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# Anaesthetist-Controlled Compared with Effect-site Patient-maintained Target-controlled Sedation (ACCEPTS)

**Submission date**
04/06/2018

**Recruitment status**
No longer recruiting

**Registration date**
12/06/2018

**Overall study status**
Completed

**Last Edited**
03/12/2021

**Condition category**
Surgery

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

## Plain English summary of protocol

Background and study aims
Over 200,000 hip or knee replacements are performed annually in the UK. Many procedures are performed with patients awake rather than unconscious under a general anaesthetic. Many patients feel apprehensive about having their surgical or medical procedure awake, so doctors and nurses often give sedation medicine to reduce anxiety. The infusion of propofol, under the direction of an anaesthetist, is a popular choice for operative sedation. Medical staff judge how much sedation to provide, but patients may receive more or less sedation than they want or need. This results in poor care. The researchers want to enable patients to control their own level of sedation, so that they receive an appropriate amount of sedation and feel empowered by being able to do so. They intend to build and test a sedation device for patients to control using a simple handset. A handheld trigger will increase their sedation level, but if the patient wishes to be more awake, they can simply keep hold of the handset but not press the trigger. The device will have safety features including a 'lock-out' to prevent overdose and will only be used under the direct supervision of a specialist doctor (anaesthetist). Similar devices already exist for painkiller medicines. The device will use an existing sedation medicine and machine, but adapt the way it is operated to allow patient control. This study will directly compare patient-maintained propofol sedation with anaesthetist-controlled propofol sedation in patients undergoing hip or knee replacements (arthroplasty). The aim is to find out whether putting patients in control of their sedation results in less overall drug being used compared to when anaesthetists control the infusion, and whether patients like being in control of their own sedation.

Who can participate?
Patients aged over 18 undergoing elective primary hip or knee arthroplasty under spinal anaesthetic

What does the study involve?
Participants are randomly allocated to one of two groups. Participants in one group ACPS receive propofol sedation under the control of the usual clinical anaesthetist. Participants in the other group receive and control propofol sedation using a device under the supervision of the

usual clinical anaesthetist and a medically qualified study investigator who possesses postgraduate qualifications in the management of sedation (Fellowship of the Royal College of Anaesthetists). Rate of propofol consumption is compared between the two groups.

What are the possible benefits and risks of participating?
This technology could benefit a huge number of patients attending hospital for operations or medical investigations such as bowel or heart examinations. The device will be patient-centred (as the patient will be in control) and should therefore improve overall experience. One of the key benefits to patients may be faster recovery from surgical and medical procedures and therefore earlier discharge from hospital.

Where is the study run from?
City Hospital Nottingham (UK)

When is the study starting and how long is it expected to run for?
August 2017 to February 2020

Who is funding the study?
National Institute for Health Research (NIHR) (UK)

Who is the main contact?
Dr Nigel Bedforth
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# Contact information

### Type(s)
Scientific

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# Additional identifiers

### EudraCT/CTIS number

### IRAS number

### ClinicalTrials.gov number

### Secondary identifying numbers
37298

# Study information

### Scientific Title
A parallel-group, randomised comparison trial of anaesthetist-controlled versus patient-maintained effect-site targeted propofol sedation during elective primary lower limb arthroplasty performed under spinal anaesthesia

### Acronym
ACCEPTS Trial (Clinical Investigation Plan version 1.3)

### Study objectives
Over 200,000 hip or knee replacements are performed annually in the UK. The majority are performed under spinal anaesthesia, which makes the operative site numb, but does not affect conscious level. Sedation is commonly given to patients during surgery because many people do not like to be fully awake during their operation.

The infusion of propofol, under the direction of an anaesthetist, is a popular choice for operative sedation. Anaesthetists however, have been shown to be inaccurate judges of patients anxiety. This could result in either insufficient or excessive dosing of propofol in relation to the actual needs of individual patients. One possibility for overcoming this is allowing patients to exert control over the amount of sedation they receive.

This study will directly compare patient-maintained propofol sedation with anaesthetist-controlled propofol sedation in patients undergoing hip or knee replacements. The trialists want to know if putting patients in control of their sedation results in less overall drug being used compared to when anaesthetists control the infusion, and whether patients like being in control of their own sedation.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
Wales REC 6, favourable opinion conditional on providing further clarification 17/05/2018, ref: 18 /WA/0190

### Study design
Randomised; Interventional; Design type: Treatment, Education or Self-Management, Device

### Primary study design
Interventional

### Secondary study design
Randomised controlled trial

### Study setting(s)

Hospital

## Study type(s)
Treatment

## Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

## Health condition(s) or problem(s) studied
Hip or knee replacements

## Interventions
Enrolled participants will be randomised by block randomisation technique to one of two groups: Group: Patient-maintained propofol sedation (PMPS) and Group: Anaesthetist-controlled propofol sedation (ACPS).

