Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of effect of Safranal and Diazepam in decreasing of anxiety before surgery

Protocol summary

Summary

The aim of this study is to compare the effect of Safranal with Diazepam on decreasing the anxiety before surgery in 6mounth in 2013 . In this parallel double blind clinical trial, 60 patients whom refer to the operating room of 15 khordad hospital of Gonabad for Varicocel are randomly assigned into group A (Safranal :15 mg) or B (Diazepam : 5 mg).Three hours before the operation a trained nurse wants the patient to fill out a Spilberger questionnaire and then before entering the operating room again will do it . Patients' vital signs will be recorded. The outcomes that will be measured are the evaluation of degree of anxiety and decreasing of it due to administering Safranal compared with Diazepam . Inclusion criteria : 1 – patients whom candidate for Varicocel. 2 – ASA class I and II. 3 – Age between 18 – 50 Exclusion criteria : 1- every ASA class except I or II, 2 - Not wanting to participate in research, 3 - Participants whom were allergic to saffron. Making our research blind : the person who deliver the drug and the patient and the nurse who deliver the questionnaire are unaware from the type of the capsule that administer to the patient .

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201304255445N4**
Registration date: **2013-09-22, 1392/06/31**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2013-09-22, 1392/06/31

Registrant information

Name

Arash Hamzei

Name of organization / entity

Gonabad University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 53 3722 3028

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research , Gonabad University of Medical sciences

Expected recruitment start date

2013-03-20, 1391/12/30

Expected recruitment end date

2013-10-23, 1392/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of effect of Safranal and Diazepam in decreasing of anxiety before surgery

Public title

Comparison of effect of Safranal and Diazepam in decreasing of anxiety before surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria : 1 – patients whom candidate for Varicocel. 2 – ASA class I and II . 3 – Age between 18 – 50 Exclusion criteria : 1- every ASA class except I or II, 2-Not wanting to participate in research, 3-Participants whom were allergic to saffron.

Age
From **18 years** old to **50 years** old
Gender
Male

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
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
Dr Mehdizade street, University campous Gonabad Gonabad
City
Gonabad
Postal code
9691793718
Approval date
2013-09-23, 1392/07/01
Ethics committee reference number
92/2/1/ک الف

Health conditions studied

1

Description of health condition studied
Anxiety
ICD-10 code
F41.9
ICD-10 code description
Anxiety disorder unspecified

Primary outcomes

1

Description
preoperative anxiety
Timepoint
Before intervention and three hours past
Method of measurement
Spilberger questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Safranal 15 mg and evaluation of Anxiety before and three hours later
Category
Treatment - Drugs

2

Description
Control group: Diazepam 5 mg and evaluation of Anxiety before and three hours later
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
15 Khordad Hospital Beydokht, Gonabad
Full name of responsible person
Dr Arash Hamzei
Street address
Gonabad, Beydokht
City
Gonabad

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research , Gonabad University of Medical sciences
Full name of responsible person
Dr.Ali mohammadpour
Street address
Dr Mehdizade street, University campous Gonabad Gonabad
City
Gonabad
Grant name
Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research , Gonabad 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

Contact
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anesthesiologist,assistant professor
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Person responsible for updating data

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Web page address

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