

# A comparison of carbetocin and oxytocin in prevention of uterine atony following emergency Caesarean section

<b>Submission date</b> 22/03/2010	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 07/04/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 29/12/2020	<b>Condition category</b> Pregnancy and Childbirth	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

Dr Nuguelis Razali

### Contact details

Department of Obstetrics and Gynaecology, University Malaya Medical Center, Lembah Pantai  
Kuala Lumpur

Malaysia

59100

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nuguelis@um.edu.my

## Additional identifiers

### Protocol serial number

N/A

## Study information

### Scientific Title

A double blind randomized comparison of carbetocin and oxytocin in prevention of uterine atony following emergency Caesarean section

**Study objectives**

A single injection of carbetocin is as effective as oxytocin in preventing excessive intraoperative blood loss after caesarean section and less likely to need additional oxytocin for uterine atony or excessive bleeding.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

University Malaya Medical Centre Ethics Committee Board, Reference no : 678.18. Date of approval 17 September 2008

**Study design**

Randomised double blind prospective single centre study

**Primary study design**

Interventional

**Study type(s)**

Treatment

**Health condition(s) or problem(s) studied**

Post delivery via emergency caesarean section

**Interventions**

This is a randomised double blind study comparing Oxytocin and Carbetocin. For each of the study subjects, the kits containing each study drugs (which are identical) will be prepared according to the randomisation made so as to secure the blinding of the clinician as well as the patient. After the foetus and placenta has been delivered, 1 ml of the study drug as prepared in each kit will be administered intravenously through the subject's intravenous line with the help of the anaesthetic staff in charge.

**Intervention Type**

Other

**Phase**

Not Specified

**Primary outcome(s)**

Need for additional uterotonic intervention within 24 hours after LSCS to maintain the adequacy of uterine tone as judged by the attending surgeon and clinician.

**Key secondary outcome(s)**

1. Drop in haemoglobin and haematocrit level by 24 hours postoperatively
2. Total estimated blood loss
3. Vital signs
4. Side effects
5. Operating time
6. Need for blood transfusion

**Completion date**

15/12/2010

## Eligibility

**Key inclusion criteria**

Women of 18 years or older with a term (more than 37 weeks period of gestation), singleton pregnancy who will be undergoing an emergency Lower Segment Caesarean Section (LSCS) under regional anaesthesia.

An emergency LSCS has been defined as an unplanned LSCS which is performed once labour has commenced or during the process of labour for any reasons indicated. Labour in this context has been defined as documented regular contractions with frequency of at least once in 10 minutes with cervical dilatation of 3cm and more.

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

Female

**Total final enrolment**

547

**Key exclusion criteria**

1. Suspected or known coagulopathy
2. Hypersensitivity to the study drugs
3. History of heart disease including
  - 3.1. Cardiac arrhythmia
  - 3.2. Hypertension
  - 3.3. Evidence of liver, renal or endocrine diseases (other than gestational diabetes)
4. LSCS is done under general anaesthesia for any reason
5. Diagnosed placenta praevia
6. Placental abruption
7. Fibroid in pregnancy

**Date of first enrolment**

15/12/2008

**Date of final enrolment**

15/12/2010

# Locations

## Countries of recruitment

Malaysia

## Study participating centre

Department of Obstetrics and Gynaecology, University Malaya Medical Center, Lembah Pantai  
Kuala Lumpur  
Malaysia  
59100

# Sponsor information

## Organisation

University Malaya Medical Centre (Malaysia)

## ROR

<https://ror.org/00vkrxq08>

# Funder(s)

## Funder type

University/education

## Funder Name

The University of Malaya (Malaysia) - research grant (ref: UMRG 108/09 HTM)

# Results and Publications

## Individual participant data (IPD) sharing plan

## IPD sharing plan summary

Not provided at time of registration

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/03/2016	29/12/2020	Yes	No