

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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 CO<sub>2</sub> 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/m<sup>2</sup>.

#### 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 desing 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 gallbladderwith 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 hearth rate >120beat/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 CO<sub>2</sub> insufflation

#### Method of measurement

High pressure liquid chromatographyfor were used for measuring adrenalin,noradrenalin and dopamineand modular AnalyticE 170 module was used for measuring cortsol

## 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

Türkay 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**

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## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Ministry of health Ankara Training and Research Hospital

**Full name of responsible person**

Türkey Çakan

**Position**

Specialist in Anesthesiology

**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*