

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Feb 2026

Comparison of Effect of Echium Amoenum on Students' Anxiety

Protocol summary

Study aim

Determination and comparison of students' anxiety in the case and control group before and after using the Echium Amoenum

Design

A clinical trial with a control group, randomization

Settings and conduct

The researcher, after the official permission of the Islamic Azad University of Kerman Branch, conducted a preliminary interview with nursing students in accordance with ethical standards and according to pre-determined criteria, and explained the purpose of the research to them. Then anxiety questionnaire was completed by them. For those who scored below the average level, they were asked to complete the written consent form, then randomly (simple draw) in two groups (case and control).

Participants/Inclusion and exclusion criteria

The disease has no physical history. Desire to collaborate on research Do not have a history of acute and chronic mental and psychological problems. Have not participated in another research No history of drug use The absence of a specific patient in the family No divorce or death of family members Non-arrival conditions: Taking any medication pregnancy

Intervention groups

Intervention group: Pour 1 g of Echium amoenum powdered in 250 cc of boiling water and use after 10 minutes of oral and daily doses were taken for four weeks. control group: Does not receive anything.

Main outcome variables

Anxiety

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130615013677N3**
Registration date: **2019-03-08, 1397/12/17**

Registration timing: **retrospective**

Last update: **2019-03-08, 1397/12/17**

Update count: **0**

Registration date

2019-03-08, 1397/12/17

Registrant information

Name

Somayeh Soltani Nejad

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 76 3366 5500

Email address

s.soltaninejad@iauba.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-11-22, 1396/09/01

Expected recruitment end date

2018-02-20, 1396/12/01

Actual recruitment start date

2017-11-22, 1396/09/01

Actual recruitment end date

2018-02-20, 1396/12/01

Trial completion date

2019-03-11, 1397/12/20

Scientific title

Comparison of Effect of Echium Amoenum on Students' Anxiety

Public title

Effect of Echium amoenum on anxiety

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

The disease has no physical history. Desire to collaborate on research Do not have a history of acute and chronic mental and psychological problems. Have not participated in another research No history of drug use The absence of a specific patient in the family No divorce or death of family members

Exclusion criteria:

Taking any medication Pregnancy

Age

From **19 years** old to **25 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **40**

Actual sample size reached: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

According to the research criteria, 40 people were selected and each person was given a code. Then, one person in the case group and the next participant in the control group were randomly selected. So, in each group, 20 people were placed.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kerman University of Medical Sciences

Street address

Kerman University of Medical Sciences, Medical University Campus, Haft-Bagh Highway, Kerman

City

Kerman

Province

Kerman

Postal code

7616913555

Approval date

2019-02-18, 1397/11/29

Ethics committee reference number

IR.KMU.REC.1397.499

Health conditions studied

1

Description of health condition studied

Anxiety

ICD-10 code

F41.1

ICD-10 code description

Generalized anxiety disorder

Primary outcomes

1

Description

Anxiety

Timepoint

Before the intervention and one month later

Method of measurement

Cattell anxiety questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The consumption of Echium amoenum was carried out in such a way that one gram of powdered Echium amoenum powder was poured into 250 cc of boiling water and after 10 minutes, the beverage was consumed orally each day for one month. At the end of the first, second and third weeks, the samples were evaluated to ensure proper use of Echium amoenum, and at the end of the fourth week, the second test was re-tested, both in the two stages of the scoring method. In the control group, the interval between two tests was one month.

Category

Other

2

Description

Control group: The subjects first completed the questionnaire and were followed by a researcher to avoid any physical or mental problems. After a month, they completed the questionnaire again.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Islamic Azad University Kerman

Full name of responsible person

Somayeh soltaninejad

Street addressIslamic Azad University Kerman Branch University
Blvd, Emam Ali, Kerman, Iran**City**

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7635131167

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soltaninejad@yahoo.com

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Islamic Azad University

Full name of responsible person

Maryam Kazemi

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Email

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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

Islamic Azad University

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**

Islamic Azad University

Full name of responsible person

Somayeh Soltaninejad

Position

Instructor

Latest degree

Master

Other areas of specialty/work

Nursery

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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

Information about the outcome of the research

When the data will become available and for how long

Start access after printing the article

To whom data/document is available

researchers, Participants in research

Under which criteria data/document could be used

The requesting person is allowed to use the research results, the resources used, the questionnaires.

From where data/document is obtainable

somayeh soltaninejad soltaninejad@yahoo.com

What processes are involved for a request to access data/document

After sending an email, it will take less than a week to reach the individual

Comments