

Standing stability among women with epidural pain relief after Cesarean delivery

Submission date 29/03/2020	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 31/03/2020	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 23/07/2021	Condition category Pregnancy and Childbirth	<input type="checkbox"/> 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

Contact name

Dr Masayuki Oshima

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet.

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 measure

Sway area measured by a posturography at baseline, one and seven days after Cesarean delivery

Secondary outcome measures

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

Overall study start date

01/01/2018

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

Age group

Adult

Sex

Female

Target number of participants

16

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

Sponsor details

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+81-4-7124-6666

ikyoku-hisho@kobari.or.jp

Sponsor type

Hospital/treatment centre

Website

<http://www.kobari.or.jp>

ROR

<https://ror.org/04yn2he76>

Funder(s)

Funder type

Other

Funder Name

Investigator initiated and funded

Results and Publications

Publication and dissemination plan

Publication of findings in a peer-review journal.

Intention to publish date

01/06/2020

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