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A pilot study comparing routine mild sedation with midazolam versus no routine sedation during spinal anaesthesia placement for elective lower-limb orthopaedic surgery

Submission date
26/05/2026

Recruitment status
No longer recruiting

Registration date
28/05/2026

Overall study status
Completed

Last Edited
27/05/2026

Condition category
Surgery

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

Plain English summary of protocol

Background and study aims
When you have a spinal anaesthetic for leg or hip surgery, the anaesthetist puts a needle in your lower back while you are awake. Some anaesthetists give a small dose of a calming medicine (called midazolam) through a drip before this happens, to help you feel less worried. Other anaesthetists do not give calming medicine and instead offer comfort measures such as music and reassurance.
Both approaches are used every day in hospitals and both are safe. Right now, we do not know which approach patients prefer. We are doing this study to find out whether it is practical to run a bigger study comparing these two approaches, and to get early information about how satisfied patients are with their experience.

Who can participate?
Patients aged 18 or older who are having planned leg or hip surgery under a spinal anaesthetic

What does the study involve?
At your pre-assessment clinic visit, the research team will give you this leaflet and explain the study. You will have time to read it at home and think about it before your surgery day. Before you go to theatre, a member of the research team will see you on the ward, answer any questions, and ask you to sign a consent form if you are happy to take part. You will then answer a few short questions (about 5 minutes) about how you are feeling.
You will be placed into one of two groups by chance (like flipping a coin). Neither you nor the research team can choose which group you go into.
Group A (no calming medicine): You will not be given calming medicine during the spinal needle placement. The anaesthetist will offer you music through headphones and will talk you through what is happening.
Group B (calming medicine): You will be given a small dose of calming medicine (midazolam) through your drip during the spinal needle placement. You will also be offered music and reassurance.

Whichever group you are in, you can ask for calming medicine at any time and you will receive it. Your comfort and safety always come first. The spinal anaesthetic itself is exactly the same in both groups. The only difference is whether you receive calming medicine while the needle is being placed.
In the recovery room (about 1 to 2 hours later), you will be asked two quick questions about your comfort during the needle placement. This takes about 1 minute.
The next day on the ward, you will be asked a few more questions about how satisfied you were and what you remember. This takes about 5 to 8 minutes. That is everything. There are no extra visits, blood tests, or scans. Your surgery and recovery carry on as normal.

What are the possible benefits and risks of participating?
Taking part will not directly help you. However, what we learn may help us give better care to future patients having spinal anaesthetics.
The risks of taking part are very small. Both approaches used in this study are part of normal hospital care.
If you are in the group that receives calming medicine (midazolam), there is a small chance you might feel a bit sleepy or lightheaded. These effects are mild and do not last long. Your anaesthetist watches you closely throughout.
If you are in the group that does not receive calming medicine, you might feel more nervous during the needle placement. But you can ask for calming medicine at any time if you feel you need it.
There is a very small chance that someone could work out who you are from the study data. We take great care to prevent this.
Both approaches in this study are part of normal care, so the chance of something going wrong because of the study is very small. All researchers are covered by the Clinical Indemnity Scheme, which is the State insurance for hospital staff.

Where is the study run from?
Cappagh National Orthopaedic Hospital (Ireland)

When is the study starting and how long is it expected to run for?
April 2026 to April 2026

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
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Additional identifiers

Study information

Scientific Title
Routine versus selective intravenous midazolam during spinal anaesthesia needling for elective lower-limb orthopaedic surgery: a single-centre pilot randomised trial (MIND-SPIN Pilot)

Acronym
MIND-SPIN Pilot

Study objectives
The primary objective of this pilot randomised trial is to determine the feasibility of a definitive randomised controlled trial comparing routine low-dose midazolam versus no routine sedation during spinal anaesthesia placement for elective lower-limb orthopaedic surgery.

