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# The effect of regional anaesthesia and sedation using dexmedetomidine on the effects of the anaesthesia after surgery

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| **Submission date**<br>20/04/2020 | **Recruitment status**<br>No longer recruiting | [X] Prospectively registered<br>[X] Protocol<br>[X] Statistical analysis plan<br>[X] Results<br>[_] Individual participant data |
| **Registration date**<br>27/04/2020 | **Overall study status**<br>Completed | |
| **Last Edited**<br>29/05/2025 | **Condition category**<br>Surgery | |

## Plain English summary of protocol

Background and study aims
One of the most frequent postoperative complications in the elderly with an incidence of 5 - 50% are postoperative cognitive disorders, namely sudden confusion (delirium) and postoperative cognitive dysfunction which is diagnosed with psychometric testing. (Cognitive dysfunction refers to deficits in attention, verbal and nonverbal learning, short-term and working memory, visual and auditory processing, problem-solving, processing speed, and motor functioning). Both delirium and Post-operative cognitive dysfunction have been associated with significant financial costs for the care of these patients both in- and out- of hospital, as well as reduced ability to carry out daily activities after leaving the hospital, which affects their quality of life and potentially disrupts the balance in their families.
Dexmedetomidine is an anxiety-reducing, sedative, and pain medication. Dexmedetomidine is notable for its ability to provide sedation without risk of respiratory depression (unlike other commonly used drugs such as propofol and fentanyl) and can provide cooperative or semi-rousable sedation. Propofol is a short-acting medication that results in a decreased level of consciousness and lack of memory for events.

Who can participate?
Adults aged over 65 years old, scheduled for total knee or hip replacement and peripheral vascular surgery under regional anaesthesia.

What does the study involve?
Participants will be randomly allocated to receive dexmedetomidine or propofol for sedation during their operation. Patients will be required to complete some questionnaires and assessments before and after the procedure and during follow up appointments.

What are the possible benefits and risks of participating?
Benefits: No direct benefit to taking part.
Risks: The main adverse effects of dexmedetomidine administration are bradycardia and hypotension. Propofol administration carries the same risks plus significant respiratory depression if it is not titrated properly.

Where is the study run from?
University Hospital of Heraklion

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

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Prof. Alexandra Papaioannou (scientific), alpapa@med.uoc.gr
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# Additional identifiers

### EudraCT/CTIS number
Nil known

### IRAS number

### ClinicalTrials.gov number
Nil known

### Secondary identifying numbers
VK 001

# Study information

### Scientific Title
Effect of dexmedetomidine on delirium and postoperative cognitive dysfunction in patients undergoing orthopedic or vascular surgery under regional anesthesia

### Study objectives
The present research protocol aims to elucidate the effect of intraoperative administration of dexmedetomidine as sedation agent on the appearance of postoperative delirium, postoperative cognitive dysfunction and quality of sleep in elderly patients undergoing orthopedic or vascular surgical procedures under regional anesthesia.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
Approved 11/03/2014, Ethics Committee and the Scientific Board of the University Hospital of Heraklion (Voutes, Heraklion, Crete, Greece; +30 2810392478; researchprot@pagni.gr), ref: 3548 /11-03-2014

### Study design
Single-centre cluster randomized study

### Primary study design
Interventional

### Secondary study design
Cluster randomised trial

### Study setting(s)
Hospital

### Study type(s)
Prevention

### Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

## Health condition(s) or problem(s) studied
Sedation during regional anaesthesia

## Interventions
Patients undergoing orthopaedic or vascular surgery under regional anaesthesia will be randomized with the method of random numbers to receive either dexmedetomidine or propofol for intraoperative sedation.

Anaesthesia and postoperative analgesia will be based solely on purely regional techniques with the following options:
A. Epidural anaesthesia/analgesia: Under local anaesthesia epidural catheter placement in the lumbar spine at the vertebral spaces L2-L3 or L3-L4. Through the catheter, there will be a titrated infusion of local anaesthetic. The catheter will remain for postoperative analgesia.
B. Spinal anaesthesia in combination with femoral nerve blocking:
Under local anaesthesia, spinal anaesthesia will be performed at the L3-L4 or L4-L5 spaces with the use of hyperbaric bupivacaine. At the end of surgery and after the partial resolution of spinal anaesthesia, femoral nerve block will be performed under ultrasound guidance.

