# Arterial cannulation with ultrasound: clinical trial protocol for a randomised controlled trial comparing handheld ultrasound *versus* palpation technique for radial artery cannulation

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## Abstract

**Background**: Early intraoperative hypotension is associated with acute kidney and myocardial injury in patients undergoing noncardiac surgery. Precise arterial blood pressure measurement before and during the induction of general anaesthesia may avert early intraoperative hypotension. However, rapid arterial cannulation in anxious, conscious patients can be challenging. We describe the protocol for a randomised controlled trial designed to test the hypothesis that readily available, handheld ultrasound-guided arterial cannulation is the optimal method in conscious patients undergoing noncardiac surgery.

**Methods**: Participants >45 yr undergoing noncardiac surgery expected to last >120 min and requiring an overnight hospital stay will be eligible. We will randomly allocate participants to undergo cannulation of the radial artery in the non-dominant arm before the induction of general or regional anaesthesia using either handheld ultrasound-guided dynamic needle position technique or palpation. The primary outcome is first-pass successful arterial cannulation, analysed by intention-to-treat. Secondary outcomes include adequacy/characteristics of the arterial waveform and complications within 24 h of cannulation. We will require 118 patients to demonstrate a doubling of successful first-pass arterial cannulation, from ~30% using the palpation approach ($\alpha=0.05$; $1-\beta=0.1$).

**Results**: This study has been approved by the NHS Health Research Authority and Health Care Research Wales (21/WA/0403) and commenced recruitment in May 2022.

**Conclusions**: This study will establish whether handheld ultrasound-guided arterial cannulation before the induction of anaesthesia should be the standard of care in patients at risk of developing perioperative organ injury after noncardiac surgery.

**Clinical trial registration**: NCT05249036.

**Keywords**: arterial cannulation; blood pressure; perioperative medicine; ultrasound; ultrasound guided

Perioperative hypotension is associated with organ injury and increased mortality in patients undergoing noncardiac surgery.[1,2] Even brief episodes of relative hypotension after the induction of general anaesthesia are associated with an increased risk of organ injury.[1] Intraoperative BP monitoring with arterial catheters detects hypotension twice as frequently as oscillometric measurements.[3] However, large limits of agreement have been observed between noninvasive

brachial cuff oscillometry *vs* invasive BP measurements in critically ill patients.[4] Provided that the arterial BP waveform is of sufficient quality,[5,6] invasive measurement before the induction of anaesthesia may enable the prompt recognition and treatment of hypotension, which may impact on clinical outcomes.[7,8] In conscious patients undergoing coronary revascularisation for ST-segment elevation myocardial infarction, invasive arterial BP monitoring reduced complications and the time to achieve vascular reperfusion.[9] Notably, comparable prospective studies are sparse in noncardiac surgery.[8]

In contrast to central venous cannulation,[10,11] the evidence base for the use of ultrasound in arterial cannulation remains unclear.[5] The most recent European Society of Anaesthesiology and Intensive Care (ESAIC) (perioperative use of ultrasound [PERSEUS] vascular access) guidelines on ultrasound-guided cannulation of an artery during elective procedures concur that the quality of evidence on which to base recommendations is generally weak, with relatively few RCTs that have a high degree of heterogeneity.[12] The advent of high-resolution low-cost handheld ultrasound probes suggests that image-guided intra-arterial access could be widely adopted. However, establishing first-pass invasive arterial BP monitoring before induction of anaesthesia with ultrasound has not been demonstrated (Table 1) in conscious, non-sedated patients at risk of perioperative organ injury,[13] in whom sedation is very likely to alter arterial BP.[14] Highly experienced cardiac anaesthetists failed to find any advantage of ultrasound-guided arterial cannulation in sedated patients before cardiac surgery.[15] This may reflect the lack of systematic examination of the dynamic needle-tip positioning approach, which appears to be superior,[16] although a recent systematic review suggests higher-quality studies are needed.[17]

