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Low-dose dexmedetomidine to prevent postoperative delirium in older adults undergoing hip fracture surgery

Submission date
22/09/2026

Recruitment status
No longer recruiting

Registration date
29/09/2026

Overall study status
Completed

Last Edited
29/09/2026

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Postoperative delirium is a common complication in older adults after hip fracture surgery. It can cause confusion, distress and poorer recovery. Dexmedetomidine is a medicine that is sometimes used during and after surgery for its sedative and pain-relieving effects. This study aims to find out whether a low dose of dexmedetomidine given around the time of surgery can reduce the number of older adults who develop postoperative delirium in the first seven days after hip fracture surgery. The study also compares delirium severity and duration, pain levels, use of rescue morphine, anaesthetic and pain-relief requirements, haemodynamic parameters and length of hospital stay between people receiving dexmedetomidine and those receiving a placebo.

Who can participate?
Adults aged 65 years or older with a femoral neck fracture or intertrochanteric femoral fracture who are scheduled to undergo surgical repair within 48 hours of hospital admission and who provide informed consent, either themselves or through a legally authorised representative.

What does the study involve?
Participants are randomly allocated to receive either dexmedetomidine or a placebo in a 1:1 ratio. The dexmedetomidine group receives the drug through a vein before and during surgery and for a period after surgery. The placebo group receives an equivalent volume of normal saline according to the same schedule. Participants, healthcare staff involved in postoperative care, outcome assessors and data analysts do not know which treatment has been allocated. All participants receive standard general anaesthesia and postoperative pain management. Researchers assess participants for postoperative delirium twice daily during the first seven days after surgery using the Confusion Assessment Method (CAM).

What are the possible benefits and risks of participating?
Participants receiving dexmedetomidine may experience a lower risk of postoperative delirium, although this cannot be guaranteed. Information from the study may help improve the care of older adults undergoing hip fracture surgery. Risks include possible side effects associated with

dexmedetomidine administration. Participants receiving placebo will not receive the active study drug.

Where is the study run from?
Saigon ITO Phu Nhuan Hospital, Ho Chi Minh City, Viet Nam.

When is the study starting and how long is it expected to run for?
December 2024 to April 2026.

Who is funding the study?
Saigon ITO Phu Nhuan Hospital, Ho Chi Minh City, Viet Nam.

Who is the main contact?
Dr Ta Duc Luan, bsluan.gmhs@gmail.com

Contact information

Type(s)
Public, Scientific, Principal investigator

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Study information

Scientific Title
Low-dose perioperative dexmedetomidine for the prevention of postoperative delirium in older adults undergoing hip fracture surgery: a randomized, double-blind, placebo-controlled trial

Study objectives
The primary objective is to evaluate whether perioperative low-dose dexmedetomidine reduces the cumulative incidence of postoperative delirium during the first 7 postoperative days in older adults undergoing hip fracture surgery.

Secondary objectives are to compare delirium severity and duration, postoperative pain intensity, 24-hour rescue morphine consumption, perioperative anaesthetic and analgesic requirements, haemodynamic parameters, and length of hospital stay between the dexmedetomidine and placebo groups.

Ethics approval required

Ethics approval required

Ethics approval(s)
Approved 07/05/2024, Scientific and Technical Ethics Committee of Saigon ITO Hospital System (305 Lê Văn S, Phưng Tân Sơn Hòa, TP.HCM, Ho Chi Minh, 10000, Viet Nam; +84 02839912030; bsluan.gmhs@gmail.com), ref: 24/HĐKHKT-SGITO

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Placebo

Assignment
Parallel

Purpose
Prevention

Study type(s)

Health condition(s) or problem(s) studied
Postoperative delirium in older adults undergoing surgery for hip fracture

Interventions
Participants were randomly assigned in a 1:1 ratio to either the dexmedetomidine group or the placebo group using a computer-generated randomisation sequence. Randomisation uses variable block sizes of four and six. Allocation concealment was maintained using sequentially numbered, sealed, opaque envelopes.Participants, postoperative outcome assessors, surgeons, ward staff, and data analysts are blinded to treatment allocation.

Dexmedetomidine group: dexmedetomidine 0.2 μg/kg administered intravenously over 10 minutes before induction of general anaesthesia, followed by a continuous intravenous infusion of 0.15 μg/kg/hour during surgery and continued postoperatively for a mean duration of 7.4 ± 0.8 hours.

Placebo group: an equivalent volume of 0.9% normal saline administered intravenously at the same infusion rate and according to the same schedule.

All participants receive standardized general anaesthesia and standardized multimodal postoperative analgesia, including continuous fascia iliaca compartment block with 0.2% ropivacaine, celecoxib, intravenous paracetamol, intravenous nefopam, and ketorolac. Rescue intravenous morphine is administered when pain control is inadequate.

Intervention Type

Drug

Phase
Not Applicable

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

Primary outcome(s)
1. Cumulative incidence of postoperative delirium within the first 7 postoperative days measured using the Confusion Assessment Method (CAM) at twice daily time points

Key secondary outcome(s)

Completion date
22/04/2026

Eligibility

Key inclusion criteria
1. Age 65 years or older
2. Diagnosis of femoral neck fracture or intertrochanteric femoral fracture
3. Scheduled to undergo surgical repair within 48 hours of hospital admission
4. Written informed consent obtained from the participant or their legally authorised representative

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
65 Years

Sex
All

Total final enrolment
486

Key exclusion criteria
1. Preoperative delirium
2. Mini-Mental State Examination (MMSE) score <18
3. Parkinson's disease
4. Severe dementia
5. Second- or third-degree atrioventricular block without a permanent pacemaker

6. Resting heart rate <50 beats/min
7. Systolic blood pressure <100 mmHg
8. Child–Pugh class C liver disease
9. Known hypersensitivity to dexmedetomidine

Date of first enrolment
01/12/2024

Date of final enrolment
15/04/2026

Locations

Countries of recruitment
Viet Nam

Sponsor information

Organisation
Saigon ITO Phu Nhuan Hospital

Funder(s)

Funder type

Funder Name
Saigon ITO Phu Nhuan Hospital

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file			23/09/2026	No	No