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Can heart rate predict low blood pressure during Caesarean section?

Submission date
25/04/2014

Recruitment status
No longer recruiting

Registration date
06/05/2014

Overall study status
Completed

Last Edited
29/05/2020

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
Spinal anaesthesia is the most frequently used anaesthetic for planned delivery of babies by Caesarean section. It allows women to be awake and pain free during the birth of their baby. It is usually safer than general anaesthesia and following the operation there is less pain, drowsiness and nausea than after general anaesthesia. A problem with spinal anaesthesia is that it often causes low blood pressure (hypotension) during the operation (in eight out of ten women) if measures are not taken to prevent it. This can cause mothers to feel nauseated, or to feel faint and dizzy during their
operation. It can also reduce delivery of oxygen to the baby. We routinely use measures to prevent hypotension, or to reduce its severity if it does occur. This includes giving fluid and a drug (phenylephrine) into a drip in the mothers arm. Despite these efforts, approximately two out of ten women still develop hypotension in our hospital (the James Cook University Hospital) before delivery of the baby.
The aim of the study is to find if the heart rate just after the spinal anaesthetic has started can predict how low the blood pressure will go during the operation. We will study whether higher heart rates just after the spinal injection are associated with lower blood pressures as the spinal anaesthetic progresses.

Who can participate?
We plan to study 111 healthy women aged > 17 years undergoing planned Caesarean section under spinal anaesthesia in our hospital.

What does the study involve?
Women scheduled for Caesarean section at our hospital will be informed about the study when they attend the pre-operative clinic. On the day of operation, following informed consent, women will receive routine spinal anaesthesia and monitoring of blood pressure and heart rate. The study will last from the start of the spinal anaesthetic until delivery of the baby. Treatment and monitoring will be the same as for those not taking part in the study.

What are the possible benefits and risks of taking part?
The will be no additional risks because treatment will be the same as for those who do not take part. There will be no benefits from taking part. Future patients may benefit from our

observations if they allow us predict which patients are most likely to develop hypotension during spinal anaesthesia for Caesarean section.

Where is the study run from?

The study will be run from the James Cook University Hospital in Middlesbrough (UK), which is the only hospital taking part.

When is the study starting and how long is it expected to run for?
The study will start in May 2014 and continue for approximately 8 12 months.

Who is funding the study?
The South Tees Hospitals NHS Foundation Trust, Middlesbrough (UK).

Who is the main contact?
Dr David William Cooper, Consultant Anaesthetist
drdavidcooper@aol.com

Contact information

Type(s)
Scientific

Contact name
Dr David Cooper

Contact details
Dept. of Anaesthesia
Cheriton House
James Cook University Hospital
Marton Road
Middlesbrough
Cleveland
United Kingdom
TS4 3BW
-
drdavidcooper@aol.com

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
2013123

Study information

Scientific Title
An observational study of the association between heart rate in the early post-spinal period and the lowest arterial pressure recorded during planned Caesarean section

Study objectives
That during spinal anaesthesia for Caesarean section there is an inverse association between early post-spinal heart rate and the lowest arterial pressure recorded between induction of spinal anaesthesia and delivery of the baby.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee North East - Newcastle & North Tyneside 1, 05/01/2014, ref: 13/NE/0168

Study design
Single centre observational cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Other

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
Hypotension during spinal anaesthesia for Caesarean section

Interventions
Patients undergoing planned Caesarean section will receive routine spinal anaesthesia, monitoring, and preventative measures for hypotension and nausea during anaesthesia. The study will last from the induction of spinal anaesthesia until the delivery of the baby (duration approximately 20 30 minutes). The standard spinal anaesthetic is 2.8 ml of hyperbaric bupivacaine 0.5% combined with 400 µg of diamorphine in 0.4 ml. Routine monitoring is with an electrocardiogram, non-invasive blood pressure and pulse oximetry. Maternal arterial pressure will be measured every two minutes following induction of spinal anaesthesia. Intravenous Hartmanns solution will be given during the spinal anaesthetic. Intravenous ondansetron will be given immediately before spinal anaesthesia as nausea prophylaxis. An intravenous infusion of phenylephrine will be commenced at 67 µg/min at the time of the spinal injection and titrated to maintain arterial pressure close to the baseline pre-operative value.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Association between the heart rate at 3-minutes post-spinal and the lowest arterial pressure recorded during spinal anaesthesia before delivery of the baby
2. A comparison of the heart rate at 3-minutes post spinal for those patients that develop hypotension before delivery of the baby compared with those that do not

Primary and secondary outcome data will be recorded by a dedicated researcher (an anaesthetist or research nurse) who will be present in addition the patients usual anaesthetist. The heart rate and arterial pressure will be recorded at baseline by the researcher when the patients are admitted to the hospital on the day of their surgery, using a non-invasive blood pressure device. Heart rate and arterial pressure will also be recorded when the patient is first brought in to the anaesthetic room and during induction of spinal anaesthesia. Following the spinal anaesthetic injection, and during the operation, heart rate will be measured continuously by an electrocardiogram and maternal arterial pressure will be measured every two minutes with a non-invasive blood pressure device.

Before the induction of spinal anesthesia the patients will be asked to immediately report any feeling of nausea or faintness that they may have during the spinal anaesthetic. The researcher will also ask the patient every five minutes whether they have any nausea or faintness. If the patient feels nauseated an additional arterial pressure reading will be measured to assess whether this is associated with low arterial pressure and to guide treatment.

Data will only be recorded up until delivery of the baby by the researcher, at which point the study ends. There will be no further data collection or patient follow up following delivery of the baby.

Secondary outcome measures
1. A comparison of the heart rate at 3-minutes post spinal for those patients that develop nausea before delivery of the baby compared with those that do not
2. Association between the heart rate at 3-minutes post-spinal and the the dose of phenylephrine given during spinal anaesthesia before delivery of the baby

Overall study start date
01/05/2014

Completion date
01/01/2015

Eligibility

Key inclusion criteria
1. Healthy women scheduled for elective Caesarean section under spinal anaesthesia
2. Singleton fetus, at least 36 weeks gestation, with no known abnormality

3. Under the care of a specialist Obstetrician at the James Cook University Hospital who consents to his/her patients being included in the trial
4. Patients giving informed consent to participate in the trial

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
111

Key exclusion criteria
1. Pregnancy induced hypertension
2. Essential hypertension
3. Baseline systolic arterial pressure >145 mmHg, even if there is no history of hypertension
4. Diabetes
5. Age below 18 years
6. BMI over 45 at term
7. Anaesthetist is unable to perform spinal anaesthesia, spinal anaesthesia alone is not considered adequate for surgery to start, or general anaesthesia is required before delivery of the baby
8. Withdrawal of patients or obstetricians consent

Date of first enrolment
01/05/2014

Date of final enrolment
01/01/2015

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Dept. of Anaesthesia
Cleveland
United Kingdom
TS4 3BW

Sponsor information

Organisation
South Tees Hospitals NHS Foundation Trust (UK)

Sponsor details
James Cook University Hospital
Marton Road
Middlesbrough
Cleveland
England
United Kingdom
TS4 3BW

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/02js17r36

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
South Tees Hospitals NHS Foundation Trust (UK)

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?

HRA research summary	28/06/2023	No	No