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# A study on carbetocin (Pabal®) versus oxytocin (Syntocinon®)

**Submission date**
16/01/2012

**Recruitment status**
No longer recruiting

**Registration date**
07/03/2012

**Overall study status**
Completed

**Last Edited**
07/08/2014

**Condition category**
Pregnancy and Childbirth

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

## Plain English summary of protocol

Background and study aims
Oxytocin (Syntocinon®) is the first-choice drug for the prevention of postpartum bleeding after Caesarean section (CS). A disadvantage of oxytocin is its short duration of action. Carbetocin (Pabal®) is the first long-acting analogue of oxytocin. Its safety is comparable with that of oxytocin. Carbetocin is indicated for the prevention of uterus atony after CS under local anaesthesia. The aim of this study is to compare the effectiveness of carbetocin with that of oxytocin by assessing the need for additional uterotonic medication after elective CS in five leading Dutch centres.

Who can participate?
Women undergoing elective CS under epidural and/or spinal anaesthesia and treated with carbetocin or oxytocin.

What does the study involve?
Information will be gathered of 50 patients per centre after a single injection of carbetocin after elective CS prescribed by the gynaecologist. No other (invasive) study-related interventions or measurements are done, other than the procedures routinely performed during CS. No effort is expected from the study subjects. In addition, charts of patients treated with oxytocin for the prevention of postpartum bleeding after elective CS, will be retrieved.

What are the possible benefits and risks of participating?
Possible benefits for the study subjects could be the long-acting contraction of the uterus owing to carbetocin resulting in less blood loss. There are no possible risks of participating, since carbetocin and oxytocin are given on prescription to women eligible to receive it. No extra study procedures are needed.

Where is the study run from?
The study is initiated by the University Hospital Utrecht, the Netherlands.

When is the study starting and how long is it expected to run for?
The study ran from July 2009 until December 2011.

Who is funding the study?
Ferring B.V., the Netherlands.

Who is the main contact?
Prof. dr. H.W. Bruinse, University Hospital Utrecht, The Netherlands

# Contact information

### Type(s)
Scientific

### Contact name
Prof Hein Bruinse

### Contact details
University Medical Center Utrecht (WKZ)
Lundlaan 6
Utrecht
Netherlands
3584 EA

# Additional identifiers

### EudraCT/CTIS number

### IRAS number

### ClinicalTrials.gov number

### Secondary identifying numbers
N/A

# Study information

### Scientific Title
Study on the use of carbetocin (Pabal®) in comparison with oxytocin (Syntocinon®) for the prevention of postpartum haemorrhage (the need for additional uterotonic medication) after elective caesarean section

### Study objectives
To compare retrospectively the efficacy of carbetocin with oxytocin by assessing the need for additional uterotonic interventions after elective Caesarean Section (CS) in five leading Dutch centres.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
According to the Dutch law (The Medical Research Involving Human Subjects Act) the study does not need to be seen by an ethics committee. The medication was given only within the label in

women eligible to receive it. No other (invasive) study-related interventions or measurements are done, other than the procedures routinely performed during CS. No effort is expected from the study subjects.

### Study design
Open-label multi-centre observational study

### Primary study design
Observational

### Secondary study design
Multi-centre

### 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
Obstetrics / Caesarean section

### Interventions
After treatment on prescription with carbetocin or oxytocin, information will be gathered from the patient's chart. The follow-up time is 24 hours after medication administration.

### Intervention Type
Other

### Phase
Not Applicable

### Primary outcome measure
Need for additional uterotonic treatment during the first 24 hours after carbetocin or oxytocin administration.

### Secondary outcome measures
1. Need for blood transfusion during the first 24 hours
2. Need for operative interventions other than the initial CS during the first 24 hours
3. Need for uterus massage during the first 24 hours
4. Change in haematocrit and haemoglobin post versus pre CS
5. Amount of intraoperative blood loss
6. Incidence of intraoperative blood loss > 500 ml
7. Incidence of intraoperative blood loss > 1000 ml
8. Position of fundus after wound closure (only in prospective part of the study)
9. Uterus tone after uterotonic treatment
10. Investigators subjective experience with oxytocin/carbetocin

### Overall study start date
01/07/2009

### Completion date
01/12/2011

## Eligibility

### Key inclusion criteria
Charts of women who have undergone elective CS under epidural and/or spinal anaesthesia and treated with carbetocin or oxytocin.

### Participant type(s)
Patient

### Age group
Adult

### Sex
Female

### Target number of participants
1500

### Key exclusion criteria
Contraindications, warnings, precautions and interactions with other drugs mentioned in the summary of product characteristics of carbetocin and oxytocin.

### Date of first enrolment
01/07/2009

### Date of final enrolment
01/12/2011

## Locations

### Countries of recruitment
Netherlands

### Study participating centre
**University Medical Center Utrecht (WKZ)**
Utrecht
Netherlands
3584 EA

# Sponsor information

**Organisation**
Ferring B.V. (Netherlands)

**Sponsor details**
Polarisavenue 130
Hoofddorp
Netherlands
2130 AD

**Sponsor type**
Industry

**Website**
http://www.ferring.nl

**ROR**
https://ror.org/03spzq317

# Funder(s)

**Funder type**
Industry

**Funder Name**
Ferring B.V. (Netherlands)

# 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