

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jun 2026

The effect of supplemental oxygen therapy on the incidence and severity of complications after cesarean surgery with spinal anesthesia method in educational and medical center of Besat-Sanandaj

Protocol summary

Summary

Objective: to evaluate the effect of supplemental oxygen therapy on the incidence and severity of complications after cesarean surgery. Study population: women with cesarean surgery with spinal anesthesia method in Besat hospital of Sanandaj. Methods: 120 samples will be assigned randomly to intervention and control groups. Vital signs and arterial blood oxygen saturation level are recorded before induction of anesthesia and 5 and 30 minutes before the completion of anesthesia and then in 1-5-10-20 and 30 minutes and every one hour to six hrs after the completion of anesthesia. For the intervention group, oxygen 60% equivalent to 10 liters per minute will be used during anesthesia and surgery and after surgery in recovery section for 6 hours using the Venturi mask. In control group routine care will be performed (oxygen 30% equivalent to 3-5 liters per minute). Surgical wound will be evaluated by ASEPSIS INDEX at the time of discharge and 14 days later. (ASEPSIS INDEX: A, additional treatment; S, serous discharge; E, erythema; P, purulent exudates; S, separation of deep tissue; I, isolation of bacteria; and S, stay as inpatient for > 14 days). Incidence of nausea and vomiting will be recorded by questionnaire and severity of pain and nausea will be recorded by standard VAS during surgery and 24 hours after surgery in recovery section.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138806192440N1**

Registration date: **2010-02-20, 1388/12/01**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2010-02-20, 1388/12/01

Registrant information

Name

Jamal Seidy

Name of organization / entity

Nursing and midwife college, Kurdistan university of medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 87 1661 0095

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Recruitment status

Recruitment complete

Funding source

Affairs Research and Information Management of Kurdistan University of medical sciences

Expected recruitment start date

2009-11-21, 1388/08/30

Expected recruitment end date

2010-02-19, 1388/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of supplemental oxygen therapy on the incidence and severity of complications after cesarean surgery with spinal anesthesia method in educational and medical center of Besat-Sanandaj

Public title

The effect of supplemental oxygen therapy on the rate of complications after cesarean surgery with Spinal anesthesia method in Besat hospital of Sanandaj

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: cesarean section operation under spinal anesthesia, fasting around 6-8 hrs before surgery, Exclusion criteria: gastrointestinal disease, history of middle ear infection and dizziness and moving illness, diabetes and blood pressure illness, smoking and alcohol consumption, using immunosuppressive, fever and infection before surgery, anesthesia and the irregular bleeding long too much, abnormal hemoglobin, receiving any drugs except antibiotics and analgesics up to six hours after surgery

Age

From **18 years** old to **40 years** old

Gender

Female

Phase

3

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

Affairs Research and Information Management of Kurdistan university of medical sciences

Street address

Pasdaran st

City

Sanandaj

Postal code

6617713446

Approval date

1387-12-28, 769/01/-812

Ethics committee reference number

12093پ14پ

Health conditions studied

1

Description of health condition studied

the complications after caesarean surgery with the spinal anesthesia method

ICD-10 code

O82.9

ICD-10 code description

Delivery by caesarean section, unspecified

Primary outcomes

1

Description

Incidence and severity of pain, nausea and vomiting

Timepoint

Immediately after surgery, 6 hours and 24 hours after surgery

Method of measurement

questionnaire and standard VAS

Secondary outcomes

1

Description

Incidence and severity of surgery wound infection

Timepoint

24hours to 14days after cesarean surgery

Method of measurement

ASEPSIS index

Intervention groups

1

Description

oxygen 60% equivalent to 10 liters per minute will be used during anesthesia and surgery and after surgery in recovery section for 6 hours using the Venturi mask

Category

Treatment - Drugs

2

Description

In control group routine care will be performed (oxygen 30% equivalent to 3-5 liters per minute)

Category

empty

Recruitment centers

1

Recruitment center

Name of recruitment center

Educational and medical center of Besat - opration

room

Full name of responsible person

Dr Fariba Farhady far

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Keshavars st.

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Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Kurdistan university of Medical sciences

Full name of responsible person

Dr Fariba Farhadifar

Position

Faculty member - board specialized Maternity

Other areas of specialty/work

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Affairs Research and Information Management,
Kurdistan University of Medical sciences

Full name of responsible person

Dr Ata alla Haydary

Street address

Kurdistan University of Medical sciences

City

Sanandaj

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Affairs Research and Information Management, Kurdistan
University of Medical sciences

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

Kurdistan university of Medical sciences

Full name of responsible person

Jamal Seidy

Position

Member of scientific group of nursing college, Ms of
operating room

Other areas of specialty/work

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Full name of responsible person

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Other areas of specialty/work

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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