

Can heart rate predict low blood pressure during Caesarean section?

Submission date 25/04/2014	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 06/05/2014	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 29/05/2020	Condition category Pregnancy and Childbirth	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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?

There 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
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Contact information

Type(s)

Scientific

Contact name

Dr David Cooper

Contact details

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Additional identifiers

Protocol serial number

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

Study type(s)

Other

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 Hartmann's 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(s)

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 to the patient's 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 anaesthesia 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.

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

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

United Kingdom

England

Study participating centre**Dept. of Anaesthesia**

Cleveland

United Kingdom

TS4 3BW

Sponsor information

Organisation

South Tees Hospitals NHS Foundation Trust (UK)

ROR

<https://ror.org/02js17r36>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

South Tees Hospitals NHS Foundation Trust (UK)

Results and Publications

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