

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

Submission date 22/03/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 07/04/2010	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 29/12/2020	Condition category 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
-
nuguelis@um.edu.my

Additional identifiers

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?
Results article	results	01/03/2016	29/12/2020	Yes	No