Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of the effects of Crocus Sativus and Mefenamic Acid on primary Dysmenorrhea in young adult female students

Protocol summary

Summary

In previous studies, extract of 3 herbs, celery, fenugreek and saffron is effective on primary dysmenorrhea. However, the health effects of saffron alone on primary dysmenorrhea have not been yet studied. The aim of this study is to examine the effects of saffron on primary dysmenorrhea and comparison with the effectiveness of Mefenamic Acid in women aged 18-27 years old that will be conducted as double blind single center study. At first, Patients are identified by questionnaire and diagnostic questions. Then patients with primary dysmenorrhea divided into three groups. Group 1 receive saffron capsule three times per day for three days of menstrual period for three consecutive menstural cycles. Group 2 receive mefenamic acid, and group 3 receive identical placebo with the same protocol as group one. Visual Analogue Scale (VAS) and Verbal Multidimensional Scoring system (VMS) will be completed and recorded at baseline and after each menstrual period.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016081329327N1**
Registration date: **2016-12-16, 1395/09/26**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-12-16, 1395/09/26

Registrant information

Name

Ramin Abrishami

Name of organization / entity

Islamic Azad University, Pharamceutical sciences branch

Country

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Recruitment status

Recruitment complete

Funding source

Investigator

Expected recruitment start date

2016-09-01, 1395/06/11

Expected recruitment end date

2017-03-01, 1395/12/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effects of Crocus Sativus and Mefenamic Acid on primary Dysmenorrhea in young adult female students

Public title

Comparison of the effects of saffron and Mefenamic Acid on Dysmenorrhea

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:primary dysmenorrhea; Not having asthma, GI problems, intolerance to NSAIDs; Age = 18-27 years; written informed consent. Exclusion criteria:pregnancy; allergy to herbal products including saffron

Age

From **18 years** old to **27 years** old

Gender
Female

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **180**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features
Based on block randomization

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Islamic Azad University of Pharmaceutical Sciences
Street address
Yakhchal Ave., Shariati st., Tehran
City
Tehran
Postal code
Approval date
2016-05-18, 1395/02/29
Ethics committee reference number
IR.IAU.PS.REC.1395.8

Health conditions studied

1

Description of health condition studied
Primary Dysmenorrhea
ICD-10 code
N94.4
ICD-10 code description
Primary dysmenorrhoea

Primary outcomes

1

Description
Pain
Timepoint
3rd day of menstural cycle
Method of measurement
Visual Analogue Scale (VAS) and Verbal Multidimensional Scoring system (VMS)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: will receive handmade saffron capsule, 30 mg dried saffron powder, three times per day for three days of menstrual period for three consecutive menstural cycles.
Category
Treatment - Drugs

2

Description
Intervention group 2: will receive mefenamic acid 250mg capsule (Amin Pharmaceuticals, Isfahan, Iran) three times per day for three days of menstrual period for three consecutive menstural cycles.
Category
Treatment - Drugs

3

Description
Control group: will receive placebo capsule three times per day for three days of menstrual period for three consecutive menstural cycles.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Islamic Azad University of Pharmaceutical Sciences
Full name of responsible person
Parastoo Azimi
Street address
Yakhchal Ave., Shariati st., Tehran
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
No sponsor used
Full name of responsible person

none

Street address

none

City

none

Grant name

Grant code / Reference number

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

Yes

Title of funding source

No sponsor used

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Islamic Azad University of Pharmaceutical Sciences

Full name of responsible person

Ramin Abrishami

Position

Assistant professor

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty