

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Comparison between effects of Echium amoenum and diazepam for reducing preoperation anxiety before orthopedic surgery

Protocol summary

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Summary

In a randomized double blind clinical trial 70 patients aged 15 -65 years old ASA I and II group, after obtaining consent, will be entered into study and are randomly assigned into two groups: 35 patients (group 1 receiving Borage and group 2 receiving diazepam). A similar method is used for anesthesia premedication. Study medications are administered orally 6 hours before anesthesia (to prevent disclosure to the patient and evaluation of the capsules, the capsules prepared in the laboratory and will be presented with a similar appearance). Information is recorded by the anxiety questionnaire and demographic data and vital signs before and 6 hours after intervention.

Recruitment status

Recruitment complete

Funding source

Ahvaz Jondishapour University of Medical Sciences

Expected recruitment start date

2012-04-15, 1391/01/27

Expected recruitment end date

2012-08-15, 1391/05/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201110237875N1**

Registration date: **2012-04-18, 1391/01/30**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-04-18, 1391/01/30

Registrant information

Name

Hossein Rahmani

Name of organization / entity

Ahvaz jondishapour university of medical sciences

Country

Iran (Islamic Republic of)

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Email address

Scientific title

Comparison between effects of Echium amoenum and diazepam for reducing preoperation anxiety before orthopedic surgery

Public title

Comparison between effects of Echium amoenum and diazepam for reducing preoperation anxiety before orthopedic surgery

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: patients aged 15 to 65 years old in ASA groups one and two and are candidates for orthopedic surgery. Exclusion criteria: dissatisfaction; history of mental illness; history of drug or a particular plant (diazepam or Borage) allergy; pregnant women and mothers in lactation

Age

From **15 years** old to **65 years** old

Gender

Both

Phase

Groups that have been masked*No information***Sample size**Target sample size: **70****Randomization (investigator's opinion)**

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees1**Ethics committee****Name of ethics committee**Ahvaz jondishapour university of medical sciences
Ethics Committee**Street address**

Ahvaz jondishapour university of medical sciences

City

Ahvaz

Postal code**Approval date**

2012-04-07, 1391/01/19

Ethics committee reference number

Eth-91s01

Health conditions studied1**Description of health condition studied**

Preoperative anxiety

ICD-10 code**ICD-10 code description****Primary outcomes**1**Description**

Anxiety

Timepoint

Six hours after intervention

Method of measurement

Beck questionnaire

Secondary outcomes

empty

Intervention groups1**Description**

Control: Diazepam 2 mg capsule once during the study will receive medications are administered orally 6 hours before anesthesia

Category

Treatment - Drugs

2**Description**

Intervention: 500 mg capsules of borage and once during the study will receive medications are administered orally 6 hours before anesthesia

Category

Treatment - Drugs

Recruitment centers1**Recruitment center****Name of recruitment center**

Razi hospital

Full name of responsible person**Street address****City**

Ahvaz

Sponsors / Funding sources1**Sponsor****Name of organization / entity**

Ahvaz jondishapour university of medical sciences

Full name of responsible person

Vice chancellor for research

Street addressAhvaz jondishapour university of medical sciences.
ahvaz. iran**City**

Ahvaz

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Ahvaz jondishapour university of medical sciences

Proportion provided by this source

100

Public or private sector*empty***Domestic or foreign origin***empty***Category of foreign source of funding***empty***Country of origin**

Type of organization providing the funding
empty

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Web page address

Person responsible for general inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Position

Student of anesthesia

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty