

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jul 2026

### Effect of Turmeric supplementation on symptoms of primary dysmenorrhea in resident students at Qazvin University of Medical Sciences student dormitory: A randomized, one-blind, placebo-controlled clinical trial

#### Protocol summary

##### Study aim

Determination of Turmeric supplementation effect on bleeding time, severity of menstrual pain, duration of pain

##### Design

In this study, 80 girls with primary dysmenorrhea who are eligible to enter the study are selected. Participants are randomly assigned to four intervention and control groups and each participant is assigned a code.

##### Settings and conduct

This study is a single-blind randomized clinical trial. Girls with primary dysmenorrhea living in student dormitory at Qazvin University of Medical Sciences entered the study. Then, 80 patients were randomly assigned to four intervention and control groups. In this study, the patient will be blinded to drugs and placebo.

##### Participants/Inclusion and exclusion criteria

Girls with primary dysmenorrhea

##### Intervention groups

First intervention group: Turmeric recipient group (500 mg daily); Second intervention group: Mefenamic acid group (250 mg daily); Third intervention group: Turmeric (500 mg daily) + Mefenamic acid (250 mg daily), control group: placebo group

##### Main outcome variables

Duration of bleeding, pain intensity of menstruation, duration of pain

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20141025019669N9**

Registration date: **2018-03-07, 1396/12/16**

Registration timing: **prospective**

Last update: **2018-03-07, 1396/12/16**

Update count: **0**

##### Registration date

2018-03-07, 1396/12/16

##### Registrant information

###### Name

Hossein Khadem Haghghian

###### Name of organization / entity

Qazvin University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 28 3375 2135

###### Email address

khadem.h@ajums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-04-09, 1397/01/20

##### Expected recruitment end date

2018-05-10, 1397/02/20

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of Turmeric supplementation on symptoms of primary dysmenorrhea in resident students at Qazvin University of Medical Sciences student dormitory: A randomized, one-blind, placebo-controlled clinical trial

##### Public title

Turmeric supplementation on symptoms of dysmenorrhea

### Purpose

Treatment

### Inclusion/Exclusion criteria

#### Inclusion criteria:

Having primary dysmenorrhea Having regular menstruation between 35-21 days Single Having a body mass index below 30 Having aged 18 to 25 years old

#### Exclusion criteria:

Having secondary dysmenorrhea (endometriosis, adenomyosis, leiomyoma, uterine anomaly, Endometrial Polyps, ovarian cyst) Intake of antioxidant supplement in the last six months

### Age

From **18 years** old to **25 years** old

### Gender

Female

### Phase

2-3

### Groups that have been masked

- Participant

### Sample size

Target sample size: **80**

### Randomization (investigator's opinion)

Randomized

### Randomization description

It will be done with simple random method using the lottery. For each patient, a number or code is provided, then the numbers will be written on pieces of paper. The pieces of paper are placed in a container and well stirred, and the sample is selected according to the sample size.

### Blinding (investigator's opinion)

Single blinded

### Blinding description

Patients are randomly divided into two groups, intervention and control groups, using randomized distribution method. In this study, the patient is blinded to medicine and placebo

### Placebo

Used

### Assignment

Factorial

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Qazvin University Of Medical Sciences

##### Street address

Qazvin University of Medical Science, Shahid Bahonar Blvd, Qazvin

### City

Qazvin

### Province

Qazvin

### Postal code

34197-59811

### Approval date

2019-02-28, 1397/12/09

### Ethics committee reference number

IR.QUMS.REC.1396.477

## Health conditions studied

### 1

#### Description of health condition studied

Primary dysmenorrhoea

#### ICD-10 code

N94.4

#### ICD-10 code description

Primary dysmenorrhea

## Primary outcomes

### 1

#### Description

Duration of bleeding

#### Timepoint

Before the intervention and after the intervention

#### Method of measurement

According to a person's report by the questionnaire

### 2

#### Description

Pain duration

#### Timepoint

Before the intervention and after the intervention

#### Method of measurement

Duration of pain based on hours

### 3

#### Description

Intensity of pain

#### Timepoint

Before the intervention and after the intervention

#### Method of measurement

Pain intensity according to the questionnaire

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Turmeric, 600 mg per daily

#### Category

Treatment - Drugs

2

**Description**

Intervention group: Mefenamic acid, 250 mg per day

**Category**

Treatment - Drugs

3

**Description**

Intervention group: Turmeric (500 mg) + Mefenamic acid (250 mg) daily

**Category**

Treatment - Drugs

4

**Description**

Control group: Placebo

**Category**

Treatment - Drugs

**Recruitment centers**

1

**Recruitment center**

**Name of recruitment center**

Qazvin University of Medical Sciences

**Full name of responsible person**

Hossein Khadem Haghighian

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khademnut@yahoo.com

**Sponsors / Funding sources**

1

**Sponsor**

**Name of organization / entity**

Qazvin University of Medical Sciences

**Full name of responsible person**

Dr. Peimani

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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**

Qazvin 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**

Qazvin University of Medical Sciences

**Full name of responsible person**

Hossein Khadem Haghighian

**Position**

Faculty member

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nutrition

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## Person responsible for updating data

### Contact

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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

Data on primary and secondary outcomes will be published.

### When the data will become available and for how long

After completing the study and analyzing the data

### To whom data/document is available

All researchers

### Under which criteria data/document could be used

There is no objection to the use of data provided the source of the resource.

### From where data/document is obtainable

IRCT site

### What processes are involved for a request to access data/document

Six months after the study

### Comments