

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of the effect of Passiflora (Relax Herb) capsule and mefenamic acid capsule on primary dysmenorrhea

Protocol summary

Study aim

Determining the effect of marigold capsule and mefenamic acid on primary dysmenorrhea

Design

Clinical trial with control group, with parallel groups, without blinding, randomized, phase 3 on 165 patients, randomization statistical software was used for randomization.

Settings and conduct

The study is a clinical trial with the aim of investigating the effect of Passiflora plant on primary dysmenorrhoea, and the samples are selected from the dormitory of Ahvaz University of Medical Sciences. In this study, the samples are randomly divided into three groups after checking the inclusion criteria. Group A consumes Passiflora plant capsules once a day, group B consumes mefenamic acid capsules every 8 days, and group C consumes placebo capsules every 8 days during the first three days of menstruation. And pain intensity is marked on the pain visual analog scale ruler every day when the person feels the most pain.

Participants/Inclusion and exclusion criteria

single age 18-25 years old regular menstrual cycle occurrence of pain before or at the same time as menstrual bleeding moderate to severe pain intensity (4 to 10 points) based on VAS no history of surgery no stressful factors no smoking no drug allergy body mass index above 30 sensitivity to drug use of oral contraceptives, supplements suffering from medical diseases use of drugs that suppress the central nervous system suffering from mental illnesses

Intervention groups

Group A uses 500 mg Passiflora capsules . Group B uses one 250 mg mefenamic acid capsule every 8 hours, and group C uses one capsule every 8 hours for two consecutive cycles and during the first three days of menstruation.

Main outcome variables

Measuring the intensity and duration of pain

General information

Reason for update

Acronym

گل ساعتی و دیسمنوره اولیه

IRCT registration information

IRCT registration number: **IRCT20230406057831N1**

Registration date: **2023-06-13, 1402/03/23**

Registration timing: **registered_while_recruiting**

Last update: **2023-06-13, 1402/03/23**

Update count: **0**

Registration date

2023-06-13, 1402/03/23

Registrant information

Name

yasamin vasy ahvazi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 903 502 9932

Email address

yasammmin@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-05-21, 1402/02/31

Expected recruitment end date

2023-07-22, 1402/04/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of Passiflora (Relax Herb) capsule and mefenamic acid capsule on primary dysmenorrhea

Public title

Comparison of the effect of passiflora plant and mefenamic acid on primary dysmenorrhoea

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

single age 18-25 years old regular menstrual cycle (25-30 days) occurrence of pain before or at the same time as menstrual bleeding moderate to severe pain intensity (4 to 10 points) based on visual analogue pain index in three days at First, menstrual bleeding no history of abdominal and pelvic surgery no symptoms such as burning, itching or abnormal secretions no stressful factors such as the death of 1st degree relatives separation of parents, etc. in the last 6 months no smoking no drug allergy

Exclusion criteria:

body mass index above 30 sensitivity to non-steroidal anti-inflammatory drugs such as mefenamic acid use of oral contraceptives, supplements or any drug and herbal decoction suffering from medical diseases such as organ disease. Genital, heart, lung disease, endocrine disorders, metabolic disease, gastric or duodenal ulcer, digestive, liver and kidney disease use of drugs that suppress the central nervous system, anticoagulants and antihypertensive drugs suffering from mental illnesses. According to the patient, it is like depression, severe anxiety and severe stress

Age

From **18 years** old to **25 years** old

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **165**

Randomization (investigator's opinion)

Randomized

Randomization description

Random Method: Block Random unit: individual Stochastic tools: statistical software For concealment, we use random allocation concealment, in such a way that the assigned group is not known before the individual is allocated. By using non-transparent envelopes sealed with a random sequence, in this method, each of the random sequences created on the outer surface of the envelopes is numbered, and finally the lids of the envelopes are glued and placed in a box respectively.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Ahvaz Jundishapur University of Medical Sciences

Street address

No. 22, Abuzar Ave, 45 metry, Golshahr Town

City

Karaj

Province

Alborz

Postal code

3138997388

Approval date

2023-05-01, 1402/02/11

Ethics committee reference number

IR.AJUMS.REC.1402.044

Health conditions studied

1

Description of health condition studied

Dysmenorrhea

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Severity of primary dysmenorrhoea

Timepoint

Measurement of primary dysmenorrhea before the start of the study and in the first three days of menstruation for two months

Method of measurement

Visual analog scale of pain

2

Description

Duration of primary dysmenorrhea

Timepoint

Measuring the duration of primary dysmenorrhea before the start of the study and in the first three days of menstruation for two months

Method of measurement

The duration of primary dysmenorrhea is measured in minutes

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group:

Category

Treatment - Drugs

2

Description

Control group:

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

خوابگاه گلستان دانشگاه جندی شاپور اهواز

Full name of responsible person

دکتر سیمین منتظری

Street address

Koi Saadi Ahvaz Darb Golestan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Dr. Mehrnoosh Zakir Kish

Street address

Koi Ustadan Ahvaz and on West Coast Boulevard,
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Fax

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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

Ahvaz 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

Ahvaz University of Medical Sciences

Full name of responsible person

Dr. Simin Montazeri

Position

Assistant professor in reproductive health

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Dr. Simin Montazeri

Position

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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

No - There is not a plan to make this available

Data Dictionary

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