ISRCTN98070045 https://doi.org/10.1186/ISRCTN98070045

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

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.

Primary study design
Observational

Study design

Open-label multi-centre observational study

Study type(s)
Treatment

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(s)
Need for additional uterotonic treatment during the first 24 hours after carbetocin or oxytocin administration.

Key secondary outcome(s)
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

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

Healthy volunteers allowed
No

Age group

Adult

Sex
Female

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)

ROR
https://ror.org/03spzq317

Funder(s)

Funder type
Industry

Funder Name
Ferring B.V. (Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration