NCT03171688 - clinical protocol Version 2

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Abstract

A single prospective cohort of women submitted to cesarean section who received spinal anesthesia will be assessed for the proposed risk factors and the incidence of nausea or vomiting will be observed during the first 48 hours.

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Protocol

Assess for eligibility

Step 1.

Check patients waiting for cesarean inclusion criteria
Inclusion Criteria:

- Cesarean section indicated
- Spinal anesthesia indicated

Both criteria are necessary, otherwise patient is not included but only adds to the not included counter.

Informed consent

Step 2.

An informed consent protocol is applied and two copies of a specific written informed consent (see file below) is signed by principal investigator and participant. One copy is stored by principal investigator and the other by the participant.

Pre-anesthesia questionary

Step 3.

Patients are asked about:

- Previous PONV (true or false)
- Previous surgery(true or false)
- Smoking history
- Cinetosis;(true or false)
- Nausea in the first trimester(true or false)
- Nausea in the third trimester(true or false)
- Age in years;
- Gestational age;

Data is stored in an online electronic data capture form that includes version control.

Postanesthesia questionary

Step 4.

Data acquired after cesarean ends:

- Spinal anesthesia only (true or false)
  - False is an exclusion criteria;
- Hyperbaric bupivacaine dose
- Spinal sufentanil dose
- Spinal fentanyl dose
- Spinal morphine dose
- Basal mean arterial pressure
- Minimum MAP after spinal before birth
- Intraoperative nausea
- Intraoperative vasopressor
- Intraoperative ondansetron dose
- Intraoperative dexamethasone dose

Data is stored in an online electronic data capture form that includes version control.

Postanesthesia care unit questionary

Step 5.

During the first two postoperative hours:

- Nausea in PACU intensity (0-10)
- Vomiting episodes in PACU (count)

Data is stored in an online electronic data capture form that includes version control.

First day (24h) questionaire

Step 6.

1. Patient is asked about PONV between 2-24 hours after cesarean:

- Nausea intensity (0-10)
- Vomiting episodes(count)

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