

# Standing stability among women with epidural pain relief after Cesarean delivery

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

## ORCID ID

<https://orcid.org/0000-0003-4438-132X>

## Contact details

Kobari General Hospital

29-1

Yokouchi

Noda

Chiba

Japan

278-0051

+81-4-7124-6666

oshimasayuki@gmail.com

# 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

29-1

Yokouchi

Noda

Chiba

Japan

278-0051

+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?
<a href="#">Results article</a>		19/07/2021	23/07/2021	Yes	No