ISRCTN13247823 https://doi.org/10.1186/ISRCTN13247823

Does adjusting the dose of spinal anaesthetic for patient height improve the reliability of spinal anaesthesia?

Submission date
16/11/2022

Recruitment status
Stopped

Registration date
22/02/2023

Overall study status
Stopped

Last Edited
10/09/2025

Condition category
Pregnancy and Childbirth

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

Plain English summary of protocol

Background and study aims
Anaesthetic doctors (anaesthetists) usually recommend a 'spinal block' for planned Caesarean section. This spinal block is similar to an epidural for labour, but it involves just a single injection of local anaesthetic into the fluid at the lower part of the back. The local anaesthetic numbs the nerves of the lower part of the body and allows the operation to be carried out without feeling pain. The effects of the local anaesthetic work very quickly (faster than an epidural). No catheter is left in the back (unlike an epidural). The spinal block allows a patient to be awake and pain-free during the birth of their baby. It is usually safer than general anaesthesia and following the operation, the patient has less pain, drowsiness and nausea than after general anaesthesia. Currently, there are a few standard doses of local anaesthetic for the spinal block that individual anaesthetists can choose to use. These doses vary according to individual anaesthetists and individual centres. However, these doses do not necessarily fully take into account individual variations such as height, which can alter the extent of the area made numb. At the University Hospital of North Durham, a height–based dose of local anaesthetic for the spinal block has been devised. This has been developed over the last 11 years, with promising results. This study will compare this height–based dose of local anaesthetic, with a standard fixed dose of local anaesthetic, to help find the 'best' dose of spinal local anaesthetic for women having a Caesarean section in the future. The research aims to identify the group that most reliably achieves good pain relief during the Caesarean section, with the least amount of side effects (such as nausea and vomiting). Other variables will be investigated, including if body weight (BMI), waist circumference, spine length and the pressure of the fluid we are injecting into, have any effect on spinal block height between the two groups. In addition, the recovery times of the spinal block will be compared between the two groups.

Who can participate?
Pregnant women undergoing elective Caesarean section

What does the study involve?
The study will compare two safe spinal doses of hyperbaric 0.5% bupivacaine for Caesarean section: a standard fixed dose (2.6ml) and a height–related dose. A Patient Information Sheet

will be provided at least 48 hours before the study day. After eligible patients have agreed to provide consent to participate in the study, height and weight will be recorded. If patients fulfil the height and weight criteria for the study, then further observations will be recorded: blood pressure, heart rate and abdominal girth. Ultrasound will be used to identify the correct level for spinal injection (L3-4). Vertebral column length will then be measured. The patients will be randomised according to their height group, to receive a fixed or height–related dose of spinal local anaesthetic. The spinal injection is performed using a standardised technique in all patients. The sensory block will be tested at ten minutes to light touch and cold, using ethyl chloride spray. Two further tests to cold will be performed at fifteen and twenty minutes. The degree of the motor block will be assessed at these three times, along with an assessment of signs of a high spinal block. A standard procedure will be used to increase the height of the sensory block, should a low spinal block be identified at ten minutes. Nausea and vomiting scores will be recorded every ten minutes. Pain scores will be recorded four times during the operation. Any analgesic supplementation administered will be recorded. The volume of fluid administered during the operation will be measured. Blood pressure will be controlled using a phenylephrine infusion protocol, and the total dose of phenylephrine administered will be recorded. Relevant surgical and neonatal information will be recorded. Recordings of spinal sensory block height, motor block, pain scores, nausea and vomiting scores, blood pressure and heart rate will continue in recovery and the ward until the motor block has resolved. Analgesic requirements and mobilisation will be assessed for the first 24 hours after completion of surgery (or until discharge, whichever is sooner).

What are the possible benefits and risks of participating?
Possible benefits of participating include that the spinal sensory block height will be monitored closely and there will be prompt position change if needed at the first test at 10 minutes, to obtain an optimal block height before surgery starts. Blood pressure will be closely regulated and any change from baseline will be treated promptly, which will minimise nausea and vomiting. Pain scores will be monitored closely (at 4 points during the operation). Any high scores will result in the patient being offered analgesic supplementation, followed by general anaesthesia if necessary. Nausea and vomiting scores will be monitored closely (every ten minutes). High scores will be treated promptly by rectifying low blood pressure or administering antiemetics. Both spinal doses used (height–related and fixed doses) are known to be safe. Ultrasound will be used to accurately identify the spinal interspace to be used (lumbar level L3-4). Two other anaesthetists will be present at the time of spinal injection and can assist if the location of the correct space proves to be difficult. There are no obvious identifiable risks of participating in the study.

