ISRCTN85517037 https://doi.org/10.1186/ISRCTN85517037

The timing and dose of dexmedetomidine on postoperative delirium

Submission date	Recruitment status	[ ] Prospectively registered
02/02/2018	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
06/02/2018	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
05/02/2018	Surgery	[ ] Record updated in last year

Plain English summary of protocol
Background and study aims
Delirium is a state of mental confusion that can occur after surgery. This is very common in elderly patients undergoing major surgery including cardiac surgery, and is a relatively frequent and serious complication. Previous studies have reported that sedation with the medication called dexmedetomidine (a medication that can reduce anxiety or used as a sedative) can be associated with a lower incidence, duration, and severity of postoperative delirium. The aim of this study is to examine three different types and timing of dexmedetomidine dosages on stress in older patients who are undergoing surgery.

Who can participate?
Adults aged 65 and older who are scheduled for a major non-cardiac surgery and will be undergoing general anesthesia.

What does the study involve?
Participants are randomly allocated to one of three groups. Those in the first group receive dexmedetomidine from the start of anaesthesia to the end of the surgery. Those in the second group receive dexmedatomidine 15 minutes before the end of surgery. Those in the last group receive saline for 15 minutes before the end of surgery. Participants are assessed for their delirium for five days after surgery.

What are the possible benefits and risks of participating?
Participants may benefit from improvements in their symptoms. There are small risks of discomfort and bleeding when providing blood samples.

Where is the study run from?
Wonkwang University Hospital (South Korea)

When is the study starting and how long is it expected to run for?
February 2016 to June 2017

Who is funding the study?
Wonkwang University (South Korea)

Who is the main contact?
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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
N/A

Study information

Scientific Title
The effect of the timing and dose of dexmedetomidine on postoperative delirium in elderly patients after laparoscopic major non-cardiac surgery

Study objectives
Various dexmedetomidine dosage and timing regimens would vary the concentration of stress hormones and systemic inflammatory response to surgery. The changes in the concentrations of stress hormones and inflammatory mediators released in response to surgery would be affected the incidence and duration of postoperative delirium.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Institutional review board of Wonkwang University Hospital, 05/04/2016, ref: Registration No. 3001

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Patients >65 years of age undergoing laparoscopic major non-cardiac surgery under general anesthesia

Interventions
Participants are randomly assigned following simple randomization procedures (computerized random numbers) to 1 of 3 treatment groups:

1. Group D1 receive dexmedetomidin in a 1 μg/kg bolus followed by 0.2 to 0.7 μg/kg/ h infusion from induction of anesthesia to the end of surgery
2. Group D2 receive dexmedetomidine in a 1 μg/kg diluted to a total volume of 10 mL in saline [0.9%] over a 10 min period) at 15 min before the end of surgery
3. Group S receive an equivalent volume of saline 15 minutes before the end of surgery.

Participants are blinded to the anesthetic agent; however, anesthesiologists and nurses are not because they needed to adjust the timing and dose of dexmedetomidine. The researchers who assess the outcomes are, however, blinded.

Participants are assessed for delirium for 5 days after surgery.

Intervention Type
Drug

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

Primary outcome measure
The incidence of delirium is mesaured using the confusion assessment method (CAM) for 5 days after surgery.

Secondary outcome measures
1. Duration of delirium is measured using the confusion assessment method (CAM) up to five days after surgery
2. Cortisol levels are measured using saliva samples at one and 24 hours after surgery
3. C-reactive protein (CRP), and cytokine (tumor necrosis factor [TNF]-alpha, interleukin [IL]-1β, IL-2, IL-6, IL-8, and IL-10) levels measured using blood samples at one and 24 hours after surgery

Overall study start date
01/02/2016

Completion date
10/06/2017

Eligibility

Key inclusion criteria
1. Patients > 65 years of age
2. Classified as class I or III according to the American Society of Anesthesiologists (ASA)
3. Scheduled for laparoscopic major non-cardiac surgery under general anesthesia

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
354

Key exclusion criteria
1. Patients with a history of kidney or liver disease
2. History of allergy to the drug being studied
3. Cognitive impairment
4. Use of antipsychotic alpha-2 agonists or antagonist medications
5. Use of anti-inflammatory drugs

Date of first enrolment
01/05/2016

Date of final enrolment
30/05/2017

Locations

Countries of recruitment
Korea, South

Study participating centre
Wonkwang University Hospital
Muwang-ro 895
Iksan
Korea, South
54538

Sponsor information

Organisation
Wonkwang University Hospital

Sponsor details
Muwang-ro 895
Iksan
Korea, South
54538

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/0183m5185

Funder(s)

Funder type
University/education

Funder Name
Wonkwang University

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
Korea, South

Results and Publications

Publication and dissemination plan
Plans to publish in the Journal of Clinical Anesthesia.

Intention to publish date
30/07/2017

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a non-publically available repository at the Institutional Review Board for five years after finishing the study.

IPD sharing plan summary
Stored in repository