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How common is intraoperative pain occur during caesarean delivery surgery when the patient is awake and what is the impact on mothers?

Submission date
03/06/2024

Recruitment status
No longer recruiting

Registration date
24/03/2025

Overall study status
Completed

Last Edited
12/08/2025

Condition category
Pregnancy and Childbirth

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
We do not have very good information about how well neuraxial anaesthesia (anaesthesia that aims to numb part of your body whilst remaining awake) 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 aims of this study are to:
1. Estimate how often awake caesarean section surgery fails and intraoperative pain is experienced
2. Use patient-centred tools to assess the impact on patients who experience pain during awake caesarean section

Who can participate?
Every adult patient aged 18 years and over 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.

What does the study involve?
There will be three 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, their satisfaction with the anaesthetic care, and the quality of the recovery. It is estimated that this will take about 10-15 minutes.
Form 3 will be filled in by a researcher who calls the patient about 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 minutes.
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.

What are the possible benefits and risks of participating?
There will be no specific benefit for the participants by taking part. For the future, 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.
The researchers do not think there are any disadvantages or risks to taking part. There is a small possibility that answering the questionnaire may cause you to worry or feel anxious about your anaesthetic or your recovery. Some of the questions asked at the 6-week telephone call will be about your current mood. In this call, the researchers will be using questionnaires aiming to screen for anxiety, depression, and post-traumatic stress, If the questionnaire scores suggest that you might have such symptoms, then the researchers will let you know at the time, and encourage you to visit your GP if you think that's right. The researchers will also write to you and your GP, letting them know. The letter for you will include resources and groups available to you, that you may find beneficial.

Where is the study run from?
University College London Hospital (UK)

When is the study starting and how long is it expected to run for?
April 2019 to August 2025

Who is funding the study?
1. National Institute of Academic Anaesthesia (NIAA) (UK)
2. NIHR Central London Patient Safety Research Collaboration (UK)

Who is the main contact?
Prof. Ramani Moonesinghe, Ramani.moonesinghe@nhs.net

Contact information

Type(s)
Principal investigator

Contact name
Prof Ramani Moonesinghe

ORCID ID
https://orcid.org/0000-0002-6730-5824

Contact details
University College London Hospital
235 Euston Road
London
United Kingdom

NW1 2BU
-
Ramani.moonesinghe@nhs.net

Type(s)
Scientific

Contact name
Dr Reshma Patel

ORCID ID
https://orcid.org/0000-0002-5577-886X

Contact details
University College London Hospital
235 Euston Road
London
United Kingdom
NW1 2BU
-
Reshma.patel21@nhs.net

Type(s)
Scientific

Contact name
Dr James O'Carroll

ORCID ID
https://orcid.org/0000-0001-7070-2276

Contact details
University College London Hospital
235 Euston Road
London
United Kingdom
NW1 2BU
-
James.ocarroll@nhs.net

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
265964

Protocol serial number
CPMS 58492, IRAS 265964, WKR0 - 2019 - 0036

Study information

Scientific Title
Snapshot obstetric national anaesthetic research project 1 (SONAR-1)

Acronym
SONAR 1

Study objectives
Study hypothesis:
Intraoperative pain during awake caesarean section has a negative impact on short- and medium-term postoperative outcomes.

Research Questions:
RQ1: What is the incidence of intraoperative pain reported by patients during caesarean birth performed with neuraxial anaesthesia?
RQ2 What is the incidence of incidence of intraoperative pain reported by clinicians during caesarean birth performed with neuraxial anaesthesia?
RQ3: What are the hospital, patient, clinician, anaesthetic, and obstetric-related factors associated with the incidence of pain during caesarean birth performed under neuraxial anaesthesia?
RQ4: What are the hospital, clinician, patient, anaesthetic, and obstetric-related factors associated with the short- and longer-term outcomes following caesarean birth performed under neuraxial anaesthesia?

