Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

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

Protocol summary

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.

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

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Name of organization / entity

Ahvaz jondishapour university of medical sciences

Country

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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

Scientific title

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

Public title

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

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion critria: patients aged 15 to 65 years old in ASA groups one and two and are candidated 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

2

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 committees

1

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 studied

1

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 groups

1

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 centers

1

Recruitment center

Name of recruitment center

Razi hospital

Full name of responsible person

Street address

City

Ahvaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz jondishapour university of medical sciences

Full name of responsible person

Vice chancellor for research

Street address

Ahvaz 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

Person responsible for general inquiries

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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