Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparative evaluation of the effect of Passiflora Incarnata and Melatonine 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

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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 Melatonine as premedication on the cognitive tests in post operative period of elective surgeries

Public title

Evaluation of the effect of Passiflora Incarnata and Melatonine 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.

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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

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

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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

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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