Patients in Group ACPS will receive the following ACPS algorithm: the effect-site concentration will be commenced at a level determined by the supervising clinical anaesthetist and incremented and decremented by them as they see fit. No maximum or baseline levels will be pre-specified. Each participant will be sedated during surgery only.

Patients in Group PMPS will receive the following PMPS algorithm: the effect-site concentration will be commenced at 0.5 μg.mL-1 and increased by 0.2 μg.mL-1 (when the patient presses the button) to a maximum of 2.0 μg.mL-1. Following a successful button-induced increase in the effect-site target, further button presses will not increase the target concentration for 2 minutes (this is termed the lockout period). If patients do not press the button for 15 minutes, the effect-site target will reduce by 0.1 μg.mL-1, and will continue to reduce by 0.1 μg.mL-1 every 15 minutes to a minimum of 0.5 μg.mL-1 in the absence of a button-press.

Both regimes will commence in the anaesthetic room and continue in the operating room until the end of surgery at Nottingham City Hospital. After discharge from PACU the patient will return to the elective orthopaedic ward at Nottingham City Hospital for ongoing care until the time of hospital discharge. The ACCEPTS trial includes a post-operative questionnaire following hospital discharge conducted over the telephone on postoperative day 7-10, but does not include any in-patient interventions following discharge from PACU.

## Intervention Type
Drug

## Phase
Not Applicable

## Drug/device/biological/vaccine name(s)
Propofol

## Primary outcome measure
Rate of propofol consumption. The total propofol consumption in milligrams received by the patient using the PMPSD will be recorded every second throughout the sedation period on a Dell 5414 Latitude Rugged laptop. At the end of surgery, consumption will be expressed as the total number of milligrams of propofol delivered, adjusted for body weight and expressed as a

rate across the duration of the sedation period (unit: milligrams per kilogram per hour). The sedation period is defined from the time of commencement of sedation by the supervising clinical anaesthetist up until the time when surgery ends, being when clips are applied by the operating surgeon to the surgical incision.

## Secondary outcome measures

1. The depth of sedation of patients will be assessed by a study investigator at five-minute intervals during the sedation period and in the post-sedation PACU phase. The Modified Observer Assessment of Alertness and Sedation (mOAA/S) Scale will be used to determine depth of sedation. Over-sedated will be defined as mOAA/S score 1 or 0
2. Peri-operative anxiety assessed (i) pre-operatively in theatres admissions lounge (THAL) using a questionnaire in which the patient is asked to provide written check-box answers to 27 questions scored on Likert scales, and (ii) post-operative in PACU using a questionnaire administered by a study investigator once the patient is fully awake and orientated, the patient is asked to provide verbal answers to 6 questions scored on a Likert scale. After discharge from hospital, anxiety levels will be baselined using responses obtained by telephone interview administered by a study investigator: patient to provide verbal answers to 6 questions scored on a Likert scale
3. Patient satisfaction with their sedation regime assessed (i) pre-operatively in THAL where the patient is asked to provide written check-box answers to 4 yes/no/unknown baseline questions, (ii) post-operative in PACU and administered by a study investigator once the patient is fully awake and orientated the patient is asked to provide verbal answers to 22 questions scored on a Likert scale (11 of which constitute the 'Iowa Satisfaction with Sedation Scale') and if assigned to the PMPS arm of the trial a further 9 questions scored on a Likert scale plus 1 open-ended question, and (iii) after discharge from hospital and administered by a study investigator question numbers depend on trial arm assignment: if to PMPS, 4 questions scored on a Likert scale plus 6 open-ended questions; if to ACPS, 4 questions scored on a Likert scale
4. Patient recovery from surgery and anaesthesia assessed using the QoR15 questionnaire, consisting of 15 questions scored on a Likert scale. The patient is asked to provide written check-box answers to all 15 baseline questions while in THAL. A study investigator will seek verbal responses to a follow-up set of 15 questions by telephone interview with the patient after discharge from hospital
5. Time to fitness for discharge from PACU: the time in minutes from the end of the sedation period to obtain a modified Aldrete Score of 9 or greater, indicating safe to discharge from PACU, assessed and written down by a study investigator
6. The effect-site concentration of propofol estimated using the Schnider pharmacokinetic model and recorded every second during the sedation period and during patient recovery from surgery in the post-anaesthesia care unit
7. Button presses: the PMPSD will record throughout the period of sedation the number of successful (triggering an increase in effect-site concentration) and unsuccessful (not triggering an increase in effect-site concentration) button presses made by the patient
8. Sedation-related side-effects are known and predictable changes in physiological parameters that may require medical intervention and treatment, these are usually dose related. The occurrence of any of the following will be recorded during the sedation period and in PACU:
8.1. Airway, sedation-related side-effects are partial or complete airway obstruction due to reduced pharyngeal tone induced by sedation that requires the usual clinical anaesthetist to apply one of the following interventions: chin lift, jaw thrust, nasopharyngeal airway insertion, oropharyngeal airway insertion, laryngeal mask inserting, endotracheal tube insertion
8.2. Respiratory, sedation-related side-effects are respiratory rate <8 breaths/minute or arterial oxygen saturation <88% in patients with COPD, or <94% in other patients
8.3. Cardiovascular, sedation-related side-effects include heart rate or blood pressure reduction

