code

3819693345

Approval date

2016-07-25, 1395/05/04

Ethics committee reference number

IR.ARAKMU.REC.1395.164

Health conditions studied

1

Description of health condition studied

Primary dysmenorrhoea

ICD-10 code

N94.4

ICD-10 code description

Primary dysmenorrhoea

Primary outcomes

1

Description

The severity of bleeding

Timepoint

Before intervention and after the first and third menstrual cycle

Method of measurement

(PBACs) Pictorial Blood Loss Assessment Chart

2

Description

Duration of bleeding

Timepoint

Before intervention and after the first and third menstrual cycle

Method of measurement

Measuring time

3

Description

The severity of pain

Timepoint

Before intervention and after the first and third menstrual cycle

Method of measurement

Visual analog scale

4

Description

Symptoms of dysmenorrhea

Timepoint

Before intervention and after the first and third menstrual cycle

Method of measurement

Verbal scale Anthresh - Mylsum

Secondary outcomes

empty

Intervention groups

1

Description

Group 1: sachet containing 1000 mg of ginger root powder and 5000 mg of chamomile with a teaspoonful of honey; 3 time a day, from 2 day before the beginning of

menstrual cycle until 5 day

Category

Treatment - Drugs

2

Description

Group 2: sachet that contain 1000 mg of ginger root powder with a teaspoonful of honey; 3 time a day, from 2 day before the beginning of menstrual cycle until 5 day

Category

Treatment - Drugs

3

Description

Group 3: sachet that contain 5000 mg of chamomile with a teaspoonful of honey; 3 time a day, from 2 day before the beginning of menstrual cycle until 5 day

Category

Treatment - Drugs

4

Description

Group 4: 250 mg mefenamic acid capsule manufactured by Raha pharmaceutical company; 3 time a day, from 2 day before the beginning of menstrual cycle until 5 day

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Girl's Dormitory of Arak University of Medical Sciences

Full name of responsible person

Fatemeh Shabani

Street address

Girl's Dormitory of Arak University of Medical Sciences, Arak, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

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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

Arak University of Medical Sciences

Proportion provided by this source

100

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**

Arak University of Medical Sciences

Full name of responsible person

Fatemeh Shabani

Position

M.Sc. in Midwifery

Latest degree

Master

Other areas of specialty/work

Midwifery

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Tehran University of Medical Sciences

Full name of responsible person

Dr. Fatemeh Nejatbakhsh

Position

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Latest degree

Medical doctor

Other areas of specialty/work

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Other areas of specialty/work

Midwifery

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available