Secondary objectives are to obtain preliminary estimates of patient satisfaction, procedural distress, recollection and safety outcomes, and to assess the suitability of candidate satisfaction instruments for the definitive trial.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 30/03/2026, National Orthopedic Hospital Cappagh Research Ethics Committee (Cappagh Road, Finglas, Dublin 11, Dublin, D11 EV29, Ireland; +353 18140461; Mary.Byrne@nohc.ie), ref: NOHC-2026-ETH-MB-CEO-393

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Open (masking not used)

Control
Active

Assignment
Parallel

Purpose
Treatment

Study type(s)

Health condition(s) or problem(s) studied
Procedural sedation in patients undergoing elective lower limb surgery under spinal anaesthesia

Interventions
Participants were randomised in a 1:1 ratio, stratified by age younger than 70 years versus 70 years or older, using random permuted blocks of variable size prepared in advance by an investigator not involved in recruitment. Allocation was held in sequentially numbered, opaque, sealed envelopes. The envelope was opened in the operating theatre by the attending anaesthetist before spinal needle insertion. Participants and clinical staff were not blinded to allocation because the intervention could not be concealed in routine clinical practice.

Participants undergoing elective lower-limb orthopaedic surgery under spinal anaesthesia were randomised 1:1 to either:
Arm A: No routine sedation during spinal anaesthesia placement.
Arm B: Routine mild anxiolysis during spinal anaesthesia placement using intravenous midazolam administered in 0.5–1 mg increments with a maximum dose of 3 mg before completion of intrathecal injection.

All participants received standard monitoring and standardised non-pharmacological comfort measures. Rescue sedation with intravenous midazolam was permitted in both groups according to predefined criteria, including patient request, significant distress, procedural difficulty, or safety concerns.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Midazolam

Primary outcome(s)

1. Recruitment rate measured using the number of participants enrolled per week during active recruitment at throughout recruitment period

2. Consent rate measured using the proportion of eligible patients approached who provide written informed consent at enrolment

3. Protocol adherence rate measured using the proportion of participants receiving assigned intervention without major protocol deviation at during spinal anaesthesia placement

4. Rescue sedation rate measured using the proportion of participants requiring rescue sedation during the spinal needling window at during spinal anaesthesia placement

5. Outcome completion rate measured using the proportion of participants with complete post-anesthesia care unit (PACU) and 24-hour outcome data at 1–2 hours postoperatively and 24 hours postoperatively

Key secondary outcome(s)
1. Patient satisfaction measured using validated anaesthesia-specific satisfaction instrument (Evaluation du Vécu de l'Anesthésie LocoRégionale [EVAN-LR]) and a single-item global satisfaction (Numeric Rating Scale [NRS]) at 24 hours postoperatively

2. Procedural distress during spinal needling measured using a 0–10 numeric rating scale at post surgery in the PACU

3. Pain during spinal needling measured using a 0–10 numeric rating scale at post surgery in the PACU

4. Recollection of spinal anaesthesia placement measured using recollection questions at 24 hours postoperatively

Completion date
30/04/2026

Eligibility

Key inclusion criteria
1. Adults aged 18 years or older
2. Scheduled for elective lower-limb orthopaedic surgery under spinal anaesthesia as the primary anaesthetic technique
3. American Society of Anesthesiologists (ASA) physical status I–III
4. Able to provide written informed consent
5. Able to complete study questionnaires in the validated study language

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
100 Years

Sex
All

Total final enrolment
67

Key exclusion criteria
1. Cases with planned general anaesthesia in combination with spinal anaesthesia from the outset
2. Known contraindication or documented hypersensitivity to benzodiazepines
3. Known history of severe paradoxical reaction to benzodiazepines
4. Severe cognitive, linguistic, or sensory communication barriers preventing valid questionnaire completion
5. Clinical situations where the attending anaesthetist determines that sedation is mandatory for patient safety prior to randomisation
6. Participation in another interventional clinical trial that may affect the outcomes of this study.

Exclusion criteria are intentionally limited to preserve the pragmatic nature of the trial and to ensure that the pilot population is representative of the population that will be enrolled in the definitive trial.

Date of first enrolment
07/04/2026

Date of final enrolment
30/04/2026

Locations

Countries of recruitment
Ireland

Sponsor information

Organisation
Cappagh National Orthopaedic Hospital

ROR
https://ror.org/03vc5bf16

Funder(s)

Funder type

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available