

# The effect of pneumoperitoneum with gas insufflation on the diameters and dimensions of big central veins like internal jugular vein and subclavian vein in laparoscopic cholecystectomy operation

|  |   |   |
|--|---|---|
| <b>Submission date</b><br>19/07/2016   | <b>Recruitment status</b><br>No longer recruiting | <input type="checkbox"/> Prospectively registered<br><input type="checkbox"/> Protocol            |
| <b>Registration date</b><br>21/07/2016 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan<br><input checked="" type="checkbox"/> Results |
| <b>Last Edited</b><br>22/08/2016       | <b>Condition category</b><br>Surgery              | <input type="checkbox"/> Individual participant data  |

## Plain English summary of protocol

### Background and study aims

A laparoscopy is a medical procedure that allows a surgeon to see inside, and have access to, the abdomen (tummy) without having to make large cuts in the skin. It is also known as keyhole surgery. It is carried out using an instrument called a laparoscope, which is a small tube with a light source and a camera attached. Images recorded from the device are displayed on a television monitor for the surgeon to see. During the procedure, carbon dioxide gas is pumped through the tube to inflate the abdomen. This allows the surgeon to see the organs more clearly and gives them more room to do the surgery. However, there is a risk of subcutaneous emphysema (a condition where gas or air occurs in the layer under the skin) and gas extravasation (escaped gas) into the peritoneal cavity (the space between the two membranes that separate the organs in the abdomen from the abdominal wall). This can lead to an increase in central venous pressure (pressure in the central veins close to the heart) as a follow on from an increase in intraabdominal pressure (pressure in the abdomen). However, no study has yet determined the effect of pneumoperitoneum (gas or air trapped within the peritoneal cavity) on cross-sectional area (CSA) of central veins (i.e. their diameter) by ultrasonography (a diagnostic imaging technique) during a laparoscopic cholecystectomy (keyhole surgery that involves removal of the gall bladder). The aim of this study was to look at changes in the CSAs of central veins by ultrasonography during this type of surgery.

### Who can participate?

Adults aged between 25-70 about to have keyhole surgery to have their gall bladder removed.

### What does the study involve?

Each patient undergoes keyhole surgery to have their gall bladder removed. During the surgery, the CSAs of central veins are measured using ultrasonography before they are placed under anesthetic, five minutes after being connected to a mechanical ventilator, five minutes after the

abdomen is inflated with carbon dioxide gas, five minutes after they carbon dioxide gas is removed and, finally, before they remove the breathing tube at the end of surgery.

What are the possible benefits and risks of participating?

There are no additional risks beyond that of the surgery itself for patients taking part in the study.

Where is the study run from?

Baskent University Konya Research Center (Turkey)

When is the study starting and how long is it expected to run for?

January 2015 to September 2015

Who is funding the study?

Baskent University Research Fund

Who is the main contact?

Mr Huseyin Ulas Pinar

[huseyinpinar2002@yahoo.com](mailto:huseyinpinar2002@yahoo.com)

## Contact information

### Type(s)

Scientific

### Contact name

Mr Huseyin Ulas Pinar

### ORCID ID

<http://orcid.org/0000-0002-9457-8983>

### Contact details

Hocacihan Mah. Saray Cd. No:1 Selcuklu

Konya

Türkiye

42080

+90 (0)332 257 0606

[huseyinpinar2002@yahoo.com](mailto:huseyinpinar2002@yahoo.com)

## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Project No: 13/254

# Study information

## Scientific Title

The effect of pneumoperitoneum on the cross-sectional areas of internal jugular vein and subclavian vein in laparoscopic cholecystectomy operation

## Study objectives

The hypothesis of the study is that there will be a increase of cross-sectional areas of central veins by pneumoperitoneum on laparoscopic cholecystectomy operation

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Baskent University, Institutional Review Board and Ethics Committee, 06/12/2013, ref: 13/254

## Study design

Cross-sectional cohort study

## Primary study design

Observational

## Secondary study design

Cohort study

## Study setting(s)

Hospital

## Study type(s)

Screening

## Participant information sheet

No participant information sheet available

## Health condition(s) or problem(s) studied

Laparoscopic cholecystectomy

## Interventions

The study included a total of 60 ASA (American Society of Anesthesiology) group I-II patients aged 25-70 years who were scheduled to undergo cholecystectomy surgery with laparoscopic method. The patients fasted for 8 hours before the operation and were hydrated with isotonic saline infusion at a rate of 2 ml/kg/hour.

