Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Investigating the effect of Oral capsule of Ziziphora tenuior plant extract on Primary Dysmenorrhoea

Protocol summary

Study aim
Determining the effect of oral capsule of ziziphora tenuior plant extract on primary dysmenorrhea in female students living in the dormitories of Shahid Beheshti University of Medical Sciences in Tehran

Design
A three-blind placebo-controlled clinical trial with parallel groups, phase 3 on 94 people, allocation of simple random samples using the function of random numbers of Excel software

Settings and conduct
Quota sampling based on the number of students from the dormitories (Al-Zahra, Hazrat Zainab, Somayeh, Gol Narges) of Shahid Beheshti Medical Sciences in Tehran and people who have moderate and severe dysmenorrhea according to the visual analog scale will be included in the research with available sampling.The samples were randomly divided into two groups, case and control, using the random numbers function of Excel software, Three blinds (researchers and research units and statisticians)

Participants/Inclusion and exclusion criteria
Inclusion criteria: Iranian, have no children, Age range between 18 and 30, lack of known chronic disease, not taking special medicine or supplement, regular cycles of 22 to 35 days, body mass index between 19.8 and 26, history of primary dysmenorrhoea according to the visual analogue scale in the last 6 months, bleeding rate between 3 and 7 days, no intermenstrual bleeding, having no history of uterine and ovarian disorders according to recent ultrasounds and Exclusion criteria: reluctance to continue treatment, Taking any herbal medicine during the study, failure to use Ziziphora tenuior capsules or placebo correctly, occurrence of liver or kidney disease during research

Intervention groups
The intervention group will take Ziziphora tenuior plant extract capsules and the control group will take placebo capsules three times a day from the first day to the third day of menstruation in two consecutive cycles.

Main outcome variables
Primary dysmenorrhea

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20240506061675N1**
Registration date: **2024-05-26, 1403/03/06**
Registration timing: **prospective**

Last update: **2024-05-26, 1403/03/06**
Update count: **0**

Registration date
2024-05-26, 1403/03/06

Registrant information

Name
Fatemeh Azarialikhanghaleh

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 58 3242 1232

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-06-08, 1403/03/19

Expected recruitment end date
2024-09-09, 1403/06/19

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of Oral capsule of Ziziphora tenuior plant extract on Primary Dysmenorrhoea

Public title

Investigating the effect of Oral capsule of Ziziphora tenuior plant extract on Primary Dysmenorrhoea

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Have no children Participants must be between the ages of 18 and 30. Be Iranian According to the statement of the person suffering from a known chronic disease such as Diabetes, Hypertension, Underlying heart disease, Infectious disease, liver disease, kidney disease, Epilepsy and Malignancy She has not taken any medication since three months before the intervention. Do not use special drugs or supplements According to the person's statement, she does not have any symptoms such as burning, itching or abnormal secretions from the Vagina and Cervix Have regular cycles from 22 to 35. Body mass index should be between 19.8 and 26. Have a history of primary dysmenorrhoea according to the Visual analog scale during the last 6 months Students living in Shahid Beheshti Medical Sciences student dormitories in Tehran The amount of bleeding should be between 3 and 7 days No bleeding between periods. There should be no stressful events such as the death of relatives and surgery in the last 6 months. Do not smoke or drink alcohol. There is no history of Uterine disorders (Myoma, Bicornuate uterus, Polyps), Ovarian disorders (Ovarian Cyst and Polycystic ovary) or Endometrial hypertrophy and Endometriosis according to recent ultrasounds.

Exclusion criteria:

Take any herbal medicine while studying. Participants do not want to continue treatment. Kidney or liver disease or cases that, according to the doctor's opinion, should stop treatment, appear during the research. Failure to correctly use Ziziphora tenuior capsules or placebo, less than 7 capsules in the first three days of menstruation.

Age

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

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Investigator
- Data and Safety Monitoring Board

Sample size

Target sample size: **94**

Randomization (investigator's opinion)

Randomized

Randomization description

Quota sampling will be done based on the number of students from the dormitories (Al-Zahra, Hazrat Zainab, Somayeh, Gol Narges and Sarshar). The sampling method is available, but the allocation of random samples will be simple using the random numbers function of Excel software. The samples will be divided into two groups of case and control by simple random and using the function of random numbers of Excel software.