Herein, we describe the protocol for an RCT designed to examine the hypothesis that arterial cannulation guided by readily available handheld ultrasound technology is superior to the more frequently used palpation technique (standard-of-care) in conscious patients before the induction of anaesthesia at increased risk of organ injury and increased mortality after noncardiac surgery (Fig 1). For the first time, this trial specifically addresses cannulation in non-sedated patients and examines whether ultrasound-guided placement reduces underdamping/resonance phenomena, which are key factors in determining the utility of physiological information derived from the radial arterial waveform.[18,19]

## Methods

### Study design

This multicentre, randomised, single-blind controlled trial has been approved by the NHS Health Research Authority and Health Care Research Wales (21/WA/0403) and registered on ClinicalTrials.gov (NCT05249036). Patient recruitment began in May 2022 at an NHS Trust in England, UK.

### Inclusion criteria

(i) Patients scheduled to undergo major elective or urgent (not requiring intervention in <24 h) noncardiac surgery under general or neuraxial anaesthesia
(ii) Age ≥45 yr
(iii) Requiring overnight hospital stay

### Exclusion criteria

(i) Anatomical deformity local to the radial artery on the non-dominant upper limb, detected either clinically or by pre-scanning with ultrasound (by an independent investigator)
(ii) Cannulation, or attempted cannulation, of the radial artery on the non-dominant upper limb within the preceding 24 h
(iii) Overlying infection on the non-dominant upper limb
(iv) Surgical site on the non-dominant upper limb

### Recruitment and screening

Eligible patients will be identified by a member of the research team either at preoperative assessment clinics or on the surgical ward if the surgical procedure is scheduled at least 24 h later. They will be given a patient information leaflet detailing the trial with an explanation of the aims, methods, anticipated benefits, and potential hazards of the trial. A member of the research team will approach potential participants and screen them against the eligibility criteria before asking for consent. All eligible patients who undergo screening will be recorded on a screening log on the investigator site file even if they decline the study. Written informed consent will be obtained on the day of surgery.

### Informed consent

The principal investigator or a suitably qualified nominee will obtain written informed consent from each participant. All potential participants are free to refuse to enter the trial or to withdraw at any time during the trial for any reason. If new safety information results in significant changes in the risk/benefit assessment, the patient information sheet and consent form will be reviewed or amended accordingly. The participants will be informed that, as defined by the UK Policy Framework for Health and Social Care Research, all documentation will be stored for a minimum of 20 yr at the end of the study.

### Investigator training

The intervention will be carried out by a senior Fellowship of the Royal College of Anaesthetists (FRCA)-qualified anaesthetist who has completed a programme of training in handheld ultrasound-guided cannulation of the radial artery. Each named investigator is required to successfully complete a programme of training run by the lead investigators. The anaesthetist must have completed the study training package (Supplementary data 1).

### Randomisation

Participants are randomly assigned (1:1) by block randomisation (by centre) to either handheld ultrasound or palpation-guided cannulation on the day of surgery to ensure a balance in sample size across groups over time (Simple + randomisation service; Sealed Envelope Ltd, London, UK). Investigators will log on to a secure web-based randomisation file to obtain a unique patient identification number and allocation to a treatment group.

**Table 1** Summary of studies detailing radial artery catheterisation in conscious participants. EMLA, eutectic mixture of local anaesthetic; N, no; SA, short axis; Y, yes.