Objectives:
1. To estimate the incidence of patient and clinician-reported intraoperative pain during caesarean birth conducted with neuraxial anaesthesia
2. To describe how intraoperative pain is managed4, and to describe how successful practice strategies are
3. To evaluate day-1 and 6-week patient-reported outcomes related to intraoperative pain during Caesarean birth
4. To evaluate the physical and psychological impact on patients of caesarean birth in the short- and medium-term using patient-reported outcome measures

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 24/05/2024, Leicester Central Research Ethics Committee (2 Redman Place, Stratford, Health Research Authority, E20 1JQ, UK; +44 (0)207 104 8066, +44 (0)207 104 8227, +44 (0)207 104 8284; leicestercentral.rec@hra.nhs.uk), ref: 24/EM/0084

Study design
Non-randomized; Both; Design type: Screening, Diagnosis, Education or Self-Management, Management of Care, Cohort study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Reproductive health and childbirth

Interventions
SONAR-1 is a study of obstetric patients undergoing caesarean sections (CS) in participating hospitals to understand how common intraoperative pain and inadequate neuraxial anaesthesia (NA)(where the patient is made numb, but is not asleep) is.

Data will be collected on all patients meeting the inclusion criteria in our participating UK hospital, UCLH, during the 4-week study period (where the aim is to recruit at least 100 patients). If the pilot study is felt to be feasible, the researchers plan to roll the study out to more hospitals, to get a feel of the scale of this problem in the whole country.

Abbreviation:
Throughout this summary the abbreviation NA is used. This stands for Neuraxial Anaesthesia. This is a collective term used to mean either:
1. An injection into the bottom of the back, which leaves the recipient awake and pain-free during surgery. This is known as a spinal.
2. 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 it 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:
1. Estimate how often NA fails and intraoperative pain is experienced during caesarean section
2. To use patient-centred tools to assess the impact on patients who experience pain during a 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 three 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, their satisfaction with the anaesthetic care, and their quality of the recovery. It is estimated that this will take about 10-15 minutes.

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, anxiety, and post-natal depression. This will probably take about 10-15 minutes.

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:
The 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 at 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 is 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. It is anticipated that Form 3 will take 15 minutes 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 is 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 by 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.

Intervention Type
Procedure/Surgery

Primary outcome(s)
The incidence of patient-reported intraoperative pain during caesarean delivery performed with neuraxial anaesthesia

Key secondary outcome(s))
1. Pain measured using the visual analog scale at 24 hours (+/- 6 hours) after delivery of the baby
2. Maternal satisfaction measured using the Maternal Satisfaction questionnaire tool at 24 hours (+/- 6 hours) after delivery of the baby
3. Pain measured using the visual analog scale at 6 weeks (+/- 3 days) after delivery of the baby
4. Anxiety measured using the Generalised Anxiety Disorder Scale (GAD7) at 6 weeks (+/- 3 days) after delivery of the baby
5. Post-traumatic stress measured using the Post-Traumatic Stress Checklist (PCL-5) at 6 weeks (+/- 3 days) after delivery of the baby
6. Depression measured using the Edinburgh Postnatal Depression Score (EPDS) at 6 weeks (+/- 3 days) after delivery of the baby

Completion date
01/08/2025

Eligibility

Key inclusion criteria
1. Aged 18 years or above
2. Gestation beyond 32/40 weeks
3. Receiving NA (spinal, labour epidural extended for surgical anaesthesia or combined spinal epidural)
4. Receiving any scheduled or unscheduled CS of any category

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group

Adult

Lower age limit
18 years

Sex
Female

Total final enrolment
3972

Key exclusion criteria
1. Patient refusal
2. Patients who are unable to provide informed consent
3. Other modes of delivery (e.g., instrumental delivery)
4. De novo GA as an anaesthetic method

Date of first enrolment
17/03/2025

Date of final enrolment
17/05/2025

Locations

Countries of recruitment
United Kingdom

England

Northern Ireland

Scotland

Wales

Australia

Study participating centre
Uclh
250 Euston Road
London
United Kingdom
NW1 2PQ

Study participating centre

Eligible NHS Hospitals
United Kingdom
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Sponsor information

Organisation
University College London

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Government

Funder Name
National Institute of Academic Anaesthesia

Alternative Name(s)
NIAA

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
United Kingdom

Funder Name
National Institute of Academic Anaesthesia

Alternative Name(s)
NIAA

Funding Body Type
Government organisation

Funding Body Subtype

Local government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request. This is because of the sensitive nature of the data, in its anonymised form in our secure web location, hosted by UCL. Access would need to be granted via the RedCap UCL team following a request from anyone other than the central study team.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		24/06/2025	25/06/2025	Yes	No
Participant information sheet	version 1.2	21/05/2024	29/07/2024	No	Yes
Protocol (other)	Lay Protocol		29/07/2024	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes