Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of Mentha longifolia L. efficacy on decrease of dysmenorrhea pain

Protocol summary

Study aim
Therapeutic
Design
A clinical trial with a control group, with cross-over groups, double-blind, randomized, phase 3 on 42 patients, random block allocation method was used for randomization.
Settings and conduct
This project was carried out in the Yazd Health Center. Patients are randomly assigned to three treatment groups A, B, and C, and they receive one of the capsules of Mentha longifolia L or mefenamic acid or placebo every 6 hours with the onset of symptoms for three days.
Participants/Inclusion and exclusion criteria
Patients with moderate to severe dysmenorrhoea pain who do not receive NSAID drugs and do not have allergy to herbal products.
Intervention groups
To investigate the effect of Mentha longifolia L plant on reducing pain caused by dysmenorrhea, 42 patients were randomly assigned to three treatment groups A, B and C, and the patient received one of Mentha longifolia L plant capsules or mefenamic acid or placebo in each menstrual cycle.
Main outcome variables
Therapeutic

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20181208041882N8**
Registration date: **2023-10-08, 1402/07/16**
Registration timing: **retrospective**

Last update: **2023-10-08, 1402/07/16**
Update count: **0**

Registration date
2023-10-08, 1402/07/16

Registrant information
Name
behrooz heydari
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2018-11-27, 1397/09/06
Expected recruitment end date
2023-03-20, 1401/12/29
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of Mentha longifolia L. efficacy on decrease of dysmenorrhea pain

Public title
Evaluation of Mentha longifolia L on dysmenorrhea pain
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Women's 15 to 45 years old Moderate to severe dysmenorrhea pain
Exclusion criteria:

Patients with mild or secondary dysmenorrhea pain
Patients have received one of the NSAID drugs.
Hypersensitivity to Mentha longifolia L Pregnancy and lactation

Age

From **15 years** old to **45 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **42**
More than 1 sample in each individual
Number of samples in each individual: **3**
In each menstrual cycle, a person will be placed in one of three groups.

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, 42 patients are randomly divided into three treatment groups (A ,B and C). Block random allocation method will be used for random allocation. In this study, 7 blocks of 6 are considered. The generated permutations include repeated letters A, B and C (eg ABACAB). These permutations are generated with the help of Random allocation software version 1. For this purpose, the list prepared by the software is from 1 to 42, which are arranged in 7 blocks of six regularly. To run this software output, we give the first qualified person number 1 and the last person will receive number 42. In order to be blind, the random allocation of this list is given to another person outside the study, and by sending a text message before assigning the type of treatment, the eligible person is asked according to the number, and thus the people enter the study. Also in the software output, both numbers 1 to 42 and permutations of the letters A, B and C can be seen.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study patients, clinical caregivers and outcome assessors were unaware of the type of medication patients were receiving. Patients in three groups received the medication in the same package

Placebo

Used

Assignment

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

School of Medicine- Shahid Sadoughi University of Medical Sciences

Street address

Shahid Sadoughi University of Medical Science, Shohadaye Gomnam Blvd, Alem Sq

City

Yazd

Province

Yazd

Postal code

8915173143

Approval date

2018-11-27, 1397/09/06

Ethics committee reference number

IR.SSU.MEDICINE.REC.1397.134

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

Dysmenorrhoea pain

Timepoint

Days 0 and 3

Method of measurement

Visual analog scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients with primary dysmenorrhoea with moderate to severe severity use one capsule of mefenamic acid every 6 hours for up to 3 days.

Category

Treatment - Drugs

2

Description

Intervention group: Patients with primary dysmenorrhoea with moderate to severe severity use two capsules of Mentha longifolia (Manufactured in Yazd Pharmacy Faculty) every 6 hours for up to 3 days.

Category

Treatment - Drugs

3

Description

Control group: Patients with primary dysmenorrhoea with moderate to severe severity use one placebo capsule (Manufactured in Yazd Pharmacy Faculty) every 6 hours for up to 3 days.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Yazd Health Center

Full name of responsible person
Behrooz Heydari

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Shahid Sadoughi University of Medical Sciences, Shohadaye Gomnam Blvd,Alem Sq

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Yazd University of Medical Sciences

Full name of responsible person
Amin Salehi Abarghouei

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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
Yazd 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
Yazd University of Medical Sciences

Full name of responsible person
Behrooz Heydari

Position
Assistant professor

Latest degree
Ph.D.

Other areas of specialty/work
Medical Pharmacy

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
After nonrecognition, all data can be share

When the data will become available and for how long
6 months after publication

To whom data/document is available
All of researchers

Under which criteria data/document could be used
nothing

From where data/document is obtainable
Behrooz Heydari email: b.heydari@ssu.ac.ir

What processes are involved for a request to access data/document
Request your information by email. The data will be sent after a week.

Comments