

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, Fegghi

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**

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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

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Person responsible for scientific inquiries

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Position

Assistant professor of surgery

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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