Where is the study run from?
University Hospital of North Durham (UK)

When is the study starting and how long is it expected to run for?
January 2020 to October 2023

Who is funding the study?
University Hospital of North Durham (UK)

Who is the main contact?
Dr Helen Brar, helen.brar@nhs.net (UK)

Contact information

Type(s)
Principal investigator

Contact name
Dr Helen Brar

ORCID ID
https://orcid.org/0000-0003-1872-3525

Contact details
University Hospital of North Durham
North Road
Durham
United Kingdom
DH1 5TW
+44 (0)7572 792915
helen.brar@nhs.net

Additional identifiers

Clinical Trials Information System (CTIS)
2022-002711-27

Integrated Research Application System (IRAS)
279712

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
IRAS 279712, CPMS 47299

Study information

Scientific Title
A randomised controlled trial comparing an individualised, height–related dose of intrathecal 0.5% hyperbaric bupivacaine with the standard fixed dose of 2.6 ml, for elective Caesarean section

Study objectives
The primary aim of this study is to test the hypothesis that adjusting the dose of spinal anaesthetic according to patient height reduces the variability in the spread of anaesthesia, compared with using a fixed dose, at ten min post spinal injection. It will also test the hypothesis that reduced variability in the spread of anaesthesia will increase the proportion of patients with a target block height of anaesthesia, defined as an upper level of the block to cold sensation up to and including the second, third or fourth thoracic dermatome (T2, T3 and T4 respectively), at ten min post spinal injection, compared with using a fixed dose of spinal anaesthetic.

As a secondary aim, the study will assess and compare the possible influence of patient term body mass index (BMI), term weight, length of the spine, patient height, term abdominal girth and an estimate of cerebrospinal fluid (CSF) pressure, on the spread of spinal anaesthesia.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 10/12/2022, West Midlands - Edgbaston Research Ethics Committee (3rd Floor Barlow House, Minshull Street, Manchester, M1 3DZ, UK; +44 (0)207 104 8070, (0)207 104 8019, (0) 2071048089; edgbaston.rec@hra.nhs.uk), ref: 20/WM/0271

Study design
Stratified randomized double-blind controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Spinal anaesthesia for elective Caesarean section

Interventions
The study will run from the participant giving consent on the morning of surgery, until discharge.

At the University Hospital of North Durham, a height-related dose of 0.5% hyperbaric bupivacaine has evolved over 11 years and 545 patients. Audit data has shown that using such an individualised dose produces predictable and reliable spinal blocks to thoracic dermatome T3. This study aims to compare an adapted version of this table dose (based on a mathematical formula) with a standard fixed dose of 2.6ml therefore at least the ED95 dose 2.6 ml 0.5% hyperbaric bupivacaine, to see if there are any differences in variability of block height at 10 min post-spinal injection, and to see if there is any difference in the proportion of patients with a target block height of T2, T3 or T4 at 10 min post spinal injection. All other variables known to affect block height will be standardised (level of injection, speed of injection, no barbotage, prompt start of phenylephrine infusion after completion of the spinal injection).

The two groups will be compared for all outcomes.
The two subgroups of patients below average height (≤ 160cm) will be compared for all outcomes.
The two subgroups of patients above average height (≥165cm) will be compared for all outcomes.

BMI or weight will not affect the dose given.

Participants in the taller and shorter populations will be allocated to receive either a fixed spinal dose (2.6ml) or a height-related spinal dose of 0.5% hyperbaric bupivacaine (the interventional dose), following computer-generated randomisation.

The computer-randomised dose group allocation (fixed or intervention group) will be placed in a sealed envelope by an initial member of the research department, who will not have any further involvement in the study. The sealed envelope containing the group allocation will be given by a second member of the research department to the spinal injector, on the morning of the Caesarean section. After viewing the group, the envelope will then be re-sealed by the spinal injector and returned to the second member of the research department, for subsequent filing. The spinal injector will not have any further direct participant contact after the spinal injection. The actual spinal dose administered, will be recorded by the injector in a second sealed envelope attached to the anaesthetic chart, should this be needed in an emergency. The envelope will be returned to the research department one day after surgery (this is expected to be unopened) for subsequent filing.

