Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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

Objectine: 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

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Jamal Seidy
Name of organization / entity
Nursing and midwife college, Kurdestan university of medical sciences
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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 Kurdestan 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, nausia and vometing

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 woud 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

Educatonal and medical center of Besat - opration

room

Full name of responsible person
Dr Fariba Farhady far

Street address
Keshavars st.

City
Sanandaj

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Affairs Research and Information Management, Kurdistan University of Medical sceinces

Full name of responsible person
Dr Ata alla Haydary

Street address
Kurdistan University of Medical sceinces

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 sceinces

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
Kurdestan universty 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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Postal code

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Fax

Email

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