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Standing stability among women with epidural pain relief after Cesarean delivery

Submission date
29/03/2020

Recruitment status
No longer recruiting

Registration date
31/03/2020

Overall study status
Completed

Last Edited
23/07/2021

Condition category
Pregnancy and Childbirth

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
Early mobilization after Cesarean delivery is encouraged to decrease blood clots (thromboembolic events) and shorten the length of hospital stay. Although postoperative pain management with epidural pain medication can perfectly fit the purpose, it might impair the capability of standing and walking due to epidural local anesthetics and opioids. The purpose of this study was to determine the safety and efficacy of different doses in epidural fentanyl in addition to local anesthetics while ambulation of those who had an elective Cesarean delivery.

Who can participate?
Any term pregnant woman with ASA I or II who undergoes an elective Cesarean delivery and receives an epidural catheter at T12/L1 following spinal anesthesia.

What does the study involve?
Participants will be randomly allocated to receive continuous epidural infusion of 0.2% ropivacaine containing either 2.5 mcg/ml (Group 1) or 5 mcg/ml fentanyl (Group 2) started at the rate of 5 ml/h after Cesarean delivery.

What are the possible benefits and risks of participating?
Possible benefits are encouragement of early mobilization after Cesarean delivery. Possible risks are falling during ambulation.

Where is the study run from?
Kobari General Hospital (Japan)

When is the study starting and how long is it expected to run for?
May 2018 to December 2019

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Masayuki Oshima, oshimasayuki@gmail.com

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Posturography can detect potential impairment of standing stability due to epidural fentanyl after Cesarean delivery

Study objectives
The objective of the current study is to compare standing stability measured by posturography between two different concentrations of epidural fentanyl in addition to local anesthetics in post-Cesarean delivery women with continuous epidural analgesia.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 26/04/2018, Local ethics committee of Kobari General Hospital (29-1, Yokouchi, Noda, Chiba, 278-0051, Japan; no tel. provided; ikyoku-hisho@kobari.or.jp), ref: 34-2018

Study design

Prospective non-inferiority pilot randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Spinal anesthesia during an elective Cesarean delivery

Interventions
Continuous epidural infusion of 0.2% ropivacaine containing either 2.5 mcg/ml (Group 1) or 5 mcg/ml fentanyl (Group 2) is randomly assigned to an individual and started at the rate of 5 ml/h postoperatively.
Total duration of treatment (i.e., continuous epidural analgesia) was 48 hours after their Cesarean delivery. And the total duration of follow-up was up to 7 days after their Cesarean delivery. Participants were randomized into 2 groups by a table of random numbers.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Sway area measured by a posturography at baseline, one and seven days after Cesarean delivery

Key secondary outcome(s))
1. Pain status with Visual Analogue Scale once a day after Cesarean delivery up to post-operative seven days
2. Motor function of legs with Bromage scale on post-operative day one

Completion date
31/12/2019

Eligibility

Key inclusion criteria
1. Term pregnant woman with ASA I or II
2. Elective Cesarean delivery
3. Received an epidural catheter at T12/L1 following spinal anesthesia

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex

Female

Total final enrolment
16

Key exclusion criteria
1. ASA III or higher
2. Needs an urgent Cesarean delivery
3. Needs general anesthesia for a Cesarean delivery

Date of first enrolment
01/05/2018

Date of final enrolment
30/04/2019

Locations

Countries of recruitment
Japan

Study participating centre
Kobari General Hospital
29-1
Yokouchi
Noda
Chiba
Japan
278-0051

Sponsor information

Organisation
Kobari General Hospital

ROR
https://ror.org/04yn2he76

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		19/07/2021	23/07/2021	Yes	No