A fixed volume of 2.6 ml 0.5% hyperbaric bupivacaine has been chosen for the control group, as a previous study has established an ED95 dose of 2.5 ml 0.5% hyperbaric bupivacaine with 400 µg of diamorphine, to prevent intraoperative supplementation during spinal anaesthesia for Caesarean section. 2.6ml is therefore at least the ED95 dose. The 400 µg of diamorphine have been replaced with preservative-free (PF) morphine (100 µg) and fentanyl (15 µg) as diamorphine is no longer consistently available in the United Kingdom. The effectiveness of the morphine and fentanyl mixture has been shown to be comparable with diamorphine.

Height ranges of patients of 161 – 164 cm will be excluded from the study in both height-related and fixed-dose groups, as all of these patients would receive a dose of 2.6 ml. A large overlap of the same dose in both study groups will therefore be avoided.

The height of the patient is routinely measured at the booking antenatal clinic and is recorded in handheld notes. The height is therefore readily accessible to the attending anaesthetist. No further measurements are necessary to determine the dose needed, should a height-related dose be given in practice.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Hyperbaric bupivacaine, morphine, fentanyl

Primary outcome(s)
1. Proportion of patients at the median block height measured using cold sensation with ethyl chloride spray, for each group, +/- one dermatome, at ten min post-spinal injection
2. Proportion of patients with a block height of T2, T3 or T4 measured using cold sensation with ethyl chloride spray, at ten min post spinal injection

Key secondary outcome(s))
1. Sensory block height measured using cold sensation with ethyl chloride spray:
1.1. The mean (or median, if skewed distribution) block height at 10, 15 and 20 min post spinal injection (with surgery allowed to start at block height T4)
1.2. Time to reach a T4 inclusive block or above (10, 15 or 20 min)
1.3. Maximum block height achieved up to 20 min post spinal injection
1.3.1 Proportion of patients with a maximum block height within the target range of T2-T4 by 20

min
1.3.2. Proportion of patients with a maximum block above the target range of T2-T4 by 20 min; T1 is relatively high and C8 or higher is high
1.3.3. Proportion of patients with a maximum block height below the target range of T2-T4 by 20 min; T5 is relatively low and T6 or below is low
1.4. Failure of block: Block not considered satisfactory to proceed by 20 min post spinal injection (even if subsequently evolves so surgery can start), or epidural or general anaesthetic required, or surgical testing inadequate (allowing up to 20 min from spinal injection)
1.5. Proportion of patients blocked to T4 bilaterally at 10 min
1.6. Necessity to alter patient position to achieve target block height (position used and time in min)

2. Motor block measured using the Bromage score at 10, 15 and 20 min post spinal injection

3. Time from spinal injection to return of motor function measured by a Bromage Motor Blockade score of 4

4. Time from spinal injection to regression of cold sensation to dermatome level T10

5. Symptoms of a high subarachnoid block measured by documenting hand grasp weakness, altered mental status and respiratory distress post-spinal injection

6. Symptoms of an inadequate block measured by documenting pain and poor muscle relaxation post-spinal injection

7. Intraoperative pain measured by quantifying analgesic supplementation and using a numerical rating score

8. Postoperative pain measured using a numerical rating score

9. Systolic arterial pressure (SAP) measured using a sphygmomanometer and documenting the incidence, duration and severity of hypotension or hypertension. Hypotension and hypertension are defined as <80% or >120% of baseline SAP, respectively. Severity is defined as the lowest or highest SAP, as a proportion of baseline, for those who have hypotension or hypertension, respectively.

