Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 May 2026

Efficacy of Aqueous Extract of Echium Amoenum on Anxiety and Perceived Stress and Onset of Menstruation in Women with Menstruation Retard : Three Blind Randomized Clinical Trial

Protocol summary

Study aim

Determining the effect of Echium Amoenum aqueous extract plant on the level of anxiety, perceived stress and occurrence of menstruation in women with menstruation retard :Three blind randomized clinical trial

Design

Clinical trial with control group, with parallel groups, double-blind, randomized, phase 3 on 82 patients. A web-based randomization list was used for randomization.

Settings and conduct

Methods: Randomly assigning patients to two groups and giving 42 capsules (drug or placebo without informing the research units) for 6 weeks (26). Capsules in a dose of 500 mg (23), (borage flower or corn flour) are prescribed once a day 30 minutes after breakfast. For the random allocation of samples, permutation blocks of 2 and 4 are used. The randomization list is generated by the analyst based on the web, then it is provided to the researcher in sealed and non-transparent envelopes.This study will be triple blind. Patients do not know about the nature of drugs due to the similarity of their appearance. Medicines and placebos are coded A and B and are provided to the project manager (Outcome assessor) in the form of 42 capsule packs with the same codes. Determining the groups in the data file will also be provided to the analyst in the form of coding. Place of study: Gonabad health and treatment centers

Participants/Inclusion and exclusion criteria

Inclusion criteria: pregnancy, suffering from underlying diseases and disorders related to the reproductive system, BMI less than 18, use of hormonal, antihypertensive and depressant and herbal drugs, Exclusion criteria: occurrence of side effects related to the use of borage, lowering blood pressure less than 20/10

Intervention groups

The intervention group will receive Echium Amoenum extract. The control group will receive a placebo.

Main outcome variables

Primary outcome: stress and anxiety Secondary outcome: Menstruation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230417057944N1**
Registration date: **2023-05-15, 1402/02/25**
Registration timing: **registered_while_recruiting**

Last update: **2023-05-15, 1402/02/25**
Update count: **0**

Registration date

2023-05-15, 1402/02/25

Registrant information

Name

Sakina Nazeri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 5722 3028

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-05-03, 1402/02/13

Expected recruitment end date

2023-08-04, 1402/05/13

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Efficacy of Aqueous Extract of Echium Amoenum on Anxiety and Perceived Stress and Onset of Menstruation in Women with Menstruation Retard : Three Blind Randomized Clinical Trial

Public title
Efficacy of Echium Amoenum on the level of anxiety, perceived stress and occurrence of menstruation
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Women of reproductive age between 18-40 years Willingness and informed consent to participate in research Negative pregnancy test Menstrual cycle delay according to the average period of each person's menstrual cycle in the last six months History of postponing menstrual bleeding for intervals of 36 days to 6 months
Exclusion criteria:
Smoking, drugs and alcohol The existence of underlying medical diseases and disorders related to the reproductive system based on individual statement. BMI less than 18 Lactation amenorrhea Suffering from known mental disorders other than stress and anxiety based on the person's statements and scores obtained from the Hamilton Anxiety Rating Scale (HARS) and Cohen's perceived stress questionnaires. Being allergic to Echium Amoenum Doing sports professionally The presence of nutritional disorders such as bulimia nervosa and anorexia nervosa or malnutrition based on the person's statements Taking hormonal, antihypertensive and depression and herbal medicines Having primary amenorrhea.
Age
From **18 years** old to **40 years** old
Gender
Female

Phase
3
Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **82**
Randomization (investigator's opinion)
Randomized
Randomization description
Sampling will be non-random (available) and for random allocation of samples to each of the intervention and control groups, permutation blocks of 2 and 4 will be used. The randomization list is generated by the analyst based on the web at the following address (www.sealedenvelope.com), then it is provided to the researcher in sealed and non-transparent envelopes.
Blinding (investigator's opinion)
Triple blinded
Blinding description
In this study, the aqueous extract of Echium Amoenum in the form of 500 mg oral capsules and capsules containing corn flour are used as a placebo. The drug and placebo are packed in the same packages in terms of shape and color and are coded with A and B codes, and in this way the study will be blinded from the point of view of the researcher and the research units.
Placebo
Used
Assignment
Parallel
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
Gonabad University of Medical Sciences, Gonabad, Iran
City
Gonabad
Province
Razavi Khorasan
Postal code
9691793718
Approval date
2023-04-03, 1402/01/14
Ethics committee reference number
IR.GMU.REC.1402.010

Health conditions studied

1

Description of health condition studied
Anxiety
ICD-10 code
F41.9
ICD-10 code description
Anxiety disorder, unspecified

2

Description of health condition studied
Stress
ICD-10 code
F43.0

ICD-10 code description
Acute stress reaction

3

Description of health condition studied
Oligomenorrhea
ICD-10 code
N91.4
ICD-10 code description
Secondary oligomenorrhea

Primary outcomes

1

Description
Anxiety mean
Timepoint
At the beginning of the study, 7, 14, 21, 28, 35, 42 days after starting to take the capsule of Echium Amoenum
Method of measurement
Hamilton Anxiety Rating Scale

2

Description
Perceived Stress mean
Timepoint
At the beginning of the study, 7, 14, 21, 28, 35, 42 days after starting to take the capsule of Echium Amoenum
Method of measurement
Cohen perceived stress scale

Secondary outcomes

1

Description
Occurrence of menstruation in a patient with oligomenorrhea or secondary amenorrhea
Timepoint
3-7 days after starting to take the capsule of Echium Amoenum, during the period of taking the medicine, 4 weeks after stopping the capsule
Method of measurement
Questionnaire for recording the daily state of menstruation

Intervention groups

1

Description
Intervention group: People in the intervention group will receive 42 capsules containing the aqueous extract of cow tongue plant in the form of 500 mg oral capsules for 6 weeks (one capsule a day, 30 minutes after breakfast). Gol Elixir Pharmaceutical Company Tos Mashhad will be the drug manufacturer.
Category
Treatment - Drugs

2

Description
:Control group: People in the control group will receive 42 capsules containing corn flour in the form of 500 mg oral capsules for 6 weeks (one capsule a day, 30 minutes after breakfast). Gol Elixir Pharmaceutical Company of Tos Mashhad will be the drug manufacturing company.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Allameh Bahloul Gonabadi Hospital
Full name of responsible person
Dr Mahdi Pasban
Street address
Allameh Bahloul Gonabadi Hospital , Nursing Boulevard, Saadi St., Gonabad, Khorasan Razavi
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Email
Bohloolipd@gmu.ac.ir
Web page address
https://bohlool.gmu.ac.ir/index.html

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Gonabad University of Medical Sciences
Full name of responsible person
Dr Reza Ahmadi
Street address
Gonabad University of Medical Sciences and Health Services Research Vice-Chancellor, on the side of the Asian road, Gonabad
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hmsjournal@gmail.com
Web page address

https://www.gmu.ac.ir/index.html

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

Gonabad University of Medical Sciences

Full name of responsible person

Sakina Nazeri

Position

Student

Latest degree

Master

Other areas of specialty/work

Reproductive Health

Street address

Dastan e Mehr Afarin complex, near to Behesht Qasim Nuqab, Bahar, Nuqab

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

Contact

Name of organization / entity

Gonabad University of Medical Sciences

Full name of responsible person

sakina Nazeri

Position

student

Latest degree

Master

Other areas of specialty/work

Reproductive Health

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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