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Patient safety and satisfaction with dexmedetomidine sedation during endoscopic oesophageal interventions

Submission date	Recruitment status	[_] Prospectively registered
03/04/2013	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
16/04/2013	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
08/03/2016	Surgery	

Plain English summary of protocol

Background and study aims
Endoscopic treatment of early neoplastic lesions in the oesophagus has become a valid and less invasive alternative than surgical resection. These endoscopic interventions are minimal invasive treatment options usually done with sedation on an outpatient basis. The aim of this study is to determine how well dexmedetomidine sedation works compared to standard propofol /alfentanil sedation during endoscopic oesophageal interventions.

Who can participate?
Patients planned to undergo an elective endoscopic oesophagus intervention.

What does the study involve?
Participants are randomly allocated to one of two groups: Group 1 will receive sedation with propofol TCI/alfentanil by an anaesthesia nurse. Group 2 will receive dexmedetomidine by anaesthesia nurse. All patients will receive a validated questionnaire to fill in before and after the procedure. Additionally, endoscopists have to fill in a validated questionnaire. Patients also have to perform the Trieger dot test (combine points with a pen). The following day there is a phone interview with another questionnaire about satisfaction.

What are the possible benefits and risks of participating?
The study will help answer the question of which form of sedation is most satisfying and safe for patients, and to improve sedation management for future patients. There are no additional risks of participating.

Where is the study run from?
AMC, Amsterdam, the Netherlands

When is the study starting and how long is it expected to run for?
July 2012 to August 2013

Who is funding the study?
AMC, Amsterdam, the Netherlands

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
2011-004206-19

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
NL36861.018.11

Study information

Scientific Title
Safety and Effectiveness using DEXmedetomidine sedation versus propofol/alfentanil sedation during oesophagus interventions

Acronym
SEDEX

Study objectives
Dexmedetomidine sedation is as safe as the standard sedation regime and results in satisfied patients.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Medisch Ethische Toetsingscommissie Academisch Medisch Centrum, 12/01/2012, NL36861.018.11

Study design
Single-center randomized controlled study

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 below to request a patient information sheet'

Health condition(s) or problem(s) studied
Elective endoscopic oesophageal interventions

Interventions
The study compares two strategies for sedation: Dexmedetomidine based sedation will be compared with propofol/alfentanil sedation both accomplished by an anaesthesia nurse.
All patients will receive a validated questionnaire to fill in before procedure and perform the Trieger test as a measure of psychomotoric recovery from sedation.
Additionally, endoscopists have to fill in a validated questionnaire.
Group 1 will receive sedation with propofol Target Controlled Infusion (TCI)/ alfentanil (100 µg) and group 2 with dexmedetomidine both supplied by an anesthesia nurse to achieve the targeted sedation score (Observers Assessment of Alertness/Sedation OAAS Scale < 4), which means the patients maximal lethargic response to their name spoken in normal tone. Patients in all three groups will be monitored using SO2, ECG, NIBP and capnography, non invasive cardiac output and sweat production/conduction. All patients will receive a face mask with 2l of oxygen from start of sedation till the end of the endoscopic procedure.
At arrival in the recovery room patients will be monitored by pulse oximetry (SO2), ECG and NIBP only.
All patients will stay in the recovery room for 2 hours. At arrival, 30 and 60 min later virtual discharge will be determined based on Aldrete Score.
Ready for discharge will be declared when an Aldrete Score of nine (9) or pre-procedure score is met.
The next day the patient is called at home to answer part 2 of the questionnaire.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Dexmedetomidine, Propofol, Alfentanil

Primary outcome measure
Which form of sedation is safer for the patient in regard to respiratory and cardiovascular problems? Surrogate parameters of pulmonary and cardiovascular problems are oxygen saturation (SO2) measured by pulse oximetry, exhaled CO2 (capnography), heart rate, arrhythmias (ECG) and blood pressure (non-invasive blood pressure measurement (NIBP) and non- invasive cardiac output measurement.

Secondary outcome measures
How is the effectiveness of dexmedetomidine compared with propofol/alfentanil during oesophagus interventions? Surrogate parameters of effectiveness are satisfaction levels, pain score, sedation score (questionnaire for patients and gastroenterologists).

Overall study start date
16/07/2012

Completion date
01/08/2013

Eligibility

Key inclusion criteria
Eligible patients for participation in this clinical trial are those planned to undergo elective endoscopic oesophagus intervention. The patients must comply with the following criteria in order to be eligible to participate in this clinical study:
1. Male and female, age range ≥ 18 years without upper age limit
2. ASA classification I III
3. Written informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants

Key exclusion criteria
1. Age range < 18 years
2. ASA classification IV and V
3. Allergic reaction to planned medication in the patients medical history
4. Unregulated hypertension
5. Hypovolemia or hypotension (systolic blood pressure <80 or mean arterial pressure <50 mmHg)
6. Severe bradycardia (heart rate < 50/min) and / or related brady-dysrhythmias (e.g. advanced heart block)
7. Impaired ventricular function (left ventricular ejection fraction <30%)
8. Impaired renal function, GFR less than 15ml/min or undergoing hemodialysis
9. Impaired liver function
10. Substance abuse

Date of first enrolment
16/07/2012

Date of final enrolment
01/08/2013

Locations

Countries of recruitment
Netherlands

Study participating centre
Academic Medical Centre
Amsterdam
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Sponsor information

Organisation
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/03t4gr691

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Academisch Medisch Centrum

Alternative Name(s)
Academic Medical Center, AMC

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
Netherlands

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?

Protocol article	protocol	30/12/2013	Yes	No
Results article	results	01/09/2016	Yes	No