

# 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

###### Country

Iran (Islamic Republic of)

###### Phone

+98 35 3820 8699

###### Email address

b.heydari@ssu.ac.ir

##### 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,  
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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

### Contact

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Yazd University of Medical Sciences  
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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