>20% from baseline but such deviation from normal is more likely to be related to the sympathetic blockade of spinal anaesthesia in the setting of lower limb arthroplasty. All incidences of bradycardia or hypotension defined above will be reviewed by a study investigator to determine if they are spinal or sedation related. There are no objective clinical criteria to determine this, but routine clinical practice is to assimilate the presented information to estimate the likely contribution from sedation, spinal anaesthesia or another cause.
Respiratory rate, arterial oxygen saturations, heart rate, systolic blood pressure, mean blood pressure and diastolic blood pressure will be recorded at five-minute intervals by a study investigator. These parameters are all monitored as part of routine clinical care in primary lower-limb arthroplasty
9. Patient health-related quality of life assessed using the EQ-5D-5L questionnaire, consisting of 5 questions scored on a Likert scale. The patient is asked to provide written check-box answers to all 5 questions while in THAL. Verbal responses to the same 5 questions will be sought by telephone interview after the patient has been discharged from hospital
10. Patient health assessed using the EQ-VAS, a 20cm vertical scale with endpoints labelled “the best health you can imagine” and “the worst health you can imagine”. It is to be administered in THAL. A corresponding verbal rating scale will be used by a study investigator during telephone interview with the patient after their discharge from hospital

### Overall study start date
01/08/2017

### Completion date
01/02/2020

## Eligibility

### Key inclusion criteria
1. Listed to undergo elective primary hip or knee arthroplasty under spinal anaesthesia
2. Expressing a pre-operative preference for sedation during surgery
3. Able to communicate in written and spoken English
4. Capable of giving informed consent
5. Age >18 years

### Participant type(s)
Patient

### Age group
Adult

### Lower age limit
18 Years

### Sex
Both

### Target number of participants
Planned Sample Size: 80; UK Sample Size: 80

### Total final enrolment

80

### Key exclusion criteria
1. Allergy to propofol
2. Medical contraindication to spinal anaesthesia (for example local infection at injection site, patient refusal, allergy to local anaesthetic agent, untreated systemic infection, untreated coagulopathy)
3. Expressing pre-operative preference for surgery to be performed awake or under general anaesthesia.
4. Inability to use handheld trigger system of the PMPSD
5. Pregnant or breastfeeding

### Date of first enrolment
01/08/2018

### Date of final enrolment
01/08/2019

## Locations

### Countries of recruitment
England

United Kingdom

### Study participating centre
### City Hospital Nottingham
Hucknall Rd
Nottingham
United Kingdom
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## Sponsor information

### Organisation
Nottingham University Hospitals NHS Trust

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### Sponsor type
Hospital/treatment centre

### ROR
https://ror.org/05y3qh794

## Funder(s)

### Funder type
Government

### Funder Name
NIHR Central Commissioning Facility (CCF); Grant Codes: II-LA-0716-20002

## Results and Publications

### Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal.

### Intention to publish date
01/02/2021

### Individual participant data (IPD) sharing plan
The data sharing plans for the current study are 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? |
|---|---|---|---|---|---|
| Protocol article | protocol | 13/02/2019 | | Yes | No |
| Results article | | 28/11/2021 | 03/12/2021 | Yes | No |
| HRA research summary | | | 26/07/2023 | No | No |