Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison the effect of Trachyspermum ammi with mefenamic acid on primary dysmenorrhea: A randomized clinical trial

Protocol summary

Study aim
Comparison the effect of Trachyspermum ammi with mefenamic acid on primary dysmenorrhea: A randomized clinical trial

Design
Patients are randomly assigned to two equal groups according to a random number table. One group will be treated with mefenamic acid and another with trachyspermum ammi capsuls. The sample size is 70, which consists of two groups of 35 people. This trial is phase 3.

Settings and conduct
After study confirmation and obtaining ethics code from the Medical Ethics Committee of IUMS and registration in IRCT, study will be started by installing a recall in the student dormitory of the TUMS. For patients who have inclusion criteria study will be explained and the consent form will be completed by them.The individual information questionnaire will be completed.The pain level will be determined based on the VAS. Duration of pain will also be checked. Also, patients will be divided into moderate and severe dysmenorrhea groups.

Participants/Inclusion and exclusion criteria
Inclusion criteria 1.Moderate to severe dysmenorrhea based on the Verbal Multidimentional Scoring System. 2. Rejection of the secondary dysmenorrhea 3. Regular cycles Exclusion criteria: 1 history of abdominal or pelvic surgery 2 taking anticoagulant drugs 3 trachyspermum ammi allergy history 4 history of hemorrhagic diseases 5 Pregnancy and breastfeeding 6 trachyspermum ammi allergy occurance during the Study 7 incorrect drug consumption 8 mefenamic acid side effect history 9 Demyelinating inflammatory diseases 10 patients with severe side effects. 11 Patients requiring other interventions. 12 patients who are reluctant to continue studying.

Intervention groups
35 patients who receive trachyspermum ammi capsules

Main outcome variables
Changes in pain duration and intensity

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180805040697N1**
Registration date: **2019-04-01, 1398/01/12**
Registration timing: **retrospective**

Last update: **2019-04-01, 1398/01/12**
Update count: **0**

Registration date
2019-04-01, 1398/01/12

Registrant information

Name
Fateme Zali

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 26 3272 2060

Email address
zali.f@tak.iums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-09-23, 1397/07/01

Expected recruitment end date
2019-03-20, 1397/12/29

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Comparison the effect of Trachyspermum ammi with mefenamic acid on primary dysmenorrhea: A randomized clinical trial

Public title
Comparison the effect of Trachyspermum ammi with mefenamic acid on primary dysmenorrhea

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
modorate to severe dysmenorrhea according to Verbal Multidimentional Scoring System exclude secondry dysmenorrhea by history taking and confirmation of primary dysmenorrhea diagnosis Regular cycles with a maximum of 3 to 4 days of priority or delay

Exclusion criteria:

Age
No age limit

Gender
Female

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **70**

Randomization (investigator's opinion)
Randomized

Randomization description
Block randomization based on random numbers

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Iran University of Medical Science.

Street address
next to Milad Tower, Hemat highway, Tehran

City
Tehran

Province
Tehran

Postal code
۱۴۴۹۶۱۴۵۳۵

Approval date
2018-09-27, 1397/07/05

Ethics committee reference number
IR.IUMS.REC1397056

Health conditions studied

1

Description of health condition studied
Primary Dysmenorrhea

ICD-10 code
N94.4

ICD-10 code description
Pain and other conditions associated with female genital organs and menstrual cycle

Primary outcomes

1

Description
primary Dysmenorrhoea

Timepoint
The day before menstruation and the first three days of menstruation in three consecutive cycles

Method of measurement
Visual Analog Scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Receiving 500 mg capsules containing seeds powder TDS, from 4 days before mensturation until the third day

Category
Treatment - Drugs

2

Description
Control group: Receiving Mefenamic acid capsules, the first dose 500 mg and then 250 mg every 8 hours if necessary

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Girls Dormitory of Tehran University of Medical Sciences

Full name of responsible person
fatemeh zali
Street address
Girls Dormitory of Tehran University of Medical Sciences, north Kargar street
City
Tehran
Province
Tehran
Postal code
1417733161
Phone
+98 21 8895 4926
Email
fatemehzali@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
..
Street address
Tehran Hemat Highway next to Milad Tower
City
Tehran
Province
Tehran
Postal code
۱۴۴۹۶۱۴۵۳۵
Phone
+98 21 86701
Email
PR@iums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Iran 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
Iran University of Medical Sciences
Full name of responsible person
Fatemeh Zali
Position
PhD student
Latest degree
Medical doctor
Other areas of specialty/work
Traditional Medicine
Street address
Behesht St. Vahdat Islami St
City
Tehran
Province
Tehran
Postal code
1114733311
Phone
+98 21 5563 9667
Email
fatemehzali@yahoo.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Fatemeh Zali
Position
PhD student
Latest degree
Medical doctor
Other areas of specialty/work
Traditional Medicine
Street address
Behesht St. Vahdat Islami St
City
Tehran
Province
Tehran
Postal code
1114733311
Phone
+98 21 5563 9667
Email
fatemehzali@yahoo.com

Person responsible for updating data

Contact
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Fatemeh Zali
Position
PhD student
Latest degree
Medical doctor
Other areas of specialty/work
Traditional Medicine
Street address
Behesht St. Vahdat Islami St

City
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Province
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Postal code
1114733311
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+98 21 5563 9667
Email
Fatemehzali@yahoo.com

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