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: 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
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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**
- 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 wound 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**
- Educational and medical center of Besat - operation room

**Full name of responsible person**
- Dr Fariba Farhady far

**Street address**
- Keshavars st.

**City**
- Sanandaj

**Sponsors / Funding sources**
1

**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**: empty
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**Person responsible for updating data**

**Contact**

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- **Web page address**: empty

**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