

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)

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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

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Tehran

Province

Tehran

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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

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Monastery Road, Islamic Azad University, Research Center

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

Girl's dormitory of Neyshabour Governmental University

Full name of responsible person

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

Tehran University of Medical Sciences

Full name of responsible person

Esmat Karimi

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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

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

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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