Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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

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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 anasthesia monitoring devices

2

Description
mean arterial pressure
Timepoint
before and during pneumoperitoneum
Method of measurement
mmHg as detected by anasthetic monitoring devices

3

Description
End tidal CO2
Timepoint
before and during pneumoperitoneum
Method of measurement
mmHg as detected by anasthetic monitoring devices

4

Description
minute ventilation
Timepoint
before and during pneumoperitoneum
Method of measurement
product of tidal volume and respiratory rate as controlled by anasthetic devices

5

Description
arterial oxygen saturation
Timepoint
before and during pneumoperitoneum
Method of measurement
percent as detected by anasthetic monitoring devices

6

Description
intraoperative complications
Timepoint
from instillation of gas till complete recovery
Method of measurement
as diagnosed by surgeon and anasthesiologist

7

Description
postoperative complications
Timepoint
from transfer of the patient to ward till discharge
Method of measurement
as diagnosed by surgeon and anasthesiologist

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-oparatively
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
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Person responsible for scientific inquiries

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Person responsible for updating data

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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