

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 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)

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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

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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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Gonabad University of Medical Sciences

Full name of responsible person

Dr Reza Ahmadi

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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

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

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Person responsible for updating data

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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