| Study | No. of patients (control/ ultrasound) | Location | Outcomes | Approach (short/long axis) | Anaesthetised | Sedation | Operator choice of side | Definition of first-attempt success (defines 'attempt' and 'success') | Mode of analgesia | EMLA | Waveform analysis | First-attempt success rate Palpation Events | First-attempt success rate Palpation Total | First-attempt success rate Ultrasound Events | First-attempt success rate Ultrasound Total | Notes |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Shiver and colleagues[20] (2006) | 60 (30/30) | Emergency department | (i) First-attempt success (ii) Number of attempts (iii) Time (iv) Number of cannulas used | SA | N | Not mentioned | Y | Y; catheter insertion | Not described | N | N | 15 (50%) | 30 | 26 (87%) | 30 | |
| Seto and colleagues[21] (2015) | 698 (351/347) | Cardiac catheterisation laboratory | (i) First-attempt success (ii) Number of attempts (iii) Time | SA | N | Y; as per local practice | Y | Y; catheter insertion | Intra-arterial or s.c. lidocaine as per local practice | N | N | 44% | | 65% | | Intra-arterial verapamil/ nitroglycerine for spasm prophylaxis |
| Hansen and colleagues[22] (2014) | 40 (40/40) | Operating theatre (cardiac) | (i) First-attempt success (ii) Time (iii) Number of attempts (iv) Number of catheters | SA | N | Not mentioned | N | Y; catheter insertion | Lidocaine s.c. for palpation group only | N | N | 23 (58%) | 40 | 38 (95%) | 40 | Crossover study |
| Levin and colleagues[23] (2003) | 69 (35/34) | Operating theatre | (i) First-attempt success (ii) Time (iii) Number of attempts (iv) Number of catheters | SA | N | Not mentioned | Y | Y; catheter insertion | Lidocaine s.c. | N | N | 12 (34%) | 35 | 21 (62%) | 34 | |
| Peters and colleagues[15] (2015) | 125 (62/63) | Operating theatre (cardiac) | (i) First-attempt success (ii) Time (iii) Number of attempts (iv) Number of redirects (v) Complications | SA | N | Y, as per local practice | Y | Y; catheter insertion | Lidocaine s.c. | N | N | 56% | | 71% | | No significant difference between palpation/ ultrasound |
| Ueda and colleagues[24] (2015) | 749 (256/249/Doppler 254) | Operating theatre | (i) First-attempt success (ii) Time (iii) Complications | SA | Y and N; at discretion of anaesthetist | Not mentioned | Y | Y; transduced arterial waveform | Lidocaine s.c. | N | N | 101 (39%) | 256 | 132 (53%) | 249 | |
| Zaremski and colleagues[25] (2013) | 183 (91/92) | Cardiac catheterisation laboratory | (i) 'Primary' success rate (ii) Time | Operator discretion | N | Not mentioned | Y | Number of attempts not clearly defined; catheter insertion | Not described | N | N | 87% | | 87% | | No difference between palpation/ ultrasound |
| Tangwiwat and colleagues[26] (2016) | 100 (50/50) | Operating theatre (neurosurgery) | (i) First-attempt success (ii) Time (iii) Complications | Both | N | Not mentioned | Y | Y; catheter insertion | Not described | N | N | 65% | | 69% | | No significant difference between palpation/ ultrasound |
| Kiberenge and colleagues[27] (2018) | 260 (128/132) | Operating theatre | (i) First-attempt success (ii) Time (iii) Number of attempts (iv) Number of catheters | SA | Y and N; at discretion of anaesthetist | Not mentioned | Y | Y; transduced arterial waveform | Not described | N | N | 48% | | 83% | | |
| Gopalasingam and colleagues[28] (2017) | 40 (40/40) | Operating theatre (cardiac) | (i) First-attempt success (ii) Time (iii) Number of attempts (iv) Number of catheter (v) Pain | SA | N | Not mentioned | N | Y; catheter insertion | Lidocaine injection | N | N | 70% | | 90% | | Crossover study |
| Gibbons and colleagues[29] (2020) | 40 (20/20) | Emergency department | (i) First-attempt success (ii) Time (iii) Number of attempts (iv) Complications | SA | N | Not mentioned | Y | Y; catheter insertion | Lidocaine injection | N | N | 0% | | 75% | | |
| Yu and colleagues[30] (2019) | 60 (30/30) | Operating theatre | (i) First-attempt success (ii) Time (iii) Complications | SA | N | Not mentioned | Y | Y; catheter insertion | Lidocaine injection | N | N | 73% | | 97% | | |
| Men and colleagues[31] (2022) | 92 (46/46) | Operating theatre (obstetrics) | (i) First-attempt success (ii) Time (iii) Number of attempts | SA | N | Not mentioned | Y | Y; transduced arterial waveform | Median nerve block with lidocaine | N | N | | | | | Ultrasound-guided cannulation in both groups: control 78% vs median nerve block 96% |

