

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparative evaluation of the effect of Passiflora Incarnata and Melatonin as premedication on the cognitive tests in post operative period of elective surgeries

Protocol summary

Summary

Given that preoperative anxiety is an important phenomenon. The aim of this project is finding of drugs that can reduce the anxiety, but does not affect the recovery time after surgery or would not produce cognitive impairment. For this purpose, in a double blind randomized clinical trial, the effect of prescribing Passiflora Incarnata and Melatonin as premedication drugs on the postoperative cognitive tests in patients with elective surgery will be evaluated. So, 52 patients 20-60 years old, ASA I & II physical class, candidated for elective surgery without history of diabetes mellitus & pregnancy will be divided randomly into two equal groups. For premedication in patients of group (1) Passiflora Incarnata and in group (2), Melatonin one hour before the surgery will be prescribed. Cognitive condition and level of sedation with standard tests before, after 60 min and after the awakening of patients from anesthesia will be evaluated and compared between two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015110824909N5**

Registration date: **2015-12-20, 1394/09/29**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-12-20, 1394/09/29

Registrant information

Name

Faranak Rokhtabnak

Name of organization / entity

Iran University of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 21 8894 6267

Email address

rolhtabnak.f@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Iran University of Medical Sciences

Expected recruitment start date

2014-06-22, 1393/04/01

Expected recruitment end date

2015-08-23, 1394/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative evaluation of the effect of Passiflora Incarnata and Melatonin as premedication on the cognitive tests in post operative period of elective surgeries

Public title

Evaluation of the effect of Passiflora Incarnata and Melatonin in post operative cognitive disfunction

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: American Society of Anesthesiologists(ASA) 1&2 ; age range of 20-60; minor to moderate surgery under general anesthesia Exclusion

criteria: Age lower than 20 and higher than 60; diabetic patients; hypertension; depression & anti depressant drug consumption; pregnant & Lactating women; seizure & anti-convulsive drug consumption

Age

From **20 years** old to **60 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **52**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Randomization with enveloped packets

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

Iran University of Medical Sciences, Hemmat Highway

City

Tehran

Postal code

1593748711

Approval date

2015-09-19, 1394/06/28

Ethics committee reference number

IR.IUMS.REC.1394.9111174013

Health conditions studied

1

Description of health condition studied

Post operative cognitive disorders

ICD-10 code

F13

ICD-10 code description

Mental and behavioural disorders due to use of sedatives or hypnotics

Primary outcomes

1

Description

Post operative cognitive disorders

Timepoint

Before intervention, one hour after intervention, discharge time from recovery room

Method of measurement

Digit Symbol Substitutional Test

Secondary outcomes

1

Description

Preoperative sedation score

Timepoint

One hour after intervention

Method of measurement

Ramsey sedation score

Intervention groups

1

Description

Intervention group1: 1000 mg Passiflora Incarnata orally one hour before operation in single dose, Natiris company

Category

Prevention

2

Description

Intervention group2: 6 mg Melatonin orally one hour before surgery one hour before operation in single dose, USA Pharmavite company (Nature Made)

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Firoozghar Hospital

Full name of responsible person

Seyedeh Somayeh Seyed Alizadeh Ganji

Street address

Firoozgar hospital, Behafarin St. Karim Khan Av.

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor of Research & Technology, Iran
University of Medical Sciences

Full name of responsible person

Seyed Ali Javad Moosavi

Street address

5th floor, Central building, Iran University of Medical
Sciences, Hemmat Highway

City

Tehran

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

Yes

Title of funding source

Vice Chancellor of Research & Technology, Iran
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**

Iran University of Medical Science

Full name of responsible person

Seyedeh Somayeh Seyed Alizadeh Ganji

Position

Anesthesiology Resident

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

Anesthesiology Department, Firoozghar Hospital,
Behafarin St. Karimkhan Av.

City

Tehran

Postal code

1593748711

Phone

+98 21 8214 1000

Fax**Email**

dr.alizadeh61@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Iran University of Medical Science

Full name of responsible person

Franak Rokhtabnak

Position

Anesthesiologist

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

Anesthesiology Department, Firoozghar Hospital,
Behafarin St. Karimkhan Av.

City

Tehran

Postal code

1593748711

Phone

+98 21 8894 6762

Fax**Email**

rkhtbnk@yahoo.com

Web page address

Person responsible for updating data

Contact**Name of organization / entity**

Iran University of Medical Science

Full name of responsible person

Seyedeh Somayeh Seyed Alizadeh Ganji

Position

Anesthesiology Resident

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+98 21 8214 1000

Fax**Email**

dr.alizadeh61@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