# Can heart rate predict low blood pressure during Caesarean section?

Submission date 25/04/2014	<b>Recruitment status</b> No longer recruiting	<ul> <li>Prospectively registered</li> <li>Protocol</li> </ul>
Registration date 06/05/2014	<b>Overall study status</b> Completed	<ul> <li>Statistical analysis plan</li> <li>Results</li> </ul>
Last Edited 29/05/2020	<b>Condition category</b> Pregnancy and Childbirth	<ul><li>Individual participant data</li><li>Record updated in last year</li></ul>

#### 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

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# 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

 Association between the heart rate at 3-minutes post-spinal and the lowest arterial pressure recorded during spinal anaesthesia before delivery of the baby
 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

 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
 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

 Under the care of a specialist Obstetrician at the James Cook University Hospital who consents to his/her patients being included in the trial
 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

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# 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

Patient-facing?

HRA research summary

No