EMLA, eutectic mixture of local anaesthetic; N, no; SA, short axis; Y, yes.
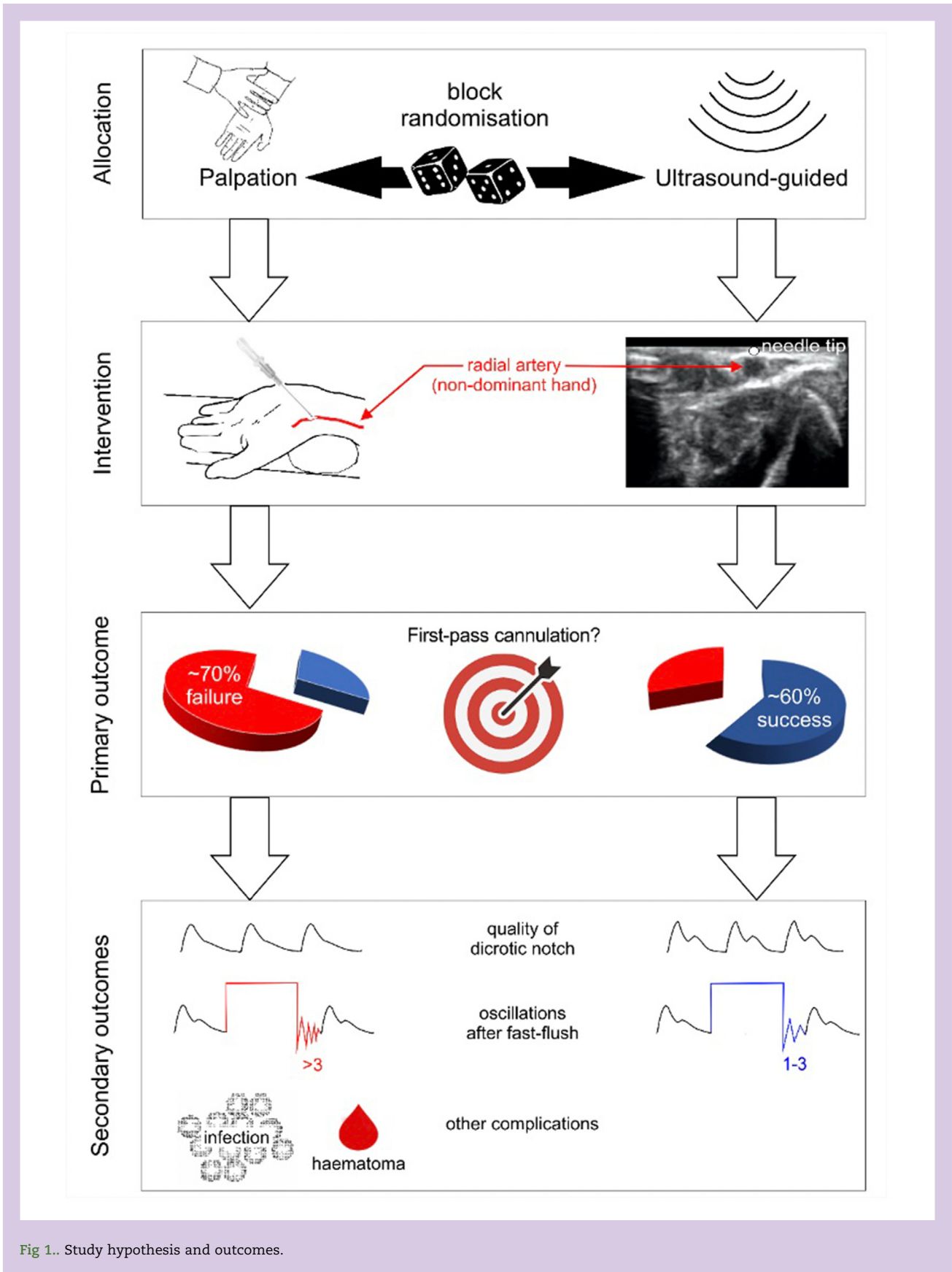
## Procedures

