Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation effectiveness of topical ginger oil pad in dysmenorrhea: Triple blind-placebo-controlled Randomized Clinical Trial

Protocol summary

Study aim
Evaluation of the effectiveness of topical ginger oil pad in dysmenorrhea

Design
Triple-blind randomized clinical trial, with control group, parallel, phase 3 on 30 patients, Permuted Block Randomization method

Settings and conduct
The location of the project will be Ahmadieh Health Center affiliated with the Faculty of Persian Medicine of Tehran University of Medical Sciences. After finding eligible cases, and taking a written consent form, all participants will be assigned to two study groups, intervention, and control, using a random allocation method. In the following, similar pockets containing the pad will be given to each group. Researchers, volunteers, outcome assessors, and statistical data analysts do not have any information about drugs and placebo groups

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age 15 to 45 years old, BMI(body mass index)≤35, regular menstruation at intervals of 21 to 35 days and regular bleeding for 3 to 10 days at least in the last 3 months, moderate and severe dysmenorrhea؛ Exclusion criteria: Pregnancy, history of secondary dysmenorrhea, history of abdominal or pelvic surgery, taking other medications, history of skin allergies to ginger

Intervention groups
Intervention group: Receive 3 pads containing ginger oil in each menstrual cycle (2 cycles), change the pad every 48 hours, place the pad under the umbilicus and above the pubic area, take one mefenamic acid capsule if they have pain no later than one hour after Use the pad. control group: Receive 3 placebo pads in each menstrual cycle (2 cycles), change the pad every 48 hours, place the pad under the umbilicus and above the pubic area, take one mefenamic acid capsule if they have pain at most one hour after using the pad.

Main outcome variables
pain intensity؛ pain duration؛ Patient satisfaction with treatment؛ Physician satisfaction with treatment

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20201010048979N3**
Registration date: **2022-05-06, 1401/02/16**
Registration timing: **prospective**

Last update: **2022-05-06, 1401/02/16**
Update count: **0**

Registration date
2022-05-06, 1401/02/16

Registrant information

Name
Marzieh Akhbari

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-05-22, 1401/03/01

Expected recruitment end date
2022-11-22, 1401/09/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation effectiveness of topical ginger oil pad in dysmenorrhea: Triple blind-placebo-controlled Randomized Clinical Trial

Public title
The effect of topical pads containing ginger oil on dysmenorrhea

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Women aged 15 to 45 years old BMI(body mass index)≤35 Regular menstruation at intervals of 21 to 35 days and regular bleeding for 3 to 10 days at least in the last 3 months Moderate and severe dysmenorrhea (based on Multidimensional Verbal Scoring System)

Exclusion criteria:
Pregnancy History of secondary dysmenorrhea History of abdominal or pelvic surgery Taking other medications History of skin allergies to ginger

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: **30**

Randomization (investigator's opinion)
Randomized

Randomization description
The study subjects are assigned to one of the intervention and control groups by Permuted Block Randomization method by random sampling method from one of the numbers 1 to 6 using SPSS software. Numbers 1 to 6 are specific codes of each sequence BBAA, AABB, ABAB, BABA ABBA, BAAB. according on selected sequence, each group of four-subject receives one of the intervention and control methods.

Blinding (investigator's opinion)
Triple blinded

Blinding description
The medicine and placebo group will receive similar pads in shape and size and in the same packages labeled with codes A and B. The patient and the researcher prescribing the drug and analyzing the data are not aware of the meaning of the codes. The results of the study are reviewed by a researcher who is not aware of the grouping and is blind to the groups and the type of drug.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Tehran University of Medical Sciences

Street address
1th Floor, Medicine School, Poursina St, Qods St, Enghelab St.

City
Tehran

Province
Tehran

Postal code
1417613151

Approval date
2022-03-16, 1400/12/25

Ethics committee reference number
IR.TUMS.MEDICINE.REC.1400.1514

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
pain intensity

Timepoint
cycle before intervention, every cycles during intervention (2 cycles)

Method of measurement
VAS (visual analog scale)

2

Description
pain duration

Timepoint
cycle before intervention, every cycles during intervention (2 cycles)

Method of measurement

hour

3

Description
Patient satisfaction with treatment
Timepoint
every cycles during intervention (2 cycles)
Method of measurement
questionnaire

4

Description
Physician satisfaction with treatment
Timepoint
every cycles during intervention (2 cycles)
Method of measurement
questionnaire

Secondary outcomes

1

Description
drug side effects
Timepoint
every cycle during the intervention (2 cycles)
Method of measurement
questionnaire

2

Description
Mefenamic acid consumption
Timepoint
cycle before intervention, every cycles during intervention (2 cycles)
Method of measurement
number

Intervention groups

1

Description
Intervention group: Each eligible patient will receive three topical pads containing ginger oil in each two menstrual cycles and a new pad will be replaced every 48 hours. the pad will be located on the abdomen under umbilicus and above the pubic area. If They have pain for a maximum of one hour after using the pad, they can take one mefenamic acid capsule. The number of capsules allowed per day is 2 and the number of capsules consumed is recorded per cycle.
Category
Treatment - Drugs

2

Description
Control group: Each eligible patient will receive three placebo pads in each two menstrual cycles and a new pad will be replaced every 48 hours. the pad will be located on the abdomen under umbilicus and above the pubic area. If They have pain for a maximum of one hour after using the pad, they can take one mefenamic acid capsule. The number of capsules allowed per day is 2 and the number of capsules consumed is recorded in per cycle.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Ahmadieh Persian Medicine Health Center in Tehran University of Medical Sciences
Full name of responsible person
Leila Shirbeigi
Street address
No. 27, Tbriz Line, North Sarparast Ave., Taleghani Ave.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
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Sixth Floor, Vice Chancellor for Research and Technology, Ghods Ave., Keshavarz Blvd.
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vcr@tums.ac.ir
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
Leila Shirbeigi
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Traditional Medicine
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available