Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

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

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 primarydysmenorrhea

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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Email
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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
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Koi Ustadan Ahvaz and on West Coast Boulevard, Golestan Boulevard
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info@ajums.ac.ir
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

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Position
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Latest degree
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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
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