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 Committe of Arak University of Medical Sciences
Street address
Arak University of Medical Sciences, Basij Square, Sardasht, Arak, Iran
City
Arak
Province
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
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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
Dr. Mohammad Rafiei
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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
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Person responsible for updating data

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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