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A study on side effects such as nausea and vomitus after medication to prevent excessive bleeding after a caesarean section

Submission date
03/02/2013

Recruitment status
No longer recruiting

Registration date
28/02/2013

Overall study status
Completed

Last Edited
07/03/2018

Condition category
Pregnancy and Childbirth

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
At the end of a cesarean section in Belgium, in general some medication is given to the mother to prevent excessive bleeding. The two products used most frequently are called carbetocin and oxytocin and work well. No difference has been demonstrated as far as the effect on prevention of bleeding is concerned. A major side effect of this kind of medication is nausea and vomitus and a lowering of blood pressure resulting in dizziness. The aim of the present study is to compare nausea, vomiting and changes in blood pressure between carbetocin and oxytocin.

Who can participate?
Any pregnant woman for whom a caesarean section is planned in a term (full grown) pregnancy without any other complication can participate.

What does the study involve?
Participants are randomly allocated to one of two groups. All women receive an intravenous medication to prevent bleeding and no one (participant, operating or treating team) will not know whether the medication used is carbetocin or oxytocin.

What are the possible benefits and risks of participating?
There is no difference with routine management during which both medications are used. The results of this study will help future patients to receive the product with the fewest side effects.

Where is the study run from?
The study will be run in the Obstetrics Ward at Antwerp University Hospital UZA, Belgium.

When is the study starting and how long is it expected to run for?
The study will be running for one year and will start in March 2013.

Who is funding the study?
This study is not funded by any pharmaceutical company, all costs are taken care of by the local Fund for perinatal Medicine of the Department of Obstetrics at Antwerp University Hospital

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
OBGYN-1

Study information

Scientific Title
OBGYN-1: A randomized controlled trial on nausea, vomitus and blood pressure changes comparing carbetocine versus oxytocine in the prevention of hemorrhage after caesarean section

Acronym
NAVOCASY

Study objectives
Single shot intraveneous carbetocin is accompanied with more nausea and vomitus as compared to intravenous oxytocin.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Ethics Committee Ethisch Comité Universitair Zieknhusi Antwerpen, 21/02/2011, ref: B300201110299

Study design
Prospective randomized 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 to request a patient information sheet

Health condition(s) or problem(s) studied
Pregnancy and delivery

Interventions
Standard intravenous carbetocin vs standard intravenous oxytocin

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Carbetocin, oxytocin

Primary outcome measure
From the moment the participant enters the operating theatre until one hour later, blood pressure and heart frequence are carefully registered every 5 minutes or more as during routine monitoring of surgery. Nausea and vomitus are evaluated before surgery (just before incision), during surgery: before giving the intravenous medication and after 5, 10 and 15 minutes based on the standardized scale:
0: no nausea, no vomitus
1: mild nausea, no vomiting
2: nausea but with retching, no vomiting
3: nausea and vomiting

Secondary outcome measures
Any other complaint

Overall study start date
15/02/2013

Completion date
15/02/2014

Eligibility

Key inclusion criteria
Term uncomplicated pregnant women who undergo a planned cesarean section

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
60

Key exclusion criteria
1. Unplanned caesarean section
2. Complications including: hypertension, preterm labour, any gastrointestinal or cardiovascular disease necessitating treatment

Date of first enrolment
15/02/2013

Date of final enrolment
15/02/2014

Locations

Countries of recruitment
Belgium

Study participating centre
Antwerp University Hospital
Edegem
Belgium
2650

Sponsor information

Organisation
Antwerp University Hospital (Belgium)

Sponsor details
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/01hwamj44

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Department of Obstetrics, Antwerp University Hospital (Belgium)

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	02/01/2018		Yes	No