ISRCTN18976822 https://doi.org/10.1186/ISRCTN18976822

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

Submission date
22/03/2010

Registration date
07/04/2010

Last Edited
29/12/2020

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Pregnancy and Childbirth

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

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
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 measure
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.

Secondary outcome measures
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

Overall study start date
15/12/2008

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

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
600

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)

Sponsor details
Department of Obstetrics and Gynaecology
Lembah Pantai
Kuala Lumpur
Malaysia
43000
-
nuguelis@um.edu.my

Sponsor type
University/education

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

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/03/2016	29/12/2020	Yes	No