Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of administration of supplemental oxygen on nausea and vomiting in patients undergoing spinal anesthesia for elective cesarean section

Protocol summary

Summary

This clinical trial will be conducted to determine the effect of supplemental oxygen administration on nausea and vomiting, in patients undergoing elective cesarean section. 120 patients will be randomly assigned in study groups. Inclusion criteria will be elective cesarean section and fasting for 6-8 hours before and 6 hours after surgery and patients who need to general anesthesia or having sever vomiting, symptomatic gastrointestinal disease, motion sickness, dizziness, heart disease, cardiovascular and pulmonary disease, middle ear diseases, diabetes mellitus, infectious disease, fever, hypertension, smoking, alcohol consumption, immunosuppressive medications, bleeding and hemoglobin less than 10 mg/dl will be excluded. In control group patients will receive 3-5 liters per minute by oxygen masks, but in the intervention group during and after surgery and in recovery for 6 hours 10 liters per minute oxygen through masks will be given. The data collection tools are check list and questionnaire. Total incidence of nausea and vomiting and its severity according to VAS standard tools will be compared in study groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201101125596N1**
Registration date: **2011-07-12, 1390/04/21**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2011-07-12, 1390/04/21

Registrant information

Name

Nasrin Galehdar

Name of organization / entity

Lorestan University of Medical Sciences and Health Services

Country

Iran (Islamic Republic of)

Phone

+98 66142099714

Email address

galehdar.n@lums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Lorestan University of Medical Sciences

Expected recruitment start date

2011-04-21, 1390/02/01

Expected recruitment end date

2012-01-21, 1390/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of administration of supplemental oxygen on nausea and vomiting in patients undergoing spinal anesthesia for elective cesarean section

Public title

Effect of oxygen therapy on nausea and vomiting

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Elective cesarean section and fasting for 6-8 hours before and 6 hours after surgery. Exclusion criteria: Need to general anesthesia or having sever vomiting, symptomatic gastrointestinal disease, motion sickness, dizziness, heart disease, cardiovascular and pulmonary disease, middle ear diseases, diabetes mellitus, infectious disease, fever, hypertension, smoking, alcohol consumption, immunosuppressive medications, bleeding, hemoglobin less than 10 mg dl and another medications other antibiotics.

Age

From **20 years** old to **45 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Lorestan University of Medical Sciences and Health Services

Street address

Pardiss complex

City

Khoramabad

Postal code

Approval date

2011-02-22, 1389/12/03

Ethics committee reference number

1182

Health conditions studied

1

Description of health condition studied

Complications of anaesthesia during labour and delivery

ICD-10 code

O74.8

ICD-10 code description

Other complications of anaesthesia during labour and delivery

Primary outcomes

1

Description

Vomiting - Nausia

Timepoint

During six hours after surgery

Method of measurement

Question and visual analoge scale

Secondary outcomes

1

Description

Alternation of level and severity of nausia-alternation of level and severity of vomiting

Timepoint

Before surgery then every half hours until 6 hours after surgery

Method of measurement

Question and visual analog scale

Intervention groups

1

Description

Control group: 3-5 liter/min oxygen with a regular mask during surgery and 6 hours after surgery

Category

Prevention

2

Description

Intervetional group: oxygen 10 liter/min by ventury mask during surgery and until 6 hours after surgery

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Assali Hospital

Full name of responsible person

Galehdar Nasrin

Street address

Palestin Ally

City

Khoramabad

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Lorestan University of Medical Sciences and Health Services
Full name of responsible person
Dr. Kaeidy MH
Street address
Lorestan University of Medical Sciences and Health Services - pardiss complex
City
Khoramabad
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Lorestan University of Medical Sciences and Health Services
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
Lorestan University of Medical Sciences and Health Services
Full name of responsible person
Galehdar Nasrin
Position
MS in Nursing Education-Faculty Member-Instractor
Other areas of specialty/work
Street address
Paramedical Faculty, Goldasht
City
Khoramabad
Postal code
6819789741
Phone
+98 66042009971
Fax
+98 66 1422 0030
Email
galehdar_nas@yahoo.co.in; galehdar.n@lums.ac.ir
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Lorestan University of Medical Sciences and Health Services
Full name of responsible person
Galehdar Nasrin
Position
Faculty Member
Other areas of specialty/work
Street address
Paramedical Faculty
City
Khoramabad
Postal code
6819789741
Phone
+98 66 1420 9971
Fax
+98 66 1422 0030
Email
Galehdar_nas@yahoo.co.in; galehdar.n@lums.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Lorestan University of Medical Sciences and Health Services
Full name of responsible person
Galehdar Nasrin
Position
Instractor
Other areas of specialty/work
Street address
Paramedical Faculty
City
Khoramabad
Postal code
6819789741
Phone
+98 66 1420 9971
Fax
+98 66 1422 0030
Email
galehdar_nas@yahoo.co.in
Web page address

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