10. Nausea and vomiting (N/V) measured by documenting the incidence of all nausea and vomiting:
10.1. Incidence of N/V related to hypotension (SAP < 80% of baseline) or presumed hypotension
10.2. Incidence of N/V not related to hypertension (SAP >120% of baseline) or presumed hypertension
10.1. From spinal to skin incision
10.1. From skin incision to umbilical cord clamping
10.1. From umbilical cord clamping to the end of the Caesarean section

11. Total dose of phenylephrine given (boluses and infusion volumes) measured using medical notes:
11.1. From spinal injection to umbilical cord clamping
11.2. From umbilical cord clamping to the end of the Caesarean section

12. Foetal outcomes measured using Apgar scores and Acid-base status soon after birth

13. Maternal satisfaction measured using a questionnaire that assesses the quality of the intra-operative spinal block experienced, using the scale of excellent, good, fair, or poor, at the end of the study on completion of the final post-operative measurements, when a Bromage score of 4 is reached

14. Surgical satisfaction measured using a questionnaire to assess the quality of the spinal block using the scale: excellent, good, fair, poor, at the end of the operation

15. Anaesthetic satisfaction from the two anaesthetic assessors measured using a questionnaire to assess the quality of the block from spinal to incision (excluding incision) and incision to end of operation, using the scale: excellent, good, fair, poor, at the end of the operation

16. Time to first request for (as required) opioid analgesia (drug and dose) after completion of spinal injection measured using medical notes

17. Total (as required) opioid administration for the first 24 hours after completion of the Caesarean section, or whilst in hospital, if discharged earlier than 24 hours (drug and dose) measured using medical notes

18. Time to walk unaided measured using medical notes

19. Length of stay measured using medical notes

Demographic factor analysis:
1. The effect of term BMI will be measured on the median dermatomal level blocked to cold sensation in the two groups at ten, fifteen and twenty min post-spinal injection, using ethyl chloride spray

2. The effect of the following demographic variables will be assessed on the median dermatomal level blocked to cold spray in the control group of 100 patients, at ten, fifteen and twenty min post-spinal injection, using ethyl chloride spray:
2.1. Variations in block height with patient height
2.2. Association of block height with vertebral column length: C7 spine to L3-4 interspace
2.3. Association of block height with term abdominal girth
2.4. Association of block height with time between the first two CSF drops to leave the needle hub

3. Variations in block height with term weight

Completion date
02/10/2023

Reason abandoned (if study stopped)
Whilst recognising the importance of the work being undertaken by Dr Brar and her research team, CDDFT formally closed the Spinal Dose Study in 2023 following a closer assessment of the Trust's managerial systems and processes.

Eligibility

Key inclusion criteria

1. Height of ≥ 150cm and ≤ 160cm or ≥ 165cm and ≤ 175cm (rounded to nearest cm)
2. Elective Caesarean section
3. Singleton pregnancy
4. Gestation 36 weeks or greater
5. American Society of Anesthesiologists (ASA) physical status II (appendix 6) with the exception for term BMI ≥ 40
6. No known foetal abnormalities

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Female

Key exclusion criteria
1. Height < 150 cm (rounded to nearest cm)
2. Height > 175 cm (rounded to nearest cm)
3. Height ≥ 161 cm and ≤ 164 cm (rounded to nearest cm).
4. Age < 18 years
5. Known or anticipated difficult airway
6. Term BMI > 50
7. Anterior or posterior placenta praevia
8. ASA physical status III or greater (appendix 6) with the exception for term BMI ≥ 40
9. Patients with pre -existing (essential) hypertension or pregnancy –induced hypertension
10. Contraindication or refusal for spinal anaesthesia
11. Any neurological disease
12. Any spinal cord abnormality
13. Any vertebral column abnormality, such as scoliosis
14. Congenital or acquired short limbs or any other lower limb abnormality causing a reduction in height
15. Patients receiving any medications affecting the cardiovascular system
16. Any additional surgery planned (with the exception of bilateral tubal ligation)
17. Pre-existing major abdominal pathology (fibroids, significant ovarian cyst)
18. Known allergy to bupivacaine, fentanyl or morphine
19. Patients under the care of His Majesty's Prison
20. Patients who lack capacity
21. Patients who require an interpreter for communication

Date of first enrolment
01/11/2022

Date of final enrolment
02/10/2023

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
County Durham and Darlington Foundation Trust
University Hospital of North Durham
North Road
Durham
United Kingdom
DH1 5TW

Sponsor information

Organisation
County Durham and Darlington NHS Foundation Trust

ROR
https://ror.org/03vamsh08

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
County Durham and Darlington Foundation Trust

Results and Publications

Individual participant data (IPD) sharing plan
The data-sharing plans are currently unknown and will be made available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No