

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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 6 month 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

Email address

arash_hamzei@gmu.ac.ir

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/الف کی

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****Name of organization / entity**

Gonabad University of Medical Sciences

Full name of responsible person

Dr Arash Hamzei

Position

anesthesiologist,assistant professor

Other areas of specialty/work**Street address**

Naser khosro st, 22Bahman Hospital.

City

Gonabad

Postal code**Phone**

+98 53 3723 1112

Fax**Email**

arash_hamzei@gmu.ac.ir; arash_hamzei@yahoo.com

Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Gonabad University of Medical sciences

Full name of responsible person

Dr Arash Hamzei

Position

Anesthesiologist, assistant professor

Other areas of specialty/work**Street address**

22Bahman Hospital - Gonabad, Naser khosro st

City

Gonabad

Postal code**Phone**

+98 53 3723 1112

Fax**Email**

arash_hamzei@gmu.ac.ir; arash_hamzei@yahoo.com

Web page address**Person responsible for updating data****Contact****Name of organization / entity**

Gonabad University of Medical Sciences

Full name of responsible person

Dr Arash Hamzei

Position

anesthesiologist, assistant professor

Other areas of specialty/work**Street address**

22Bahman Hospital - Gonabad, Naser khosro st

City

Gonabad

Postal code**Phone**

+98 53 3723 1112

Fax**Email**

arash_hamzei@gmu.ac.ir; arash_hamzei@yahoo.com

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