All patients were administered oral alprazolam 0.5 mg the night before the operation. All patients were administered general anesthesia. Anesthesia induction was achieved by i.v. propofol 2mg/kg, i.v. fentanyl 1 µgr/kg, and i.v. rocuronium 0.6 mg/kg, and endotracheal intubation was followed anesthesia induction. Anesthesia maintenance was achieved by sevoflurane 1-2% and i.v. remifentanyl 0.1-0.5 µgr/kg/min infusion. Mechanical ventilation was provided in the volume-controlled mode with an airway pressure not exceeding 20 cmH<sub>2</sub>O, providing a tidal volume of 6-7 ml/kg, respiratory rate of 12/min, and %40/%60 O<sub>2</sub>/air mixture.

ECG, peripheral oxygen saturation, and noninvasive blood pressure monitorization were performed during surgery.

All patients were applied pneumoperitoneum in supine position via CO2 insufflation (flow rate 2-4 L/min) to achieve an intraabdominal pressure of 12 mmHg. Respiratory rate was adjusted to reach an end-tidal carbon dioxide level of 30-35 mmHg during surgery. CSAs and diameters of right SCV and right IJV were measured in supine position on operating table at both end-expiration and end-inspiration by an ultrasonography device (M-TurboTM; Fujifilm SonoSite Inc., Washington, United States) using a 6 MHz two-dimensional flat ultrasonography transducer (band width of 13-6 MHz, depth 6 cm) before anesthesia induction (Control, T1), 5 minutes after intubation and connection to mechanical ventilator (T2), 5 minutes after creating pneumoperitoneum (T3), at the end of pneumoperitoneum (T4), and after desufflation and before extubation (T5). There is no follow up for patients after intraoperative period.

## **Intervention Type**

### **Primary outcome measure**

Cross-sectional areas of internal jugular vein and subclavian vein, measured with ultrasonography before anesthesia induction (T1), 5 minutes after connecting to mechanical ventilator (T2), 5 minutes after creation of pneumoperitoneum (T3), at the end of pneumoperitoneum (T4), and 5 minutes after desufflation and before extubation (T5) both at end-expiration and end-inspiration.

### **Secondary outcome measures**

N/A

### **Overall study start date**

01/01/2015

### **Completion date**

30/09/2015

## **Eligibility**

### **Key inclusion criteria**

1. ASA ( american society of Anesthesiologists) I-II physical status patients
2. 25-70 years age range
3. Both genders

### **Participant type(s)**

Patient

### **Age group**

Adult

### **Sex**

Both

### **Target number of participants**

60 patients

**Key exclusion criteria**

1. Patients with cardiovascular disease, severe COPD, chest wall deformity
2. History of use of any drug altering vascular tonus
3. History of neck, clavicle, lung, great vessel, or chest wall surgery

**Date of first enrolment**

01/02/2015

**Date of final enrolment**

30/09/2015

**Locations****Countries of recruitment**

Türkiye

**Study participating centre**

**Baskent University Konya Research Center**

Hocacihan mah saray cad no:1 selçuklu

Konya

Türkiye

42080

**Sponsor information****Organisation**

Baskent University

**Sponsor details**

Baglica Kampusu, Eskisehir Yolu 20. Km., 06810 Etimesgut

Ankara

Türkiye

06810

+90 (0)312 246 6666

webmaster@baskent.edu.tr

**Sponsor type**

University/education

**ROR**

<https://ror.org/02v9bqx10>

**Funder(s)**

**Funder type**

University/education

**Funder Name**

Baskent University Research Fund

## Results and Publications

**Publication and dissemination plan**

Planning publication of our results in an anesthesiology journal at August 2016.

**Intention to publish date**

01/08/2016

**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not expected to be made available

**Study outputs**

| Output type                     | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---------------------------------|---------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a> | results | 11/08/2016   |            | Yes            | No              |