Blinding (investigator's opinion)

Triple blinded

Blinding description

This is a Triple blind clinical trial study in which both the participants, the researcher and the Data Safety and Monitoring Committee, are not aware of the type of drug used. For the purpose of blinding, the pharmacist will put the drugs in two separate categories with completely identical appearance and coded A and B without the knowledge of the researcher. Then each of the samples will be given an envelope with a specific code and in similar packaging.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of School of Pharmacy and Nursing & Midwifery of Shahid Beheshti Universi

Street address

Faculty of Nursing and Midwifery, in front of Shahid Rajaei Heart Hospital, Niayesh Intersection, Waliasr Street

City

Tehran

Province

Tehran

Postal code

1985717443

Approval date

2024-04-29, 1403/02/10

Ethics committee reference number

IR.SBMU.PHARMACY.REC.1403.004

Health conditions studied

1

Description of health condition studied

Primary dysmenorrhea

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Primary dysmenorrhea
Timepoint
before the intervention and after the end of the intervention, after each menstrual cycle in two consecutive cycles
Method of measurement
Visual Analogue Scale

Secondary outcomes

1

Description
Systemic symptoms associated with primary dysmenorrhea
Timepoint
Before the intervention and after the end of the intervention, after each menstrual cycle in two consecutive cycles
Method of measurement
Verbal multidimensional scoring system

Intervention groups

1

Description
Intervention group: In this study, the intervention group consumes the oral capsule of Ziziphora tenuior plant extract. In this research, the Ziziphora tenuior plant was collected from the authentic perfumers of Bojnoord city, North Khorasan province, and it was confirmed by the respected botanist of the Faculty of Pharmacy of Shahid Beheshti University of Medical Sciences. Half a gram of extract is obtained from every 10 grams of dried leaves of this plant, and each capsule contains 350 milligram of Ziziphora tenuior extract. The capsule will be prepared in collaboration with the pharmacology specialist of the Faculty of Pharmacy of Shahid Beheshti University of Medical Sciences, which is prescribed in two cycles and in three divided doses every 8 hours during the menstrual cycle.
Category
Treatment - Drugs

2

Description
Control group: In this study, the control group consumes placebo. In this research, placebo refers to placebo capsules containing 350 milligram of dry bread, which are three daily during the first three days of menstruation that These capsules were prepared in the Faculty of Pharmacy, which were similar to the capsules of the Ziziphora tenuior plant extract in terms of color, smell, shape and size and the capsule of Ziziphora tenuior plant extract and the placebo capsule are both placed next to each other due to the similarity of the smell and will be provided to the samples in the same packaging.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Al-zahra girls' dormitory
Full name of responsible person
Mrs. Leila Karami
Street address
Niayesh Campus Dormitory (Al-Zahra), in front of Shahid Rajaei Hospital, Niayesh Intersection, Valiasr Street
City
Tehran
Province
Tehran
Postal code
۱۹۹۶۸۳۵۱۱۹
Phone
+98 21 8877 1281
Email
fateme.azari@sbmu.ac.ir

2

Recruitment center
Name of recruitment center
Gol Narges girls' dormitory
Full name of responsible person
Mrs. Zahra Varmarziar
Street address
No. 49, in front of Maskan Bank, Shahid Khodami St., Above Vanak Square
City
Tehran
Province
Tehran
Postal code
1994762724
Phone
+98 21 8877 6045
Email
fateme.azari@sbmu.ac.ir

3

Recruitment center
Name of recruitment center
Somayeh girls' dormitory
Full name of responsible person
Mrs. Fatemeh Bashkol
Street address
Shariati has not reached Motahari
City
Tehran

Province
Tehran
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1639646851
Phone
+98 21 8847 5737
Email
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4

Recruitment center
Name of recruitment center
Hazrat Zainab girls' dormitory
Full name of responsible person
Mrs. Zahra Varmarziar
Street address
next to the telecommunications building, not reaching Naft St., Vahid Dastjerdi St. (Zafar), Shariati St.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Doctor Afshin Zarghi
Street address
5th Floor, Building No. 2, Shahid Arabi Street, Yemen Street, Shahid Chamran Highway, Tehran
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1373916632
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+98 21 23871
Email
info@sbmu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Fateme Azarialikhanghaleh
Position
Midwifery master's student
Latest degree
Bachelor
Other areas of specialty/work
Midwifery
Street address
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Person responsible for scientific inquiries

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Full name of responsible person
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Position
Midwifery master's student
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Person responsible for updating data

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Fateme Azarialikhanghaleh

Position

Midwifery master's student

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

Street address

Niayesh Campus Dormitory (Al-Zahra), in front of Shahid Rajaei Hospital, Niayesh Intersection, Valiasr Street

City

Tehran

Province

Tehran

Postal code

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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