Observational study of peripheral skin temperature changes following spinal anaesthesia for category 4 lower segment caesarean section (LSCS)

IRAS ID number: 263967

Research protocol Version 8 Dated 06/05/2021

Research protocol

Study Title:

Observational study of peripheral skin temperature changes following spinal anaesthesia for category 4 lower segment caesarean section (LSCS).

Chief Investigator:

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Purpose:

In the literature there is very little observational data for the changes in peripheral limb skin temperature following regional anaesthesia in the obstetric population. It has been documented previously in the non-pregnant population that the blockade of sympathetic nerve fibres by regional anaesthesia (including spinal, epidural and lumbar plexus anaesthesia) results in vasodilation of peripheral blood vessels and an increase in the blood flow to the skin, increasing the peripheral skin temperature[1-7]. Saito et al reviewed the thermoregulatory effects of spinal and epidural anaesthesia during caesarean delivery but did not review the changes in peripheral limb skin temperature [8]. Griffin and Reynolds explored the correlation between sensory block asymmetry and a disparity in foot temperature following epidural bupivacaine administration in labour. Their findings indicated a clear association between sensory block asymmetry and the difference between the temperature of the feet. This difference can be detected simply by feeling the feet [9]. However, they did not review findings following spinal anaesthesia. The hypothesis of this study is that peripheral skin temperature will increase following regional anaesthesia/analgesia due to sympathetic block and that this temperature change could potentially be used as an indicator of potential efficacy of regional anaesthesia/analgesia. Spinal anaesthesia should reliably produce a bilateral sympathetic block. Therefore if a sympathetic block produces an increase in peripheral temperature this effect should be observable in women who have successful spinal anaesthesia for caesarean section. We propose measuring this peripheral foot temperature with Covidien Mon-a-Therm skin temperature probes and a Braun Welch Allyn tympanic membrane thermometer device. If this effect is found then this finding could be investigated in future studies to determine the value of using peripheral temperature measurement with a Braun Welch Allyn tympanic membrane thermometer device, as a marker and predictor of the efficacy of labour epidural analgesia.

Primary research question:

The hypothesis is that peripheral skin temperature of the dorsum of the feet will rise bilaterally following establishment of a spinal anaesthetic block and that the peripheral skin temperature will change with regression of the spinal anaesthetic block.

Secondary research question:

The secondary hypothesis is that an infrared tympanic thermometer could be as reliable a method of measuring temperature as a skin temperature probe and therefore be a practical accessible method for measuring peripheral skin temperature in delivery rooms.

Methods:

This is an observational study. We will obtain ethics committee approval for conducting the study. ASA 1 and 2 full term (37-42 weeks), parturients with singleton pregnancy, normal placental position, scheduled for category 4 LSCS under 'single-shot' spinal anaesthesia will be recruited. We intend to recruit 60 parturients. The parturients will undergo an informed consent process including an explanation of the methods and risks of the study. A patient information leaflet will be provided for the parturients.

The data will be collected on a password protected spread-sheet with no patient identifiable information. A grant for funding will be applied for from the Obstetric Anaesthetists' Association.

Prior to establishment of spinal anaesthesia, the skin temperature of the women's feet will be measured on the dorsum of the right and left feet above space between the 2nd and 3rd metatarsal bones while she is lying supine with left lateral tilt. The temperature will be measured by Covidien Mon-a-Therm skin temperature probes and a Braun Welch Allyn tympanic membrane thermometer device. Following spinal injection when the woman is lying supine with lateral tilt, the temperature will be re-measured by Covidien Mon-a-Therm skin temperature probes and a Braun Welch Allyn tympanic membrane thermometer device. The skin temperature of the women's feet will be monitored continuously by the Covidien Mon-a-Therm skin temperature probes using the GE Healthcare monitor with readings transcribed every 1 minute by the research investigator until transfer onto the bed at the end of surgery. The skin temperature of the women's feet will be measured and recorded every 1 minute using a Braun Welch Allyn tympanic membrane thermometer device until the sterile drapes are applied prior to commencing the operation and then again after removal of the drapes prior to transfer onto the bed. Following transfer to the post-operative recovery area, the skin temperature of the women's feet will be measured and recorded every 10 minutes using a Braun Welch Allyn tympanic membrane thermometer device until discharged to the ward from the recovery area (usually 2 hours from departmental guidelines).

Theatre room temperature will be measured and recorded at the start of anaesthesia and at the end of surgery using a room thermometer. Surgical drapes will be applied over the parturient's lower limbs during the caesarean section procedure as per our routine practice. The ambient temperature under the surgical drapes will be measured and recorded at the start of anaesthesia and at the end of surgery using a room thermometer.

Tympanic temperature will be measured by a Braun Welch Allyn tympanic membrane thermometer device before spinal anaesthesia and then every 30 minutes until the end of surgery as per NICE clinical guideline 65.

