Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Investigating the Effect of Sumac Capsule Consumption on the Severity of Primary Dysmenorrhea and Quality of Life Among Female Students at the Asadabad School of Medical Sciences

Protocol summary

Study aim

Determining the Effect of Sumac Capsule Consumption on the Severity of Primary Dysmenorrhea

Design

Convenience sampling will be conducted among eligible students. Subsequently, written informed consent will be obtained from students who meet the inclusion criteria and are willing to participate, following an explanation of the research objectives. After the students are randomly assigned to the two study groups, a checklist regarding individual and obstetric demographic characteristics will be completed. The severity of primary dysmenorrhea and quality of life will be assessed at baseline (prior to the intervention) and again one and two months post-intervention, using the Visual Analog Scale (VAS) and a quality-of-life questionnaire.

Settings and conduct

After obtaining the necessary approvals from the Ethics Committee of the Asadabad Faculty of Medical Sciences, the researcher will visit the female dormitory. A convenience sampling method will be used to select eligible students.

Participants/Inclusion and exclusion criteria

Study inclusion criteria were: being single; residing in the Asadabad University of Medical Sciences dormitory; age 15–45 years; having a regular menstrual cycle (interval of 21–35 days and bleeding duration of less than 7 days) Study exclusion criteria included: marriage; adverse reactions or allergy to sumac; occurrence of an untoward event; onset of illness; use of any herbal, chemical, or traditional medicine treatments during the intervention;

Intervention groups

Individuals take the capsules every 8 hours from day 1 to day 7 across two consecutive menstrual cycles.

Main outcome variables

Menstrual pain severity، quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150424021915N2**
Registration date: **2026-10-14, 1405/07/22**
Registration timing: **prospective**

Last update: **2026-10-14, 1405/07/22**
Update count: **0**

Registration date

2026-10-14, 1405/07/22

Registrant information

Name

Azin Niazi

Name of organization / entity

Mashhad Univercity of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 66 3340 9914

Email address

azin_niazi65@yahoo.com

Recruitment status

Not yet recruiting

Funding source

Expected recruitment start date

2026-11-22, 1405/09/01

Expected recruitment end date

2027-11-22, 1406/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Investigating the Effect of Sumac Capsule Consumption on the Severity of Primary Dysmenorrhea and Quality of Life Among Female Students at the Asadabad School of Medical Sciences

Public title
Investigating the Effect of Sumac Capsule Consumption on the Severity of Primary Dysmenorrhea and Quality of Life Among Female Students at the Asadabad School of Medical Sciences

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Single; residing in the Asadabad University of Medical Sciences dormitory; aged 15–45 years; having a regular menstrual cycle (intervals of 21–35 days and bleeding duration of less than 7 days); free from chronic diseases; not taking any medication affecting pain or the menstrual cycle; Body Mass Index (BMI) <30 kg/m²; self-reported absence of sumac allergy; no consumption of alcohol, cigarettes, or illicit drugs; self-reported absence of psychiatric disorders; and experiencing moderate to severe dysmenorrhea (VAS ≥4) for at least two days per menstrual cycle.

Exclusion criteria:
Marriage; an adverse reaction or sensitivity to sumac; occurrence of an untoward event; onset of illness; use of any herbal, chemical, or traditional medicine treatments during the intervention; failure to complete or incomplete completion of the VAS form; irregular medication use; and unwillingness to continue participation.

Age
From **15 years** old to **45 years** old

Gender
Female

Phase
2

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size
Target sample size: **112**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization is performed using balanced randomization blocks. The principal investigator generates a random sequence of blocks of two and four using the website www.Sealedenvelope.com. Based on this, participants are assigned to either the sumac group or the control group.

Blinding (investigator's opinion)
Triple blinded

Blinding description
The medications for both groups are packaged in vials of identical shape and size and then coded using a pre-generated table of random numbers; the researcher is unaware of the specific medication type.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Office of the Vice-Chancellor for Research, Asadabad Faculty of Medical Sciences

Street address
Asadabad, 22 Bahman Boulevard, former Amir-al-Mo'menin Hospital building, Department of Education.

City
asadabad

Province
Hamadan

Postal code
6541914438

Approval date
2026-01-01, 1404/10/11

Ethics committee reference number
IR.ASAUMS.REC.1405.012

Health conditions studied

1

Description of health condition studied
Dysmenorrhea

ICD-10 code
N94.4

ICD-10 code description
N94.4

2

Description of health condition studied
Dysmenorrhea

ICD-10 code
N94.4

ICD-10 code description
N94.4

Primary outcomes

1

Description
Moderate to severe dysmenorrhea (VAS ≥ 4)

Timepoint

One and two months after the intervention, using the Visual Analog Scale (VAS) for pain.

Method of measurement

Visual analogue scale (VAS)

2

Description

Quality of Life

Timepoint

One and two months after the intervention

Method of measurement

SF-36 Quality of Life Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In this study, 500 mg oral capsules containing dry sumac extract with a 30% yield (equivalent to 1 g of sumac) will be used. Students will be asked to take the capsules every 8 hours from the first to the seventh day across two consecutive menstrual cycles.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Asadabad School of Medical Sciences

Full name of responsible person

azin niazi

Street address

Asadabad, 22 Bahman Boulevard, former Amir-ol-Momenin Hospital building.

City

asadabad

Province

Hamadan

Postal code

6541914438

Phone

+98 81 3313 2015

Email

azin_niazi65@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Asadabad University of Medical Sciences

Full name of responsible person

azin niazi

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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

Asadabad 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

Asadabad University of Medical Sciences

Full name of responsible person

azin niazi

Position

instructor

Latest degree

Master

Other areas of specialty/work

Midwifery

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Phone

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Email

azin_niazi65@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Asadabad University of Medical Sciences

Full name of responsible person
azin niazi

Position
مربی

Latest degree
Master

Other areas of specialty/work
Midwifery

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Person responsible for updating data

Contact

Name of organization / entity
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
Data are available upon contact with the corresponding author.

When the data will become available and for how long
One year after the article was published

To whom data/document is available
All faculty members of medical universities

Under which criteria data/document could be used
If they wish to conduct a more precise statistical analysis of the data, they should employ newer diagnostic methods to assess the study outcome.

From where data/document is obtainable
Corresponding author

What processes are involved for a request to access data/document
Phone call, email

Comments