Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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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+98 21 6692 7171

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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

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
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2

Recruitment center
Name of recruitment center
Girl's dormitory of Neyshabour Govermental University
Full name of responsible person
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42 central dormitories, The 15th of Khordad Avenue
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Province
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9319774400
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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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Number 23, Dameshgh Street, Valiasr Street, Tehran, Iran
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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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Latest degree

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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