

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Sep 2026

### Comparing physiologic consequences and side effects of N2O and CO2 pneumoperitoneum for laparoscopic cholecystectomy

#### Protocol summary

##### Summary

This is a triple blind clinical trial, comparing nitrous oxide and carbon dioxide for creating pneumoperitoneum in laparoscopic cholecystectomy to assess relative advantages or disadvantages of these two gases regarding their physiologic effects and side effects. After controlling the inclusion and exclusion criteria and informed consent, 64 patients will assigned randomly to carbon dioxide or nitrous oxide group by block randomization. The patients blindly and with complete concealment, will be operated laparoscopically. The hemodynamic and respiratory parameters (heart rate, mean arterial blood pressure, end-tidal CO2, minute ventilation, and O2 saturation) before pneumoperitoneum and during it will be recorded. Pain, as perceived by patients, is measured 2,4 and 24 hours after the procedure by visual analogue scale. Vomiting and use of analgesics and antiemetics will be recorded and compared.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT138806092389N1**  
Registration date: **2011-04-22, 1390/02/02**  
Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2011-04-22, 1390/02/02

##### Registrant information

##### Name

Mehdi Asgari

##### Name of organization / entity

Jundi Shapur Medical University of Ahvaz

##### Country

Iran (Islamic Republic of)

##### Phone

+98 61 1333 3050

##### Email address

asgarime@ajums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Jundi Shapur Medical University

##### Expected recruitment start date

2010-07-06, 1389/04/15

##### Expected recruitment end date

2010-10-23, 1389/08/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparing physiologic consequences and side effects of N2O and CO2 pneumoperitoneum for laparoscopic cholecystectomy

##### Public title

Use of nitrous oxide for laparoscopic cholecystectomy

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

inclusion criteria:cholelithiasis, suitable for laparoscopic cholecystectomy, informed consent, ASA Score=1&2  
exclusion criteria: complicated cholelithiasis including cholecystitis and suppurative cholangitis, complete inability to move, mental disorder percluding communication, pregnancy, known cancer case

##### Age

No age limit

##### Gender

Both

**Phase**  
N/A

**Groups that have been masked**  
*No information*

**Sample size**  
Target sample size: **64**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**

**Blinding (investigator's opinion)**  
Triple blinded

**Blinding description**

**Placebo**  
Not used

**Assignment**  
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**  
Jundi Shapur Medical University

**Street address**  
Medical Science School, Shahrak Daneshgahi

**City**  
Ahvaz

**Postal code**

**Approval date**  
2010-10-23, 1389/08/01

**Ethics committee reference number**  
u-89140

## Health conditions studied

### 1

**Description of health condition studied**  
cholelithiasis

**ICD-10 code**  
K80.2

**ICD-10 code description**  
Calculus of gallbladder without cholecystitis

## Primary outcomes

### 1

**Description**  
heart rate

**Timepoint**  
before and during pneumoperitoneum

**Method of measurement**  
beat per minute with anesthesia monitoring devices

### 2

**Description**  
mean arterial pressure

**Timepoint**  
before and during pneumoperitoneum

**Method of measurement**  
mmHg as detected by anesthetic monitoring devices

### 3

**Description**  
End tidal CO2

**Timepoint**  
before and during pneumoperitoneum

**Method of measurement**  
mmHg as detected by anesthetic monitoring devices

### 4

**Description**  
minute ventilation

**Timepoint**  
before and during pneumoperitoneum

**Method of measurement**  
product of tidal volume and respiratory rate as controlled by anesthetic devices

### 5

**Description**  
arterial oxygen saturation

**Timepoint**  
before and during pneumoperitoneum

**Method of measurement**  
percent as detected by anesthetic monitoring devices

### 6

**Description**  
intraoperative complications

**Timepoint**  
from instillation of gas till complete recovery

**Method of measurement**  
as diagnosed by surgeon and anesthesiologist

### 7

**Description**  
postoperative complications

**Timepoint**  
from transfer of the patient to ward till discharge

**Method of measurement**  
as diagnosed by surgeon and anesthesiologist

### 8

**Description**  
pain

**Timepoint**  
2, 6 and 24 hour post-operation

**Method of measurement**  
visual analogue scale

## 9

### **Description**

shoulder pain

### **Timepoint**

every time before discharge

### **Method of measurement**

as declared by patient upon questioning

## 10

### **Description**

vomiting

### **Timepoint**

every time before discharge

### **Method of measurement**

as declared by patient upon questioning

## 11

### **Description**

analgesics administered post-operatively

### **Timepoint**

during admission of the patient

### **Method of measurement**

mg/kg as documented by nurse

## 12

### **Description**

antiemetics administered postoperatively

### **Timepoint**

during admission of the patient

### **Method of measurement**

mg/kg as documented by nurse

## 13

### **Description**

ability to move in bed

### **Timepoint**

6 hour post-operatively

### **Method of measurement**

as assessed by researcher

## 14

### **Description**

ability to move out of bed

### **Timepoint**

6 hour post-operatively

### **Method of measurement**

as assessed by researcher

## **Secondary outcomes**

empty

## **Intervention groups**

## 1

### **Description**

Use of nitrous oxide for creating pneumoperitoneum in

laparoscopic cholecystectomy.

### **Category**

Treatment - Other

## 2

### **Description**

Use of carbon dioxide for creating pneumoperitoneum in laparoscopic cholecystectomy.

### **Category**

Treatment - Other

## **Recruitment centers**

## 1

### **Recruitment center**

#### **Name of recruitment center**

Razi Hospital

#### **Full name of responsible person**

Mehdi Asgari, M.D.

#### **Street address**

Razi Hospital, Chamran street

#### **City**

Ahvaz

## **Sponsors / Funding sources**

## 1

### **Sponsor**

#### **Name of organization / entity**

Jundi Shapur Medical University

#### **Full name of responsible person**

Mostafa, Feghhi

#### **Street address**

University Campus, Vice chancellor or research

#### **City**

Ahvaz

#### **Grant name**

129006

#### **Grant code / Reference number**

10506

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

Yes

#### **Title of funding source**

Jundi Shapur Medical University

#### **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**

Jundi Shapur Medical University

**Full name of responsible person**

Mehdi, Asgari

**Position**

medical school staff, surgeon

**Other areas of specialty/work****Street address**

Razi Hospital, Chamran Street

**City**

Ahvaz

**Postal code****Phone**

+98 61 1333 3050

**Fax****Email**

asgarime@ajums.ac.ir

**Web page address****Email**

asgarime@ajums.ac.ir

**Web page address**

## Person responsible for updating data

### Contact

**Name of organization / entity**

Jundi Shapur Medical University

**Full name of responsible person**

Mojtaba, Ahmadzadeh

**Position**

resident of surgery

**Other areas of specialty/work****Street address**

Razi Hospital, Chamran Street

**City**

Ahvaz

**Postal code****Phone**

+98 61 1391 0339

**Fax****Email**

mojahmad@gmail.com

**Web page address**

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Jundi Shapur Medical University

**Full name of responsible person**

Mehdi, Asgari

**Position**

Assistant professor of surgery

**Other areas of specialty/work****Street address**

Razi Hospital, Chamran Street

**City**

Ahvaz

**Postal code****Phone**

+98 61 1333 3050

**Fax**

## 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*