Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison the effect of oxygen therapy with face mask and nasal cannula on blood oxygen saturation, nausea, vomiting and patient comfort in patients undergoing spinal anesthesia during Caesarean section at Shohada hospital in Gonbad

Protocol summary

Summary

The purpose of the randomized clinical trial study is comparing the effectiveness of two methods of oxygen therapy with face mask and nasal cannula on oxygen saturation of arterial blood, nausea, vomiting and patient comfort during surgery in patients undergoing cesarean section via spinal anesthesia at Shohada hospital in Gonbad in 2014. This study was designed in two groups. Convenience sampling will be used and 25 patients will be allocated randomly in treatment groups with face mask or nasal cannula group. Patients in group of face mask receive oxygen 8 liters per minute and in nasal cannula group receive 4 liters per minute of oxygen in two steps, immediately after spinal anesthesia and postoperative get to the recovery unit. Then arterial blood oxygen saturation, nausea and vomiting and patient comfort during surgery and in the recovery unit will be measured.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014080218649N1**
Registration date: **2015-04-14, 1394/01/25**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2015-04-14, 1394/01/25

Registrant information

Name

Khadijeh Yazdi

Name of organization / entity

Golestan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Golestan University of Medical Sciences, Deputy of Research and Technology

Expected recruitment start date

2014-08-06, 1393/05/15

Expected recruitment end date

2014-11-21, 1393/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effect of oxygen therapy with face mask and nasal cannula on blood oxygen saturation, nausea, vomiting and patient comfort in patients undergoing spinal anesthesia during Caesarean section at Shohada hospital in Gonbad

Public title

Comparison of two methods of oxygen therapy

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Patients undergoing spinal anesthesia

for elective cesarean section, first Class of American Society of Anesthesiologists, aged from 18 to 35 years, ability to communicate verbally, body mass index in the normal range, lake of breathing problems, lack of history of gastrointestinal disease, having no risk of pregnancy, absence of any nausea and vomiting 24 hours before cesarean, not receiving preoperative intravenous narcotic, preoperative SPO2 more than 95% and Hemoglobin more than 11. Exclusion criteria: Alteration in spinal anesthesia to general anesthesia, patient's unwillingness to continue participation in the study, need for any additional surgery other than cesarean section for patients and prolonged bleeding during operation.

Age
From **18 years** old to **35 years** old

Gender
Female

Phase
4

Groups that have been masked
No information

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
The samples will be selected by through convenience method and then they will be allocated in two groups using table of random numbers

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Golestan University of Medical Sciences

Street address
Falsafi Educational Campus, Shastkola Road, Gorgan

City
Gorgan

Postal code

Approval date
2014-03-02, 1392/12/11

Ethics committee reference number
36439212119

Health conditions studied

1

Description of health condition studied
Oxygen therapy

ICD-10 code
O82

ICD-10 code description
Single delivery by caesarean section

2

Description of health condition studied
Oxygen therapy

ICD-10 code
O82.0

ICD-10 code description
Delivery by elective caesarean section

3

Description of health condition studied
Oxygen therapy

ICD-10 code
O89.5

ICD-10 code description
O89.5 Other complications of spinal and epidural anaesthesia during the puerperium

Primary outcomes

1

Description
Arterial Oxygen Saturation

Timepoint
At 5 minutes intervals during surgery and in the recovery unit

Method of measurement
Pulse oximetry for oxygen saturation

Secondary outcomes

1

Description
Nausea,Vomiting and Patient Comfort

Timepoint
At 5 minutes intervals during surgery and in the recovery unit

Method of measurement
Visual scale for nausea, vomiting and patient comfort

Intervention groups

1

Description
Patients in this group will receive oxygen 8 liters per minute via face mask in two steps: immediately after administration of spinal anesthesia and at postoperative

recovery unit. During the entire operation and up to 30 minutes after in the recovery unit oxygen saturation will be measured via pulse oximetry. Nausea, vomiting and patient comfort will be measured also.

Category

Other

2

Description

Patients in this group will receive oxygen 4 liters per minute via nasal cannula in two steps: immediately after administration of spinal anesthesia and postoperative recovery unit. During the entire operation and up to 30 minutes after in the recovery unit oxygen saturation will be measured via pulse oximetry. Nausea, vomiting and patient comfort will be measured also.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shohada Hospital

Full name of responsible person

Ainaz Kor, Student in Master of Science in Critical Care Nursing

Street address

South Imam Khomeini Street, Gonbad

City

Gonbad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Golestan University of Medical Sciences, Deputy of Research and Technology

Full name of responsible person

Masoud Khosh Nia

Street address

Falsafi Educational Campus, Shastkola Road, Gorgan

City

Gorgan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Golestan University of Medical Sciences, Deputy of Research and Technology

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

Golestan University of Medical Sciences

Full name of responsible person

Ainaz Kor

Position

Student in Master of Science in Critical Care Nursing

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Position

Assistance Professor of Medical Surgical Nursing

Other areas of specialty/work

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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