Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison of the effects of consuming sumac fruit powder capsules with meflamic acid capsules on menstrual pain and fatigue in women of reproductive age

Protocol summary

Study aim
Determining the effect of consuming sumac fruit powder capsules on menstrual pain and fatigue in women of reproductive age

Design
A randomized, double-blind clinical trial in 3 intervention groups and phase 2 on 90 women, and for randomization using RASS software

Settings and conduct
Study setting: in comprehensive health service centers of Gonabad city; Population: women aged 18 to 30 years; Blinding: there will be no blinding

Participants/Inclusion and exclusion criteria
Inclusion criteria: Women aged 18 to 30 years; BMI18.19 to 29; Moderate (4-7) or severe (8-10) dysmenorrhea for at least one day of first three days of menstruation without taking medication in three consecutive cycles before start of the study; Having a regular menstrual cycle (21-35); Normal bleeding duration (3-7) and normal bleeding volume. Exclusion criteria: Sumac allergy according to individual's statement; History of pregnancy; History of surgery on the uterus and ovaries; Undergoing infertility treatment; Taking aspirin, warfarin, according to the individual's statement and medical record

Intervention groups
Intervention group 1: first menstrual cycle receiving 250 mg mefenamic acid capsules, second cycle receiving 1 gram sumac capsules and in the third month receiving 1 gram sumac and 250 mg mefenamic acid capsules; Intervention group 2: first menstrual cycle receiving 1 gram sumac capsules, second cycle receiving 1 gram sumac capsules and 250 mg mefenamic acid capsules and in the third month receiving 250 mg mefenamic acid capsules. Intervention group 3: first menstrual cycle receiving 1 gram sumac capsules and 250 mg mefenamic acid capsules, second cycle receiving 250 mg mefenamic acid capsules and in the third month receiving 1 gram sumac capsules

Main outcome variables
Menstrual pain; fatigue

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20251016067648N1**
Registration date: **2025-12-15, 1404/09/24**
Registration timing: **prospective**

Last update: **2025-12-15, 1404/09/24**
Update count: **0**

Registration date
2025-12-15, 1404/09/24

Registrant information

Name
rasol rahmani

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 51 5722 2655

Email address
rasolrahmani2020@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2026-01-09, 1404/10/19

Expected recruitment end date
2026-06-03, 1405/03/13

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effects of consuming sumac fruit powder capsules with meflamic acid capsules on menstrual pain and fatigue in women of reproductive age

Public title

The effect of taking sumac fruit powder capsules on menstrual pain and fatigue in women of reproductive age

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Women aged 18 to 30 years Body mass index is 18.19 to 29. Moderate (4-7) or severe (8-10) dysmenorrhea for at least one day out of the first three days of menstruation without taking medication in three consecutive cycles before the start of the study, according to the score obtained from the pain severity assessment tool. Having a regular menstrual cycle (21-35), duration of normal bleeding (3-7), and volume of normal bleeding according to the individual's statement, history, and examination by the therapist.

Exclusion criteria:

Sumac allergy self-reported Pregnancy and childbirth history Medical conditions including thyroid disorders, diabetes, endometriosis, ovarian cysts, uterine fibroids, glandular disorders, polycystic ovary, primary or secondary amenorrhea, cancer, cardiovascular, kidney and liver, and urinary and genital infections, as stated by the individual and medical records, and examination by the therapist and ultrasound. History of surgery on the uterus and ovaries Undergoing infertility treatment Medication use of aspirin, warfarin, heparin, and tranexamic acid as reported by the individual and in the medical record

Age

From **18 years** old to **30 years** old

Gender

Female

Phase

2

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

In the first month of the study, women who meet the inclusion criteria will be sampled in a non-random (accessible) manner, and blocks of 6 will be used to randomly assign samples to each of the 3 groups one, two, and three. In this way, first the possible states of the blocks (CCBBAA, ..., AABBCC) are listed and a number is assigned to each block. Then, randomly and proportionally to the desired sample size, the required blocks (15 blocks) are selected, and then, based on the order specified in the blocks, the individuals are assigned to the group receiving mefenamic in the first month (A), the group receiving mefenamic and sumac in the first month (B), and the group receiving sumac in the first month (C).

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, in order to reduce bias and increase the validity of the results, double-blinding will be used; so that neither the participants nor the main researcher will be aware of the allocation of individuals to the intervention and control groups. The blinding process will be carried out according to the following steps: First, eligible participants will be randomly assigned to 3 groups. To maintain impartiality, this assignment will be done by an independent person who will not be involved in the data collection and analysis of the results. All participants will be informed of the consumption method in the same way, without receiving information about their assigned group. Also, the researcher who will be responsible for collecting and analyzing the data will not be aware of information related to the codes and the type of intervention. After the data collection process is completed, the codes will be opened and the data will be analyzed. Using this method will reduce the possibility of conscious or unconscious bias on the part of the researcher and participants and will increase the internal validity of the research.

