Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Jun 2026

Study of the effect of Trachyspermum ammi (L.) (Ajowan) and Apium graveolens L. (Wild Celery) on dysmenorrhea compared to mefenamic acid

Protocol summary

Study aim
Study of the effect of Trachyspermum ammi (L.) (Ajowan) and Apium graveolens L. (Wild Celery) on dysmenorrhea compared to mefenamic acid

Design
clinical trial with a parallel group, triple blinded, randomised

Settings and conduct
The present study was conducted on 81 single girl students living in a dormitory in Yazd University of Medical Sciences in 2018. The data collection method was a questionnaire. Using the visual analog scale, the severity of the patient's pain was ranged from very severe to mild.The severity of pain was evaluated using a visual analog scale (VAS) from zero to 10 degrees.

Participants/Inclusion and exclusion criteria
Inclusion criteria: age between 19 to 31 years the single person living in a dormitory No specific disease history has no history of taking oral contraceptive pills or herbal drug allergy Exclusion criteria: Patients with chronic diseases (diabetes, hypertension, kidney disease, etc.) if take oral contraceptives during the research Surgical history in the genital area Report any allergies to plants

Intervention groups
After receiving the code of ethics and obtaining the necessary permissions from the University's Ethics Committee, according to entry and exit criteria, individuals were randomly divided into four groups. The intervention group 1 consists of people with primary dysmenorrhea who receive the Trachyspermum ammi (Ajowan) The intervention group 2 consists of people with primary dysmenorrhea who receive the Apium graveolens (celery) The intervention group 3 consists of people with primary dysmenorrhea who receive the Trachyspermum ammi (Ajowan) and Apium graveolens (celery) The intervention group 4 consists of people with primary dysmenorrhea who receive the Mefenamic acid

Main outcome variables
Intensity of pain Rate of bleeding

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20160503027729N3**
Registration date: **2019-06-28, 1398/04/07**
Registration timing: **registered_while_recruiting**

Last update: **2019-06-28, 1398/04/07**
Update count: **0**

Registration date
2019-06-28, 1398/04/07

Registrant information

Name
Moneyreh Modares Mosadegh

Name of organization / entity
Shahid Sadoughi University of Medical Sciences

Country
Iran (Islamic Republic of)

Phone
+98 35 3820 3419

Email address
modares@ssu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-05-18, 1397/02/28

Expected recruitment end date
2019-07-18, 1398/04/27

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Study of the effect of Trachyspermum ammi (L.) (Ajowan) and Apium graveolens L. (Wild Celery) on dysmenorrhea compared to mefenamic acid

Public title
Effect of Celery seeds and Ajowan seeds on menstrual pain versus Mefenamic acid
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
age between 19 to 31 years the single person living in a dormitory No specific disease history has no history of taking oral contraceptive pills or herbal drug allergy
Exclusion criteria:
Patients with chronic diseases (diabetes, hypertension, kidney disease, etc.) if take oral contraceptives during the research Surgical history in the genital area Report any allergies to plants
Age
From **19 years** old to **31 years** old
Gender
Female

Phase
N/A
Groups that have been masked

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

Sample size
Target sample size: **81**
Randomization (investigator's opinion)
Randomized
Randomization description
Method of randomization: Simple randomization Unit of randomization: individual using random numbers table Allocation concealment: Sequentially numbered, sealed, opaque envelopes
Blinding (investigator's opinion)
Triple blinded
Blinding description
participants, main investigator, outcome assessor and data safety monitoring board will be blind in this study.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Shahid Sadoughi University of Medical Sciences, Yazd
Street address
Alem square
City
Yazd
Province
Yazd
Postal code
8915173149
Approval date
2018-05-18, 1397/02/28
Ethics committee reference number
IR.SSU.MEDICINE.REC.1397.152

Health conditions studied

1

Description of health condition studied
Primary dysmenrrhea
ICD-10 code
N94.4
ICD-10 code description
Primary dysmenorrhea

Primary outcomes

1

Description
Intensity of pain
Timepoint
Before starting treatment, one month and two months after starting treatment
Method of measurement
Visual Analogue Scale

Secondary outcomes

1

Description
intensity of pain
Timepoint
Before starting treatment, one month and two months after starting treatment
Method of measurement
Visual Analogue Scale

Intervention groups

1

Description

Intervention group:Patients in a group of Trachyspermum ammi will use 50 mg of a Trachyspermum ammi every 8 hours, from 24 hours before to 48 hours after menstruation

Category

Treatment - Drugs

2

Description

Intervention group: Patients in the Apium graveolens group will use 50 mg of a celery every 8 hours, from 24 hours before to 48 hours after menstruation

Category

Treatment - Drugs

3

Description

Intervention group:Patients in the Trachyspermum ammi-Apium graveolens group will use 50 mg of a Trachyspermum ammi and 50 mg of celery every 8 hours, from 24 hours before to 48 hours after menstruation

Category

Treatment - Drugs

4

Description

Intervention group: Patients in the Mefenamic Acid Group will take one capsule (250 mg) every 8 hours, from 24 hours before to 48 hours after menstruation

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Dormitory and Sports Hall of Yazd University of Medical Sciences

Full name of responsible person

Mohadeseh Barzin

Street address

Imam Hussein and Bahonar and Alam Square

City

Yazd

Province

Yazd

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8915173149

Phone

+98 35 3820 3419

Email

modares@ssu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research and Technology of Shahid Sadoughi University of Medical Sciences

Full name of responsible person

Dr. Mehrparvar

Street address

Third floor, Centeral Building, Bahonar Square

City

Yazd

Province

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Postal code

8915173149

Phone

+98 35 3146 2136

Email

ah.mehrparvar@gmail.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice Chancellor for Research and Technology of Shahid Sadoughi 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

Shahid Sadoughi University of Medical Sciences

Full name of responsible person

Moneyreh Modares Mosadegh

Position

Faculty of Dept. of Pharmacology/ Pharm.D.

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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Person responsible for scientific inquiries

Contact

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Shahid Sadoughi University of Medical Sciences
Full name of responsible person
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Position
Faculty of Dept. of Pharmacology/ Pharm.D.
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Other areas of specialty/work
Medical Pharmacy
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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