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Dilution of ropivacaine by saline can decrease its dose requirement in spinal anesthesia for cesarean section

Submission date
23/07/2011

Recruitment status
No longer recruiting

Registration date
09/12/2011

Overall study status
Completed

Last Edited
08/05/2017

Condition category
Pregnancy and Childbirth

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Women who are undergoing a cesarean delivery require a long-acting local anesthetic in order to prevent pain during surgery. There are many different drugs used for this, such a ropivacaine, a spinal anesthesia that was recently approved for usage in China. There is not a lot of research about its usage in cesarean deliveries. Ropivacaine is less potent than other anesthetics so the dose range needs to be determined. Studies have determined that the median effective dose (ED50) (the dose that produces an effect in 50% of the population that uses it) and the ED95 (the amount required for 95% of the population) is 16.7 mg and 26.8 mg. However, other studies have shown that even with a high dose of ropivacaine, there is still 25% failure rate. The aim of this study is to determine the ED50 of ropivacaine for intrathecal administration and the difference in the effects of ropivacaine between dilution by saline and cerebrospinal fluid.

Who can participate?
Adult women who are undergoing an elective cesarean delivery

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first receive an anesthesia that contains ropivacaine diluted to 5 mg/ml by saline by an injection into the spinal canal. Those in the second group receive an anesthesia that contains ropivacaine diluted to 5 mg /ml by cerebrospinal fluid by an injection into the spinal canal. Participants are followed up to see if the difference between the two different groups.

What are the possible benefits and risks of participating?
Participants may benefit from the effects of ropivacaine and anesthesia. There is a risk of possible complications with anesthesia.

Where is the study run from?
6th Affiliated Hospital to Shanghai Jiaotong University (China)

When is the study starting and how long is it expected to run for?
July 2011 to October 2011

Who is funding the study?
6th Affiliated Hospital to Shanghai Jiaotong University (China)

Who is the main contact?
Dr Zhen Zeng

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Study information

Scientific Title
Dilution of ropivacaine by saline can decrease its dose requirement in spinal anesthesia for cesarean section: a randomized blinded controlled trial

Study objectives
There are difference in terms of effect of ropivacaine between dilution by saline and cerebrospinal fluid in spinal anesthesia

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethical Review Committee of the Sixth People's Hospital affiliated to Shanghai Jiaotong University approved on 12 June 2010, ref: 20100323

Primary study design
Interventional

Study design
Randomized blinded controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied
Elective cesarean delivery

Interventions
The patients were randomly allocated to 2 groups to receive combined spinal epidural anesthesia for cesarean section.

Group RS received intrathecal isobaric 1% ropivacaine (Naropin, AstraZeneca, China) diluted to 5 mg/ml by saline.

Group RC received intrathecal isobaric 1% ropivacaine (Naropin, AstraZeneca, China) diluted to 5 mg/ml by cerebrospinal fluid (CSF). Using Dixon up-down sequential allocation technique, the amount of local anesthetic drug received by a particular parturient was determined by the response of the previous parturient in the respective group. Based on previous clinical experience, the first parturient in each group received 20mg ropivacaine.The inadequate anesthesia cases in each group were managed by epidural volume extension. Patients were given 10ml 1% Lidocaine through the epidural catheter into epidural space.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Ropivacaine

Primary outcome(s)
1. Effective Dose 50 (ED50) of ropivacaine for intrathecal administration
2. The rate of adequate anesthesia

Key secondary outcome(s)
1. Heart rate
2. Systolic, diastolic, and mean arterial blood pressure
3. Hemoglobin oxygen saturation

Completion date
01/10/2011

Eligibility

Key inclusion criteria
1. American Society of Anesthesiologists (ASA) physical status I to II
2. Undergoing elective cesarean delivery
3. No contraindications to subarachnoid anesthesia

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Key exclusion criteria
1. Allergic to local anesthetics
2. Emergent cesarean deliveries
3. Body mass index (BMI) < 22 or >30
4. Hypertensive disorders
5. Peripartum hemorrhagic conditions
6. Neurologic, cardiac or hematologic diseases
7. Diabetes
8. Eclampsia
9. Fetal distress, or known fetal anomalies

Date of first enrolment
31/07/2011

Date of final enrolment
01/10/2011

Locations

Countries of recruitment
China

Study participating centre
No. 600 Yishan Road
Shanghai
China
200233

Sponsor information

Organisation
6th Affiliated Hospital to Shanghai Jiaotong University (China)

ROR
https://ror.org/049zrh188

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
6th Affiliated Hospital to Shanghai Jiaotong University (China)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration