Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the effect of Citrus Aurantium extract with Mefenamic Acid on the intensity of Primary Dismenorrhea

Protocol summary

Study aim

Comparison and determination of the effect of Citrus Aurantium extract, Mefenamic acid and placebo capsules on the severity of primary dysmenorrhea

Design

Double-blind clinical trial with parallel and randomized blocking in 3 groups of each 35 sample

Settings and conduct

This study is a double-blind(participants and researcher) clinical trial with parallel and randomized blocking groups.After obtaining permission from the Ethics Committee of Tabriz University of Medical Science,the study will be performed in three groups, each of 35 eligible participants with moderate to severe dysmenorrhea from three selected high schools in Tabriz, unaware of eachother.Each group will recieve 250 mg capsule of Citrus aurantium extract or Mefenamic acid or Placebo randomly for the first three days of each period.They will mark their pain intensity on the McGill pain Scale and complete other relevant questionnaires.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Being single-Age from 15 to 20-Primary Dysmenorrhea with moderate to severe intensity- Regular distance between cycles- No history of abdominal or pelvic surgery- No irritation, burning or abnormal vaginal secretions- No history of pelvic inflammatory disease,Endometriosis,Myoma and tumor-No stressful situations like death of first degree relatives, seperation of parents,... in the last 6 months.Exclusion criteria: Unwillingness to use medicine due to severe side effects or discontent-Use of any medicine or herb-Allergy to Citrus aurantium

Intervention groups

Citrus Aurantium extract capsule group Mefenamic Acid capsule group Placebo capsule group

Main outcome variables

Citrus aurantium group -Mefenamic Acid group -Placebo group Severity of Primary Dysmenorrhea- Age of the menarche -Age The distance between two cycles - Number of bleeding days-Physical activity-Complications of intervention- Father's education-Mother's education

General information

Reason for update

Adding the recriument and trial completion dates

Acronym

IRCT registration information

IRCT registration number: **IRCT20180524039815N1**
Registration date: **2018-05-31, 1397/03/10**
Registration timing: **prospective**

Last update: **2021-04-11, 1400/01/22**
Update count: **1**

Registration date

2018-05-31, 1397/03/10

Registrant information

Name

Farkhondeh Aboualsoltani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3331 0477

Email address

Abolsoltanif@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-06-22, 1397/04/01

Expected recruitment end date

2018-10-23, 1397/08/01

Actual recruitment start date

2018-06-22, 1397/04/01

Actual recruitment end date

2019-02-14, 1397/11/25

Trial completion date

2019-07-11, 1398/04/20

Scientific title

Comparison of the effect of Citrus Aurantium extract with Mefenamic Acid on the intensity of Primary Dismenorrhea

Public title

Effect of Citrus Aurantium extract on painful menstruation

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Being single-Age from 15 to 20 Having Primary Dysmenorrhea with moderate to severe intensity accourding to Mcgill pain scale atleast for the last cycle Regular distance between menstrual cycles No previous abdominal or pelvic surgery No symptomes like irritation, burning or abnormal vaginal secretions No past history of pelvic inflammatory disease,Endometriosis,Myoma and tumor No stressful situations like death of first degree relatives, seperation of parents,... in the last 6 months.

Exclusion criteria:

Unwillingness to take medication for different reasons like severe side effects or discontent Using any medicine or herbal product Being allergic to Citrus Aurantium flower.

Age

From **15 years** old to **20 years** old

Gender

Female

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **105**

Actual sample size reached: **105**

Randomization (investigator's opinion)

Randomized

Randomization description

Initially the qualified participants will be asked to fill the individual, demoghraphic,menstrual and visual pain scale questionnaires one month before beginning of the medications(Citrus Aurantium extract,Mefenamic Acid,Placebo) and in the first three days of the cycle. Randomization will be based on Fixed size block randomization. In selection of blocks random numbers table will be used.

Blinding (investigator's opinion)

Double blinded

Blinding description

250 mg capsules containing Citrus Aurantium extract or Mefenamic Acid or Placebo(Starch) which are similar in shape, color, size and aroma, are made at Tabriz Faculty of Pharmacy and Tabriz Medical Science Research and Development Center. They are placed in the envelopes A, B and C by the pharmacist. Each code indicates that there is one type of capsule inside the envelope. The researcher will randomly distribute the envelopes among eligible participants in the study. Apart from the pharmacist, investigator or participants, will be unaware of the envelopes content. The researcher will not know which of the participants will use the envelope A or the envelope B or the envelope C. The type of the medicines inside the envelopes will not be obvious to the researcher and participants.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tabriz University of Medical Sciences

Street address

Daneshgah Ave, Pharmacy Faculty

City

Tabriz

Province

East Azarbaijan

Postal code

51664-14766

Approval date

2018-04-21, 1397/02/01

Ethics committee reference number

IR.TBZMED.REC.1397.105

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 Dysmenorrhea

Timepoint

Monthly

Method of measurement
Visual Analogue Scale(VAS) - Mcgill pain scale

2

Description
Days of bleeding
Timepoint
Daily
Method of measurement
Questionnaire

3

Description
Distance between two cycles
Timepoint
Day
Method of measurement
Questionnaire

4

Description
Physical activity
Timepoint
Monthly
Method of measurement
Questionnaire

Secondary outcomes

1

Description
Complications of interventions
Timepoint
During intervention
Method of measurement
Questionnaire-Report-Observation

Intervention groups

1

Description
Intervention group: Citrus Aurantium extract 250 mg capsule every 8 hours during the first three days of the cycle
Category
Treatment - Drugs

2

Description
Intervention group: Mefenamic Acid 250 mg capsule every 8 hours during the first three days of the cycle
Category
Treatment - Drugs

3

Description
Intervention group: Placebo 250 mg capsule(containing starch) every 8 hours during the first three days of the cycle
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Nokhbegan mandeghar private High school
Full name of responsible person
Farkhondeh Aboualsoltani
Street address
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Recruitment center
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Recruitment center
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Recruitment center

Name of recruitment center
Peik Saadat private High school

Full name of responsible person
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Deputy of Research of Tabriz University of Medical Sciences

Full name of responsible person
Dr.Mohammad Reza Rashidi

Street address
No.2 Central building,Tabriz University of Medical Sciences,Gholgasht Ave.

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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
Deputy of Research of Tabriz 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
Tabriz University of Medical Sciences

Full name of responsible person
Dr.Parvin Bastani

Position
Associate Professor

Latest degree
Subspecialist

Other areas of specialty/work
Gynecology and Obstetrics

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Person responsible for scientific inquiries

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Name of organization / entity
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Farkhondeh Aboualsoltani

Position
Resident

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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
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
Individual information is publicable after making unrecognisable

When the data will become available and for how long
Access is provided 2 months after publication of the results

To whom data/document is available
Researchers may ask for data of the study

Under which criteria data/document could be used
Statistical analysis on data and assesing prevalance is permitted

From where data/document is obtainable
The following address may be used for requesting information: Far_absl@yahoo.com

What processes are involved for a request to access data/document
After contacting the mentioned address and evaluation of the request, answer will be provided in two weeks

Comments