Patients intraoperatively will receive either dexmedetomidine (study group) or propofol or midazolam for sedation according to the clinical practice (control group). The aim of intraoperative sedation will be to maintain the patient at stage 3 or 4 of the Ramsay sedation scale 3-4
Postoperatively in order to enhance analgesia, patients will receive oral paracetamol 1 gr every 8 hours, while in case of inadequate analgesia with regional techniques, tramadol 100mg will be administered.

Patients will receive the allocated treatment i.e. sedation with either dexmedetomidine or propofol intraoperatively, that is 1.5 – 3 hours, and they will be followed up for up to 4 months postoperatively.

## Intervention Type
Drug

## Phase
Phase IV

## Drug/device/biological/vaccine name(s)
Dexmedetomidine, propofol

## Primary outcome measure
1. Postoperative delirium. All patients will be monitored daily for the immediate post-operative period for the appearance of confusion or delirium or for any anesthetic or surgical complications. For the diagnosis of delirium, the Confusion Assessment Method will be used.
2. Postoperative cognitive dysfunction. The mental state of patients will be controlled by a group of assays, (European Psychometric Test - EUPT battery):
2.1. Visual Verbal Learning Test
2.2. Concept Shifting Task
2.3. Stroop Colour-Word Test

2.4. Letter-Digit Coding Test
Postoperatively patients who will experience a reduction of> 20% of their performance in at least 2 of these trials will be considered to have postoperative mental dysfunction
2.5. The Cognitive Failure Questionnaire and the Zung Self-Calibrated Depression Scale will be used in the form of a questionnaire completed by the patient and a rough subjective indicator of his mental and psychological state

Patients will undergo psychometric tests at three times:
• Before anaesthesia and during the pre-anesthetic examination
• The fourth to seventh postoperative day and before the patient leaves the hospital, and
• Two to three months after surgery. If patients are unable to go to the hospital, they will be examined at home.
In all three sessions, patients will be examined by the same investigator, who will not know the type of sedation given to the patient.

### Secondary outcome measures
1. The quality of sleep measured using the Pittsburgh Sleep Quality Index (PSQI) the day before surgery and all the postoperative days they remain hospitalized
2. The incidence of chronic pain after total hip or knee replacement 2-3 months after the operation measured using the painDETECT screening questionnaire

### Overall study start date
05/02/2014

### Completion date
10/05/2023

## Eligibility

### Key inclusion criteria
1. Undergoing orthopaedic or vascular surgery under regional anaesthesia
2. Age >65 years
3. Medical history and preoperative anaesthetic assessment to allow regional anesthesia to be used
4. Must know writing and reading
5. Remain in the hospital for at least four days
6. Expected postoperative survival is at least one year (on malignant neoplasms) and with a small chance of re-operation within three months

### Participant type(s)
Patient

### Age group
Senior

### Lower age limit
65 Years

### Sex
Both

### Target number of participants
120 per group

### Total final enrolment
80

### Key exclusion criteria
1. Refuse to receive regional anesthesia or to participate in the study
2. Central nervous system disease (infectious, metabolic, degenerative, neoplastic, or major psychosis)
3. Severe vision or hearing impairment
4. Alcoholics or drug abusers
5. Severe general condition or in end-stage neoplasm
6. Contraindications for regional anaesthesia:
6.1. Coagulation disorders:
6.1.1. INR> 1.4
6.1.2. Platelet count <100,000 / μl
6.1.3. Active/uncontrolled bleeding
6.1.4. Lack of coagulation factors
6.1.5. Administration of anticoagulants/antiplatelet drugs in a prophylactic dose for thromboembolic episodes (prior to epidural puncture)
6.2. Inflammation at the lumbar region
6.3. Increased intracranial pressure of any cause or CNS tumor
7. Less than 24 points in the Mini Mental Status Exam during the preoperative assessment

### Date of first enrolment
10/05/2020

### Date of final enrolment
10/02/2023

## Locations

### Countries of recruitment
Greece

### Study participating centre
**University Hospital of Heraklion**
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University/education

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**ROR**
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# Funder(s)

**Funder type**
Other

**Funder Name**
Investigator initiated and funded

# Results and Publications

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

**Intention to publish date**
10/05/2024

**Individual participant data (IPD) sharing plan**
All data generated or analysed during this study will be included in the subsequent results publication.

**IPD sharing plan summary**
Other

**Study outputs**

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Protocol file | | | 18/05/2020 | No | No |
| Statistical Analysis Plan | | | 22/02/2024 | No | No |
| Results article | | 22/05/2025 | 29/05/2025 | Yes | No |