

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Comparison of hemodynamic and metabolic stress responses caused by endotracheal tube and Proseal laryngeal mask airway in laparoscopic cholecystectomy

Protocol summary

Summary

We aimed to compare hemodynamic and endocrine alterations caused by stress response due to Proseal laryngeal mask airway and endotracheal tube usage in laparoscopic cholecystectomy in this randomized double blinded trial. Sixty-three ASA I-II patients scheduled for elective laparoscopic cholecystectomy were included in the study. Patients were randomly allocated into two groups of endotracheal tube and Proseal laryngeal mask airway. Standard general anaesthesia was performed in both groups with the same drugs in induction and maintenance of anaesthesia. After anaesthesia induction and 20 minutes after CO₂ insufflations, venous blood samples were obtained for measuring adrenalin, noradrenalin, dopamine and cortisol levels. Hemodynamic and respiratory parameters were recorded at the 1st, 5th, 15th, 30th and 45th minutes after the insertion of airway devices.

General information

Acronym

Stress response caused by airway devices

IRCT registration information

IRCT registration number: **IRCT201202128979N1**

Registration date: **2012-03-09, 1390/12/19**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2012-03-09, 1390/12/19

Registrant information

Name

türkay çakan

Name of organization / entity

Ministry of health ankara training and research hospital

Country

Turkey

Phone

+90 312 5953175

Email address

turkaycakan@yahoo.com

Recruitment status

Recruitment complete

Funding source

No funding source

Expected recruitment start date

2008-03-01, 1386/12/11

Expected recruitment end date

2008-06-30, 1387/04/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of hemodynamic and metabolic stress responses caused by endotracheal tube and Proseal laryngeal mask airway in laparoscopic cholecystectomy

Public title

Two different airway device in laparoscopic cholecystectomy

Purpose

Prevention

Inclusion/Exclusion criteria

ASA I-II patients, aged between 20-70 years scheduled for elective laparoscopic cholecystectomy, were included in the study/. Exclusion criteria were a known or predicted difficult airway, hypertension, diabetes

mellitus, chronic obstructive pulmonary disease, cardiac disease, history of allergic reaction, history of corticosteroid drug usage, and body mass index greater than 35 kg/m².

Age

From **20 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

No other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

ministry of health ankara training and research
hospital local ethics committee

Street address

ulucanlar caddesi

City

Altındağ

Postal code

Approval date

2008-03-26, 1387/01/07

Ethics committee reference number

2031

Health conditions studied

1

Description of health condition studied

Cholecystitis

ICD-10 code

K80-K87

ICD-10 code description

calculus of gallbladder with other cholecystitis

Primary outcomes

1

Description

Heart rate and mean arterial blood pressure (MAP)

Timepoint

1., 5., 15., 30. and 45. minutes after insertion of airway devices. 25% increase or decrease in MAP and heart rate >120 beat/minute or <50 beat/minute.

Method of measurement

ECG and non-invasive blood pressure measurement

Secondary outcomes

1

Description

Adrenalin, noradrenalin, dopamine and cortisol

Timepoint

After induction of anesthesia and 20 minutes after CO₂ insufflation

Method of measurement

High pressure liquid chromatography for were used for measuring adrenalin, noradrenalin and dopamine and modular Analytic E 170 module was used for measuring cortisol

Intervention groups

1

Description

Endotracheal tube

Category

Treatment - Surgery

2

Description

proseal laryngeal mask usage

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ministry of health Ankara Training and Research
Hospital

Full name of responsible person

Türkey Çakan

Street address

Ulucanlar caddesi

City

Altındağ

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

PI initiated

Full name of responsible person

No sponsor

Street address

No sponsor

City

no sponsor

Grant name

Grant code / Reference number

No code

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

PI initiated

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

Associate professor in Anesthesiology ankara training and research hospital

Full name of responsible person

Hülya Başar

Position

Chief of department of anesthesiology

Other areas of specialty/work

Street address

ulucanlar caddesi

City

Altındağ

Province

Ankara

Postal code

Phone

0090 312 5953180

Fax

Email

hulya_basar@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Associate professor in Anesthesiology in ankara training and research hospital

Full name of responsible person

Hülya Başar

Position

Chief of department of anesthesiology

Other areas of specialty/work

Street address

Ulucanlar caddesi

City

Altındağ

Province

Ankara

Postal code

Phone

00903125953180

Fax

Email

hulya_basar@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Ministry of health Ankara Training and Research Hospital

Full name of responsible person

Türkay Çakan

Position

Specialist in Anesthesiology

Other areas of specialty/work

Street address

Ulucanlar caddesi

City

Altındağ

Province

Ankara

Postal code

Phone

00903125953175

Fax

Email

turkaycakan@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