

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jun 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 address**

Islamic Azad University Kerman Branch University  
Blvd, Emam Ali, Kerman, Iran

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Kerman

**Province**

Kerman

**Postal code**

7635131167

**Phone**

+98 34 3321 0043

**Email**

soltaninejad@yahoo.com

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

Islamic Azad University

**Full name of responsible person**

Maryam Kazemi

**Street address**

Islamic Azad University Kerman Branch University  
Blvd, Emam Ali, Kerman, Iran

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**Province**

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**Postal code**

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**Phone**

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**Email**

soltaninejad@yahoo.com

**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

**Street address**

Islamic Azad University Campus, Universities Blvd ,  
Bandar Abbas

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7915893144

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**Person responsible for scientific 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**

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**Fax**

**Email**

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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**