Topical local anaesthetic cream will be applied 1–4 cm above the crease of the wrist on the ventral forearm of the non-dominant upper limb approximately 45 min before cannulation. Several RCTs have reported that eutectic mixture of local anaesthetic (EMLA) is superior to local infiltration by reducing pain associated with radial artery cannulation and improving the success rate of the procedure compared with subcutaneous local lidocaine infiltration.[32–34] EMLA may also avoid the potential confounding of injected lidocaine influencing the development of local vasospasm,[35] bleeding, and bruising. The non-dominant hand will be draped to avoid the participant viewing the procedure and placed at the optimal extension angle of 45° for radial artery cannulation.[36] Because multiple studies have demonstrated the presence of compensatory recruitable collateral vessels that appear to be functionally recruited with ischaemia, we do not routinely undertake a modified Allen's test. This is consistent with current American Heart Association guidelines for radial arterial canulation, which observes that, 'Routine application of the Allen or Barbeau test is not a useful triage strategy, and an abnormal test should not preclude transradial access'.[37] Pre-scanning Vscan™ (GE Healthcare, Chalfont St Giles, UK) will be conducted by an independent operator to quantify radial artery diameter and any anatomical abnormalities. The Vscan probe enables cloud storage of the images.

After randomisation, under sterile conditions (chlorhexidine), the radial artery will be cannulated using a 20G catheter (Leadercath Arterial; Vygon, Swindon, UK). Cannulation will take place before the induction of general anaesthesia. Sedation will not be used to facilitate cannulation. If the participant is allocated to the ultrasound guidance group, the radial artery will be cannulated using the out-of-plane dynamic needle tip positioning technique (Fig 1) using a handheld ultrasound probe.[38] Visualisation of the needle tip using the central axis guide and intra-arterial localisation will be required to ensure consistency of technique. For participants allocated to the palpation technique group, the investigator will use their usual palpation technique using the same positioning approach. A maximum of one attempt will be allowed, defined by a single needle puncture of the skin. Further attempts to cannulate in the conscious patient will be left to the discretion of the attending clinical team. In this case, further cannulation attempts may take place for clinical indications but are not stipulated by the study protocol. An example of such a situation may be a patient with critical aortic stenosis who requires invasive haemodynamic monitoring before induction of anaesthesia.

## Data collection

On the morning of surgery, clinical data and operation type will be recorded (Supplementary data 2). The electronic patient record will be reviewed at 24 h after surgery for defined complications related to the cannulation. Data will be entered electronically on a secure database (Research Electronic Data Capture [REDCAP]).[39]

## Bias and blinding

Participants will be masked to the intervention allocation by draping of the non-dominant hand. Researchers performing arterial cannulation cannot be blinded to the allocation. However, the characteristics of the arterial waveform will be assessed by an independent investigator who is masked to the treatment allocation.

## Primary outcome

The primary outcome is the successful transduction of an arterial waveform after cannulation of the radial artery at the first attempt.

