

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

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		<input type="checkbox"/> Protocol
<b>Registration date</b> 09/12/2011	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 08/05/2017	<b>Condition category</b> Pregnancy and Childbirth	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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**  
Dr Zhen Zeng

**Contact details**  
No. 600 Yishan Road  
Shanghai  
China  
200233

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
N/A

## 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

**Study design**

Randomized blinded 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 the contact details below to request a patient information sheet

**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 measure**

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

## **Secondary outcome measures**

1. Heart rate
2. Systolic, diastolic, and mean arterial blood pressure
3. Hemoglobin oxygen saturation

## **Overall study start date**

31/07/2011

## **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

## **Age group**

Adult

## **Sex**

Female

## **Target number of participants**

60

## **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)

**Sponsor details**

Department of Anesthesiology

Shanghai

China

200233

**Sponsor type**

Hospital/treatment centre

**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**

**Publication and dissemination plan**

Not provided at time of registration

**Intention to publish date**

## **Individual participant data (IPD) sharing plan**

### **IPD sharing plan summary**

Not provided at time of registration