

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparative of the Effectiveness of Turmeric Extract with Mefenamic Acid on Pain Intensity of Primary Dysmenorrhea

#### Protocol summary

##### Study aim

Comparative of the Effectiveness of Turmeric Extract with Mefenamic Acid on Pain Intensity of Primary Dysmenorrhea

##### Design

A double-blind with parallel groups and randomized clinical trial is conducted

##### Settings and conduct

Clinical trial is conducted on the female students of Neyshabour dormitories. The medicine will be coded as A and B by the pharmacist and the codes will be randomly selected by the samples themselves.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Being single, Aged between 18-28, At least one semester has been left, Having dysmenorrhea with the features of primary dysmenorrhea in most menstrual cycles in the last 6 months, Not participating in other studies  
Exclusion criteria: lack of interest in continuing the participation during the study for any reason, Getting married during the study, any Unmodified side effects

##### Intervention groups

Every participant will be randomly given 27 Mefenamic acid capsules or 27 turmeric capsules for three consecutive cycles. After explaining how each drug is taken, (i.e. three capsules should be taken in the duration of 8 hours from the first day of menstrual period for three days), they will be asked to complete the forms after taking the drug. The medicine will be coded as A and B by the pharmacist and the codes will be randomly selected by the samples themselves. At the end of the study, the cases of study in the two groups receiving turmeric and Mefenamic acid will be evaluated for the pain intensity and possible side effects.

##### Main outcome variables

pain intensity and possible side effects.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20160821029446N5**

Registration date: **2018-06-20, 1397/03/30**

Registration timing: **prospective**

Last update: **2018-06-20, 1397/03/30**

Update count: **0**

##### Registration date

2018-06-20, 1397/03/30

##### Registrant information

##### Name

Maryam Damghanian

##### Name of organization / entity

Nursing and Midwifery Faculty, Tehran University of Medical Science

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 6692 7171

##### Email address

m-damghanian@sina.tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-06-22, 1397/04/01

##### Expected recruitment end date

2018-09-21, 1397/06/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

Comparative of the Effectiveness of Turmeric Extract with Mefenamic Acid on Pain Intensity of Primary Dysmenorrhea

## Public title

Comparative of the Effectiveness of Turmeric Extract with Mefenamic Acid on Pain Intensity of Primary Dysmenorrhea

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Being single Aged between 18-28 At least one semester has been left Having dysmenorrhea with the features of primary dysmenorrhea in most menstrual cycles in the last 6 months Having regular menstrual cycle (21-35 days) Not having female genital problems (ovarian cysts, fibroma, abnormal uterine bleeding) Absence of coagulation disorders Absence of abdominal and pelvic surgery history Absence of drug interaction such as glycemic control drugs and high blood pressure drugs Absence of allergy to turmeric and its compounds Absence of allergy to non-steroidal anti-inflammatory drugs Not using relaxation techniques over the last 6 months Absence of physical and mental illness Not participating in other studies

### Exclusion criteria:

Unwillingness to continue the participation during the study for any reason Getting married during the study any Unmodified side effects

## Age

From **18 years** old to **28 years** old

## Gender

Female

## Phase

3

## Groups that have been masked

- Participant
- Investigator
- Outcome assessor

## Sample size

Target sample size: **132**

## Randomization (investigator's opinion)

Randomized

## Randomization description

The sampling method will be stratified quota sampling in which each dormitory will be considered as a stratify. After selecting the samples from the first dormitory, they were randomly divided into two groups receiving Mefenamic acid capsules and turmeric extract capsules. The samples were selected randomly in the second dormitory like those of the first one.

## Blinding (investigator's opinion)

Double blinded

## Blinding description

A double-blind randomized clinical trial is conducted. The study is blinded by coding the drugs by the pharmacist (A and B), and the pharmacist placed the provided drugs (i.e. mefenamic acid and turmeric extract capsules) in the cans with the same colors and shapes and randomly

coded them. Three capsules should be taken for three days in a month during three months and the researcher and participants do not have any idea about which drug is coded as A or B. For each half of the participants in the dormitory, codes are written on the pieces of the paper and then are placed in a bag. At the beginning of the treatment cycle, the participants were asked to take a code from the bag by chance and then they were given a drug according to the selected code.

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Nursing and Midwifery and Rehabilitation Faculty of Tehran University of Medical

##### Street address

Nursing and Midwifery Faculty of Tehran University of Medical Sciences, Tohid Square, Tehran

##### City

Tehran

##### Province

Tehran

##### Postal code

1419733171

#### Approval date

2018-04-08, 1397/01/19

#### Ethics committee reference number

IR.TUMS.FNM.REC.1397.4933

## Health conditions studied

### 1

#### Description of health condition studied

Dysmenorrhea

#### ICD-10 code

N94.4

#### ICD-10 code description

Primary dysmenorrhea

## Primary outcomes

### 1

#### Description

Dysmenorrhea intensity

#### Timepoint

In 2 control cycles and then after taking drugs In the form of three capsules every 8 hours for three days until 3 cycles.

**Method of measurement**

verbal multidimensional scoring system

**2****Description**

Blood loss during menstrual cycle

**Timepoint**

In 2 control cycles and then after taking drugs In the form of three capsules every 8 hours for three days until 3 cycles.

**Method of measurement**

Pictorial Blood Loss Assessment

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Intervention group: Every participant will be randomly given 27 turmeric capsules for three consecutive cycles. After explaining how each drug is taken, (i.e. three capsules should be taken in the duration of 8 hours from the first day of menstrual period for three days), they will be asked to complete the forms after taking the drug.

**Category**

Treatment - Drugs

**2****Description**

Control group: Every participant will be randomly given 27 Mefenamic acid capsules for three consecutive cycles. After explaining how each drug is taken, (i.e. three capsules should be taken in the duration of 8 hours from the first day of menstrual period for three days), they will be asked to complete the forms after taking the drug.

**Category**

Treatment - Drugs

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Girl's dormitory of Neyshabour Azad University

**Full name of responsible person**

Monireh Soghandi

**Street address**

Monastery Road, Islamic Azad University, Research Center

**City**

Neyshabour

**Province**

Razavi Khorasan

**Postal code**

9319797139

**Phone**

+98 51 4262 1910

**Email**

Neyshabur@iau-neyshabur.ac.ir

**2****Recruitment center****Name of recruitment center**

Girl's dormitory of Neyshabour Governmental University

**Full name of responsible person**

Maryam Modiri

**Street address**

42 central dormitories, The 15th of Khordad Avenue

**City**

Neyshabour

**Province**

Razavi Khorasan

**Postal code**

9319774400

**Phone**

+98 51 4262 1731

**Email**

Neyshabur@iau-neyshabur.ac.ir

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Esmat Karimi

**Street address**

Number 23, Dameshgh Street, Valiasr Street, Tehran, Iran

**City**

Tehran

**Province**

Tehran

**Postal code**

1419733171

**Phone**

+98 21 6105 4222

**Email**

maryam\_damghanian@yahoo.com

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Tehran 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**

Tehran University of Medical Sciences

**Full name of responsible person**

Maryam Yazdi

**Position**

MSc Student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Midwifery

**Street address**

Iran, Tehran, Tohid Square, Tehran University of Medical Sciences, Faculty of Nursing and Midwifery

**City**

Tehran

**Province**

Tehran

**Postal code**

1419733171

**Phone**

+98 21 2966 1717

**Email**

yazdimaryam20@yahoo.com

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Maryam Damghanian

**Position**

Associate Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Midwifery

**Street address**

Iran, Tehran, Tohid Square, Tehran University of Medical Sciences, Faculty of Nursing and Midwifery

**City**

Tehran

**Province**

Tehran

**Postal code**

1419733172

**Phone**

+98 21 6692 7171

**Email**

Maryam\_damghanian@yahoo.com

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Maryam Damghanian

**Position**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Midwifery

**Street address**

School of Nursing & Midwifery, East Nosrat Ave, Towhid Square, Tehran, Iran

**City**

Tehran

**Province**

Tehran

**Postal code**

1419733171

**Phone**

+98 21 5016 2224

**Email**

maryam\_damghanian@yahoo.com

**Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

There is no more information

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

No - There is not a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available