Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of Oral Passiflora Incarnata and Oxazepam on Preoperative Anxiety in Ambulatory Surgery Patients: A Double Blind, Placebo Controlled Study

Protocol summary

Summary

OBJECTIVES: Controlling preoperative anxiety (PAN) without increasing post-operative psychomotor dysfunction has been an anesthesia concern especially in ambulatory surgeries; therefore using a strong anxiolytic with minimal psychomotor dysfunction for premedication is very desirable. In this study, it was hypothesized that Passiflora incarnata decreases PAN as much as Oxazepam. Design: A Double Blind, Placebo Controlled Study. METHODS: In this double blinded placebo controlled study, 128 patients would be divided into Passiflora group (n=68) receiving oral Passiflora incarnata and oxazepam group (n=60) receiving Oxazepam (10 mg), 90 min before surgery. A numerical rating scale (NRS) would be used for each patient to evaluate patients' anxiety, before, and 90 min after premedication. Psychomotor function would be assessed with Trieger Dot Test (TDT) and Digit-Symbol Substitution Test (DSST) at arrival in operating room, and 90 min after tracheal extubation. Inclusion criteria: Patients referring to our anesthesia clinic, classified as American Society of Anesthesiologists (ASA) physical status of I or II, aged 18-60, who will be candidated for ambulatory inguinal herniorhaphy. Exclusion criteria: Patients with a history of anxiety disorders or consuming sedative, analgesic, antidepressant, or anti epileptic drugs; addict patients; patients with numerical rating scale (NRS) of less than one, for anxiety; Patients with any contraindications to the medications of study. Interrvention: Passiflora incarnata, 500 mg, (Passipy TM Iran Darouk) orally used 120 min before surgery in one group, and Oxazepam, 10 mg, orally used, 120 min before surgery in another group. Main outcome variables: Investigation and comparison of anxiety reduction in both groups, evaluating and comparing occurrence of psychomotor disorder between the both groups. Design: A Double Blind, Placebo Controlled Study. METHODS: In this double blinded placebo controlled study, 128 patients will randomize into Passiflora group (n=68) receiving oral Passiflora incarnata and oxazepam group (n=60) receiving oxazepam (10 mg), 90 min before surgery. A numerical rating scale (NRS) will be used for each patient to assess patients' anxiety, before, and 90 min following premedication. Psychomotor function will be assessed with Trieger Dot Test (TDT) and Digit-Symbol Substitution Test (DSST) at arrival in operating room, and 90 min after tracheal extubation. Inclusion criteria: Patients referring to our anesthesia clinic, classified as American Society of Anesthesiologists (ASA) physical status of I or II, aged 18-60, who will be candidated for ambulatory inguinal herniorhaphy. Exclusion criteria: Patients with a history of anxiety disorders or consuming sedative, analgesic, antidepressant, or antiepileptic drugs; addict patients; patients with numerical rating scale (NRS) of less than one, for anxiety; Patients with any contraindications to the medications of study. Interrvention: Passiflora incarnata, 500 mg, (PassipyTM IranDarouk) orally 120 min before surgery in one group, Oxazepam, 10 mg, orally, 120 min before surgery in another group.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013121315774N1**
Registration date: **2014-04-12, 1393/01/23**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2014-04-12, 1393/01/23

Registrant information

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Recruitment status
Recruitment complete
Funding source
none declared

Expected recruitment start date
2014-05-01, 1393/02/11
Expected recruitment end date
2015-04-29, 1394/02/09
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of Oral Passiflora Incarnata and Oxazepam on Preoperative Anxiety in Ambulatory Surgery Patients: A Double Blind, Placebo Controlled Study

Public title
Comparison of Oral Passiflora Incarnata and Oxazepam on Preoperative Anxiety in Ambulatory Surgery Patients
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: Patients referring to our anesthesia clinic, classified as American Society of Anesthesiologists (ASA) physical status of I or II, aged 18-60, who will be candidated for ambulatory inguinal herniorhaphy. Exclusion criteria: Patients with a history of anxiety disorders or consuming sedative, analgesic, antidepressant, or antiepileptic drugs; addict patients; patients with numerical rating scale (NRS) of less than one, for anxiety; Patients with any contraindications to the medications of study.
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **128**
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
Keshavarz Blvd, Ghods St, Tehran University of Medical Sciences building, 6th floor, Research deputy
Street address
Tehran
City
Tehran
Postal code
Approval date
2010-09-23, 1389/07/01
Ethics committee reference number
21425

Health conditions studied

1

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

2

Description of health condition studied
Psychomotor function
ICD-10 code
F44.4
ICD-10 code description
Dissociative motor disorders

Primary outcomes

1

Description
Psychomotor function
Timepoint
) at arrival in the operating room, and 90 min after tracheal extubation
Method of measurement
assessed with the Trieger Dot Test (TDT) and the Digit-

Symbol Substitution Test (DSST)

2

Description
Anxiety
Timepoint
90 min before surgery and 90 min following premedication
Method of measurement
A numerical rating scale (NRS) for each patient to assess anxiety

Secondary outcomes

empty

Intervention groups

1

Description
Passiflora incarnata, 500 mg, (PassipyTM IranDarouk) orally 120 min before surgery.
Category
Treatment - Drugs

2

Description
Oxazepam, 10 mg, orally, 120 min before surgery
Category
Treatment - Drugs

3

Description
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Dr Ali Shariati Hospital
Full name of responsible person
Dr Ali Movafegh
Street address
Department of Anesthesiology and Critical Care, Dr Ali Shariati Hospital, Ḱargar Shomali St, Jalal-Al Ahmad Street
City
Tehran

2

Recruitment center
Name of recruitment center
Full name of responsible person
Street address
City

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences, Department of Anesthesiology
Full name of responsible person
Dr Atabak Najafi
Street address
Imam Khomeini Complex, Imam Khomeini Hospital, Office of Department of Anesthesiology
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran University of Medical Sciences, Department of Anesthesiology
Proportion provided by this source
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

2

Sponsor
Name of organization / entity
Full name of responsible person
Street address
City
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Proportion provided by this source
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

Full name of responsible person
Position
Other areas of specialty/work
Street address
City
Postal code
Phone
+98 21 6650 9059
Fax
Email
z-esfandiari@razi.tums.ac.ir
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Full name of responsible person
Position
Other areas of specialty/work
Street address
City
Postal code
Phone
+98 21 6650 9059
Fax
Email
Poupak_rah@hotmail.com
Web page address

Person responsible for updating data

Contact

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