

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jul 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 severe 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)

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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 severe 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 - Nausea

Timepoint

During six hours after surgery

Method of measurement

Question and visual analogue scale

Secondary outcomes**1****Description**

Alternation of level and severity of nausea-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 analogue 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**

Interventional 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-Instructor

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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