Spinal anaesthesia will be conducted as per usual practice. All intravenous fluids will be given through a fluid warmer.

Patient data to be recorded will include: Age, Weight, Height, BMI, total dose of intra-operative vasopressor given, highest estimated dermatome level of anaesthesia to cold (ethyl chloride spray) bilaterally prior to commencing surgery, level motor block using straight leg raise as per normal

practice when anaesthesia ready for surgery, duration of surgery, estimated blood loss, total volume of intravenous fluids given (including any blood products).

Dermatome level of anaesthesia will be measured to cold (ethyl chloride spray) level and motor block will be measured using straight leg raise as per normal practice, in recovery, every 30 minutes.

6 parturients will be recruited as a control group. The skin temperature of these women's feet will be measured on the dorsum of the right and left feet above space between the 2nd and 3rd metatarsal bones while she is lying supine with left lateral tilt in theatre. The temperature will be measured by Covidien Mon-a-Therm skin temperature probes and a Braun Welch Allyn tympanic membrane thermometer device. The sterile drapes will be applied and the skin temperature of the women's feet will be monitored continuously by the Covidien Mon-a-Therm skin temperature probes using the GE Healthcare monitor with readings transcribed every 1 minute by the research investigator for 30 minutes. After 30 minutes, the skin temperature of the women's feet will be measured and recorded every 1 minute using a Braun Welch Allyn tympanic membrane thermometer device for 5 minutes. Theatre room temperature will be measured and recorded for this control group of parturients. The ambient temperature under the surgical drapes will be measured and recorded using a room thermometer.

Inclusions / exclusions:

Parturients will be excluded from the study if they refuse or if they have medical conditions that may affect their peripheral temperature and therefore the results of the study. Our exclusion criteria are: Parturients converted to other forms of anaesthesia (not just spinal anaesthesia); Parturients with a pyrexia / sepsis; Parturients with peripheral vascular disease (including Raynaud's); Parturients with cardiovascular disease; Parturients with diabetes mellitus (gestational, type 1 or 2); Hypertensive disorders of pregnancy; ASA 3+ Parturients; BMI >40 or <18; Parturient refusal.

Consent:

We will assess the participants to check that they have capacity and therefore we will obtain valid consent from them. We will confirm that participants understand the purpose and nature of the research; understand what the research involves, the benefits (or lack of benefits), risks and burdens; understand the alternatives to taking part. We will also confirm that participants are able to retain the information long enough to make an effective decision, are able to make a free choice and are capable of making this particular decision at the time it needs to be made.

Informed consent will be taken from participants themselves by anaesthetists who have completed good clinical practice. Informed consent will be taken on a written consent form after a patient information leaflet detailing the study has been provided and a discussion of the details of the study has taken place.

Risks, burdens and benefits:

We have chosen methods for measuring skin temperature that are safe for patient use and already easily available in our hospital. Therefore these methods could be readily used if the results of the

trial mean that this method of temperature measurement to assess regional block can be extended to routine clinical practice.

The main risk may be allergy or skin reaction to the adhesive used on the skin temperature probe. However the probes are used routinely already in the hospital to measure skin temperature and therefore the risk is low.

Confidentiality:

Person-identifiable information will not be used unless it is absolutely necessary. If person-identifiable information is used, the minimum necessary will be used. Access to person-identifiable information will be on a strict need-to-know basis. Everyone with access to person-identifiable information will be made aware of their responsibilities. The data will be collected on a password protected spread-sheet with no patient identifiable information. If any problems arise from the processing of identifiable data these will be handled in line with data protection laws.

At the end of the study personal data will be kept for 6-12 months in case we need to check it, but anonymised research data will be kept for 10 years. This data will be saved for the purposes of data verification in a separate key, on password protected Cambridge University Hospitals NHS Foundation Trust secure computers linked to the study data by a unique participant ID.

Regulatory approval:

Before the start of the study, the following approvals will be sought:

- Health Research Authority (HRA) Approval
- NHS Research Ethics Committee (REC) review
- Confirmation of Capacity and Capability from the NHS research site.

An annual progress report (APR) will be submitted to the NHS REC within 30 days of the anniversary date on which the favourable opinion was given, and annually until the study is declared ended. It is the responsibility of the study team to produce the annual reports as required.

The study team will notify the NHS REC of the end of the study. If the study is ended prematurely, the study team will notify the NHS REC, including the reasons for the premature termination

Within one year after the end of the study, the study team will submit a final report with the results, including any publications/abstracts, to the NHS REC.

Peer review:

The study has received independent peer review from the CUH Research Advisory Committee.

Indemnity:

NHS indemnity will apply for the design, management and conduct of the study.

Amendments:

All amendments to the protocol will be discussed with the CUHNFT R&D department and submitted for HRA and REC review. Amendments submitted for regulatory review will not be implemented until the necessary regulatory approvals are received.

References:

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