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Efficacy of Dexmedetomine versus Ketofol for sedation of postoperative mechanically ventilated patients with obstructive sleep apnea

Submission date
10/04/2017

Recruitment status
No longer recruiting

Registration date
12/04/2017

Overall study status
Completed

Last Edited
07/06/2023

Condition category
Respiratory

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Obstructive sleep apnoea (OSA) is a common condition in which the upper airways (wind pipe) collapse repeatedly during sleep, stopping the flow of air into the lungs. This prevents the sufferer from being able to breathe properly while they are asleep, causing excessive sleepiness throughout their waking hours. Patients with OSA are at risk of developing lung complications following surgery, meaning that use of pain killers and sedatives during care after surgery needs to be restricted. Dexmedetomidine is an anxiety reducing, sedative, and pain medication, which may be useful in the post-operative period for patients with OSA who are having surgery. Ketofol is a medication made from a mixture of ketamine (a medication mainly used for starting and maintaining anesthesia) and propofol (a sedative), which has been shown to be effective at reducing the dose of sedatives needed by patients and so reducing the risk of lung complications. The aim of this study is to look at the effectiveness of dexmedetomine versus ketofol for sedation of patients with OSA after surgery that need help breathing.

Who can participate?
Adults aged between 18 and 50 years who have obstructive sleep apnea and require mechanical ventilation.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group receive dexmedetomine through a drip and those in the second group receive ketofol through a drip to provide sedation. Both groups receive sedation for a total of 12 hours after surgery while they undergo mechanical ventilation (use of a breathing machine). The length of time they need to stay on the breathing machine and the length of their hospital stay is recorded. In addition, their vital signs are monitored throughout.

What are the possible benefits and risks of participating?
There are no notable benefits or risks involved with participating.

Where is the study run from?
Benisuef University Hospital (Egypt)

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

Who is funding the study?
Investigator initiated and funded (Egypt)

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
Efficacy of Dexmedetomine versus Ketofol for sedation of postoperative mechanically ventilated patients with obstructive sleep apnea

Study objectives

The aim of this study is to compare the efficacy of Dexmedetomine versus Ketofol for sedation of postoperative mechanically ventilated patients with obstructive sleep apnea.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Faculty of Medicine- Beni Suef University Research Ethical Committee, 19/03/2017, ref: FWA00015574

Study design
Randomised parallel trial

Primary study design
Interventional

Secondary study design
Randomised parallel 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
Obstructive sleep apnea

Interventions
Patients are randomised into one of two groups using sealed closed opaque envelopes.

Group 1: Patients receive a loading dose infusion of Dexmedetomine 1 ug/kg over 10 minutes followed by maintenance infusion of 0.5 ug/kg/h.

Group 2: Patients receive ketofol in an initial bolus dose 500 ug/kg of ketamine/propofol 1:1 followed by maintenance dose of 10 ug/kg/min.

Infusion starts for participants in both groups after admission to SICU for short-term sedation of less than 12 hours. All participants are followed up until discharge from the SICU.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Dexmedetomine, ketamine, propofol

Primary outcome measure
1. Duration of mechanical ventilation and stay in the SICU is measured in hours
2. Mean time to extubation is measured in minutes
3. Sedation level is assessed using Ramsay sedation scores at baseline, 1 hour after start of the sedation and then every 3 hours until weaning from mechanical ventilation and extubation

Secondary outcome measures
1. Heart rate is measured by ECG at baseline, 1 hour after start of the sedation and then every 3 hours until weaning from mechanical ventilation and extubation
2. Invasive mean blood pressure is measured by arterial line at baseline, 1 hour after start of the sedation and then every 3 hours until weaning from mechanical ventilation and extubation
3. Oxygen saturation is measured by pulse oximetry at baseline, 1 hour after start of the sedation and then every 3 hours until weaning from mechanical ventilation and extubation

Overall study start date
01/05/2016

Completion date
01/04/2017

Eligibility

Key inclusion criteria
1. Aged 18-50 years
2. Obstructive sleep apnea
3. Require mechanical ventilation postoperatively

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
50 Years

Sex
Both

Target number of participants
24 patients

Total final enrolment
24

Key exclusion criteria
1. Prolonged sedation and mechanical ventilation
2. Epileptic patient
3. Patients with known allergy to the studied drugs
4. Pregnancy
5. Severe hepatic, renal or cardiac diseases

Date of first enrolment
10/05/2016

Date of final enrolment
10/03/2017

Locations

Countries of recruitment
Egypt

Study participating centre
Benisuef University Hospital
Mohamed Hassan Street
Beni Suef
Egypt
62511

Sponsor information

Organisation
Beni Suef University

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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/05pn4yv70

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
01/04/2018

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		28/01/2018	07/06/2023	Yes	No