Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Effect of preoperative oral Passiflora Incarnata on cough during extubation in Ambulatory Surgery Patients: A Double Blind, Placebo Controlled Study

Protocol summary

Summary

An smooth extubation and decreasing cough on extubation 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 cough on extubation. Design: A Double Blind, Placebo Controlled Study. METHODS: In this double blinded placebo controlled study, 120 patients would be divided into Passiflora group (n=60) receiving oral Passiflora incarnata and placebo group (n=60) receiving placebo, 90 min before surgery. After extubation patients are observed to record any coughing or other adverse effects such as bronchospasm. 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 Placebo, orally used, 120 min before surgery in another group. Main outcome variables: Investigation and comparison of cough reduction in both groups, evaluating and comparing occurrence of psychomotor disorder between the both groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201301075140N8**
Registration date: **2014-11-23, 1393/09/02**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2014-11-23, 1393/09/02

Registrant information

Name

Omid Azimaraghi

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 2206 6194

Email address

cazimaraghi@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences, Department of Anesthesiology

Expected recruitment start date

2014-08-01, 1393/05/10

Expected recruitment end date

2014-12-31, 1393/10/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of preoperative oral Passiflora Incarnata on cough during extubation in Ambulatory Surgery Patients: A Double Blind, Placebo Controlled Study

Public title
Effect of Oral Passiflora Incarnata on cough during extubation
Purpose
Prevention
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
N/A
Groups that have been masked
No information
Sample size
Target sample size: **120**
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 Tehran University of Medical Sciences
Street address
Research deputy, Ethics Committee of Tehran University of Medical Sciences, 6th floor, Tehran University of Medical Sciences building, Ghods St,Keshavarz Blvd
City
Tehran
Postal code
Approval date
2013-07-23, 1392/05/01
Ethics committee reference number
235416/12

Health conditions studied

1

Description of health condition studied
Other and unspecified abnormalities of breathing
ICD-10 code
R06.8
ICD-10 code description
unspecified abnormalities of breathing

Primary outcomes

1

Description
cough
Timepoint
cough after tracheal extubation
Method of measurement
Observation

Secondary 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)

Intervention groups

1

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

2

Description
Placebo , orally, 120 min before surgery
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Dr. Shariati Hospital

Full name of responsible person
Dr. Omid Azimaraghi

Street address
Dr Shariati Hospital, North Kargar Ave ,Amirabad

City
Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor of research-Tehran University of Medical Sciences

Full name of responsible person
Dr. Shahin Akhoondzadeh

Street address
Tehran University of Medical Sciences, Poorsina street ,Keshavarz avenue,

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-Tehran 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
Chief Resident of Anesthesiology , Dr Shariati Hospital

Full name of responsible person
Dr. Omid Azimaraghi

Position
Chief Resident of Anesthesiology

Other areas of specialty/work

Street address
Dr Shariati Hospital, North Kargar Ave ,Amirabad

City
Tehran

Postal code

Phone
+98 21 2206 6194

Fax

Email
o.azimaraghi@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Dr. Shariati Hospital

Full name of responsible person
Dr. Ali Movafegh

Position
Professor of anesthesiology

Other areas of specialty/work

Street address
Dr.Shariati Hospital, North Kargr ave, Amir Abad

City
Tehran

Postal code

Phone
+98 21 2206 6194

Fax

Email
movafegh@tums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity
Department of Anesthesiology, Dr Shariati Hospital

Full name of responsible person
Omid Azimaraghi

Position
Resdent of Anesthesiology

Other areas of specialty/work

Street address
Dr. Shariati Hospital, North Kargar Ave,Amir Abad,

City
Tehran

Postal code

Phone
+98 21 2206 6194

Fax

Email
o.azimaraghi@gmail.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