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.

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Nursing and midwife college, Kurdistan university of medical sciences

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Iran (Islamic Republic of)

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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
12093

Health conditions studied

1
Description of health condition studied
the complications after caesarean surgery with the spinal anesthesia method

ICD-10 code
082.9

ICD-10 code description
Delivery by caesarean section, unspecified

Primary outcomes

1
Description
Incidence and severity of pain, nausia 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 woud infection

Timepoint
24 hours to 14 days 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 - opreation 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 Sciences
Full name of responsible person
Dr Ata alla Haydary
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Kurdistan University of Medical Sciences
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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

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Name of organization / entity
Kurdistan universty of Medical sciences
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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