

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 dysmenorrhea

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

Postal code

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, Central Building, Bahonar Square

City

Yazd

Province

Yazd

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****Name of organization / entity**

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Person responsible for updating data**Contact****Name of organization / entity**

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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