

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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 herniorrhaphy. 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. Intervention: *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 herniorrhaphy. 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