SNAPSHOT OBSTETRIC NATIONAL ANAESTHETIC RESEARCH PROJECT 1 (SONAR 1)

INITIAL INFORMATION

Sponsored by - University College London (UCL)

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Principal investigator – Dr James O'Carroll MBBS FRCA. A principal investigator is the leader of the researchers at a specific site (e.g. a hospital) for a specific study.

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Study duration/length – 3 months

Abbreviation

Throughout this document the abbreviation NA is used. This stands for *Neuraxial Anaesthesia.* This is a collective term used to mean either:

- an injection into the bottom of the back, which leaves the recipient awake and pain-free during surgery. This is known as a spinal.
- an injection in the bottom of the back, which is done to place a catheter through which pain medication can be given. This is known as an epidural. If an anaesthetist gives specific additional medication through the epidural, then the epidural can be used to keep a patient comfortable during a caesarean section (CS).

NA is the ideal mode of anaesthesia used for caesarean sections but is not always possible for medical reasons. In these cases, a general anaesthetic (GA) is used. This is sometimes referred to as 'going off to sleep'.

Introduction

We do not have very good information about how well neuraxial anaesthesia during caesarean section performs, nor how intraoperative pain should be managed, or what the outcomes are for patients who experience pain during awake caesarean sections.

The aim of SONAR 1 is to:

- Estimate how often NA fails and intraoperative pain is experienced during caesarean section
- To use patient centred tools to assess the impact on patients who experience pain during caesarean section

Who will we involve?
Every adult patient who has a caesarean section, including if the caesarean section is planned or unplanned (an urgent or emergency case), at any time of day or night, and is done awake using NA.

Data Collection
There will be 3 points of data collection.

- Form 1 will be completed by the responsible anaesthetist for the case. It will collect basic anaesthetic, obstetric, and surgical information. There will be nothing on Form 1 that is not already routinely collected by hospitals for all caesarean sections.
- Form 2 will be filled in by the researcher together with the patient between 18 and 30 hours after the caesarean. It will consist of questions regarding their experience of the caesarean section, any intraoperative pain or discomfort they may have experienced, and their satisfaction with the anaesthetic care, and their quality of the recovery. It is estimated that this will take about 10-15 mins.
- Form 3 will be filled in by a researcher who calls the patient approx. 6 weeks after the caesarean section. The form will consist of questionnaires to help identify the impact to those who have had any negative experiences, compared to those who did not. These are validated questionnaires that are used to identify Post-Traumatic Stress and Post-Natal Depression. This will probably take about 10-15 mins.
- Should a patient score above a specific threshold on these Form 3 questionnaires, they will receive a letter informing them, with a list of resources. Their GP will also be informed by letter.

The results of this study will help us to better understand and manage pain during caesarean section, but also have better information when consenting patients for caesarean section and discussing risks.

Study schedule

- Patient is given a Patient Information Sheet about the surgery as early as possible within reason. This might be in a clinic, or a delivery suite, or a consultant-led labour ward. If there are any study-specific questions, these will be answered by a researcher on site. In urgent or emergency cases, this may occur after the baby is born.

- Patients are approached to be consented into the study as the earliest opportunity after the caesarean section within reason. This will likely be in the recovery area.
- If the patient has been given the Patient Information Sheet after the baby is born, then they will be given at least one hour to consider the information before being approached for consent.
- Form 1 will have already been completed by the anaesthetist, and as it solely obstetric, anaesthetic and surgical data that is routinely collected, consent is not required.
- All patients who consent will be entered into the study log, so that they can be followed up at 24 hours and 6 weeks. Patients who do not consent are also entered into the study log kept on site, but only so that researchers know how many people do not wish to consent. They will not then be contacted by the researchers.
- Only researchers who have undergone confidentiality and research method training will have access to the study log.
- Patients who do consent will complete Form 2 with a researcher no later than 24 hours (+/- 6 hours) after the caesarean section.
- Patients will then be contacted by telephone using a number they provide whilst completing Form 2 at 6 weeks (+/- 3 days) following the caesarean section. Three attempts will be made to contact the patients, but appropriate judgement will be used as it is not always possible to find time to speak on the phone in the newborn period. We anticipate that Form 3 will take 15 mins to complete. Researchers will be led by the patients as to when might be a good time for us to call.
- All the information from all the forms are entered into a study database, and there is no identifiable patient information on that database. It is specifically encrypted so that no one can be identified from the looking at the database.

Withdrawal

- Participants are free to withdraw from the study at any time and without reason. This will be recorded in the study log only to prevent unnecessary follow up.
- If they withdraw before recruitment is complete, their data will be removed from the study log and not used for analysis. If withdrawal is after the study closes, it will not be possible to remove their data as analysis will have started. This will be made clear on the study Information Sheet.

Data handling and management

- All researchers will be expected to comply with the Data Protection Act 2018
- The paper data collection forms will be kept in a secure location accessible only to the local researchers.
- Information from the paper forms will then be entered onto a central online database via a secure web-based portal

- The database will hold only anonymised data. Only researchers involved in data analysis will have access to the database. They will only be able to access it from their own hospital.
- The paper forms will be destroyed 3 months after the study closes and the database will be securely destroyed 20 years after the study closes. This is in case there are any queries about the findings.

The study was approved by both the National Research Ethics Service and the Health Research Authority.