## Secondary outcomes

(i) Arterial waveform characteristics: the presence of dicrotic notch or two to three oscillations after fast flush of the arterial line indicates a satisfactory quality of waveform.[5]
(ii) Adequacy of arterial cannulation in the first 24 h after cannulation, including the need for replacement within 24 h of the procedure
(iii) Central–radial BP gradient, using noninvasive BP obtained immediately before the cannulation
(iv) Complications related to arterial cannulation at 24 h (including bleeding, thrombosis, and infection)

## Sample size

The most similar ultrasound-specific study to ours reported a first-pass success rate for ultrasound-guided radial artery catheterisation using the short-axis approach of 42% in patients undergoing cardiac angiography, although in this study liberal use of sedation was reported (Table 1). Because our study is not performed under general anaesthesia, we estimated a conservative patient withdrawal rate of 10%, a technical failure rate of 5%, and hence an approximately 35% success rate for patients randomly allocated to the palpation group. Therefore, 118 consecutive patients will be assigned to either ultrasound-guided or palpation technique to examine whether handheld ultrasound-guided cannulation improves first-pass cannulation from 35% using the palpation technique to 70% ($\alpha=0.01$; $1-\beta=0.9$; StataCorp. 2015. Stata Statistical Software: Release 14. College Station, TX).

## Statistical analysis

An independent trial statistician will analyse the primary outcome by intention to treat. Analyses will follow the intention-to-treat principle, whereby all randomised patients will be included in the analysis and analysed according to the treatment to which they were randomised. Patients will be included in the analysis, regardless of whether the treatment they received was compliant with the protocol. Patients with missing outcome data will not be excluded from the analysis. For the analysis of the primary outcome, each secondary outcome, and all process measures, we will present the following information:

(i) The number of patients included in each analysis, by treatment group
(ii) A summary statistic (e.g. mean [standard deviation] and number [%]), by treatment group
(iii) The estimated treatment effect
(iv) A 95% confidence interval for the estimated treatment effect
(v) A two-sided *P*-value

### Sensitivity analysis

A multilevel analysis will cater for the number of operators that perform procedures. There will be no more than 10 highly experienced FRCA-qualified operators with experience of >200 radial arterial cannulations plus the ultrasound study-specific training package.

### Trial management and data monitoring

The sponsor organisation is Queen Mary University of London (Joint Research Management Office, London, UK). Daily trial management will be coordinated by a trial management group consisting of the chief investigator and their support staff. An independent study committee will oversee the trial, including assessing the safety of the intervention, reviewing relevant new external evidence, and monitoring the overall conduct of the trial. This committee consists of an independent clinical triallist, lay representative, and an independent chair. Any protocol modifications will be reported by the chief investigator to the trial sponsor.

### Adverse events

Any adverse events (other than pre-specified complications) directly related to the trial intervention will be recorded.

### Confidentiality

Information related to participants will be kept confidential and managed in accordance with the Data Protection Act (UK), NHS Caldicott Principles (UK), Research Governance Framework for Health and Social Care (UK), and the conditions of the Research Ethics Committee approval. The principal investigator will maintain in strict confidence trial documents (e.g. patients' written consent forms) and patients' confidentiality. Representatives of the trial management team will require access to patient notes for quality assurance purposes and source data verification.

### Auditing

The sponsor will have oversight of the trial conduct. The trial team will ensure compliance with the requirements of Good Clinical Practice, including data quality control and safety reporting.

## Dissemination plans

Data arising from the research will be made available to the scientific community in a timely and responsible manner. A detailed scientific report will be submitted to a widely accessible scientific journal. Authorship of the final article(s), interim publications, or abstracts will be decided according to active participation in the design, accrual of eligible patients, and statistical analysis. Contributing/participating investigators will be acknowledged in the final article. We have included Kate Rivett as a lay study member, who contributed to the design of the patient information sheet. Findings from the study will be made available at www.qmul.ac.uk/ccpmg/projects/.

## Authors' contributions

Study protocol design: VL-P-K, GLA, TCE.

Drafting of article: all authors.
Subsequent revisions: all authors

## Declarations of interest

GLA is editor of the *British Journal of Anaesthesia* and performs consultancy work for GlaxoSmithKline unrelated to this work. The other authors declare no competing financial interests.

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## Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.bjao.2022.100111.

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