Placebo

Not used

Assignment

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Gonabad University of Medical Sciences

Street address

Dr. Mehdizadeh Boulevard

City

Gonabad

Province

Razavi Khorasan

Postal code

9691793718

Approval date

2024-11-04, 1403/08/14

Ethics committee reference number
IR.GMU.REC.1403.075

Health conditions studied

1

Description of health condition studied
Menstrual pain
ICD-10 code
N94
ICD-10 code description
Pain and other conditions associated with female genital organs and menstrual cycle

2

Description of health condition studied
Fatigue
ICD-10 code
R53.83
ICD-10 code description
Other fatigue

Primary outcomes

1

Description
Pain score after receiving interventions
Timepoint
In three stages, pain scores are measured during the first three days of menstruation for each group.
Method of measurement
To measure pain intensity, a standard 100 mm VAS tool, whose validity has been previously determined, will be used, and pain intensity will be measured using a graduated ruler, with a score of 10 representing the most severe pain and a score of 0 representing no pain.

2

Description
Fatigue score
Timepoint
In three stages, pain scores are measured during the first three days of menstruation for each group.
Method of measurement
Multidimensional Fatigue Index (MFI)

Secondary outcomes

1

Description
Mouse Menstrual Distress Questionnaire Score
Timepoint
It will be done every three months on the first three days of menstruation.
Method of measurement
Mouse Questionnaire

2

Description
Amount of menstrual bleeding
Timepoint
It will be done every three months on the first three days of menstruation.
Method of measurement
Higham Chart or PBAC Blood Loss Assessment Chart

3

Description
Energy received
Timepoint
It will be done every three months on the first three days of menstruation.
Method of measurement
24-hour recall questionnaire

4

Description
Protein intake
Timepoint
It will be done every three months on the first three days of menstruation.
Method of measurement
24-hour recall questionnaire

5

Description
Carbohydrate intake
Timepoint
It will be done every three months on the first three days of menstruation.
Method of measurement
24-hour recall questionnaire

6

Description
Fat intake
Timepoint
It will be done every three months on the first three days of menstruation.
Method of measurement
24-hour recall questionnaire

Intervention groups

1

Description
First intervention group: The first menstrual cycle received 250 mg mefenamic acid capsules, the second cycle received 1 gram sumac capsules, and in the third month received 1 gram sumac and 250 mg mefenamic acid capsules. It should be noted that the duration of the intervention will be the first three days of menstruation every 8 hours.
Category

Treatment - Drugs

2

Description
Intervention group 2: In the first menstrual cycle, they will receive a capsule containing 1 gram of sumac, in the second cycle, a capsule containing 1 gram of sumac and a capsule containing 250 mg of mefenamic acid, and in the third month, a capsule containing 250 mg of mefenamic acid. It should be noted that the intervention period will be every 8 hours for the first three days of menstruation each month.
Category
Treatment - Drugs

3

Description
Third intervention group: The first menstrual cycle, the recipient received 1 gram sumac capsules and 250 mg mefenamic acid capsules, the second cycle, the recipient received 250 mg mefenamic acid capsules and in the third month, 1 gram sumac capsules. It should be noted that the duration of the intervention will be the first three days of menstruation every 8 hours in each month.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Health centers of Gonabad University of Medical Sciences
Full name of responsible person
Dr. Abdul Javad Khajovi
Street address
Next to Municipality, Imam Khomeini Boulevard
City
Gonabad
Province
Razavi Khorasan
Postal code
9691793718
Phone
+98 51 5722 3513
Email
roghaiehrahmany@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Gonabad University of Medical Sciences
Full name of responsible person
Dr. Ali Firouzi
Street address
Deputy for Research and Technology, University Campus, Gonabad University of Medical Sciences, Mahdizadeh Blvd.
City
Gonabad
Province
Razavi Khorasan
Postal code
9691793718
Phone
+98 51 5722 5027
Email
Bohloolipd@gmu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Gonabad 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
Tabriz University of Medical Sciences
Full name of responsible person
Rasol Rahmani Bailandi
Position
Student
Latest degree
Master
Other areas of specialty/work
Nutrition
Street address
Golestan Dormitory, Sari Zami Blvd, Molla Sadra Blvd, Farhangian District, Tabriz, Iran
City
Tabriz
Province
East Azarbaijan
Postal code
5165995131
Phone
+98 51 5722 5666
Email
rasolrahmani2020@gmail.com

Person responsible for scientific

inquiries

Contact

Name of organization / entity
Gonabad University of Medical Sciences

Full name of responsible person
Roghaieh Rahmani Bailandi

Position
Associate Professor

Latest degree
Ph.D.

Other areas of specialty/work
Midwifery

Street address
No. 1, Opposite Imam Ali 4, Imam Ali Blvd., Gonabad, Khorasan Razavi Province, Iran

City
Gonabad

Province
Razavi Khorasan

Postal code
9691997980

Phone
+98 51 5722 5666

Email
roghaiehrahmany@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Gonabad University of Medical Sciences

Full name of responsible person
Roghaieh Rahmani Bailandi

Position
Associate Professor of Medical Sciences

Latest degree
Ph.D.

Other areas of specialty/work
Midwifery

Street address
No. 1, Opposite Imam Ali 4, Imam Ali Blvd., Gonabad, Khorasan Razavi Province, Iran

City
Gonabad

Province
Razavi Khorasan

Postal code
9691997980

Phone
+98 51 5722 5666

Email
roghaiehrahmany@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 further information other than the publication of the article.

Study Protocol
Undecided - It is not yet known if there will be 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