

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	☐ Prospectively registered ☐ Protocol
Registration date 12/04/2017	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 07/06/2023	Condition category Respiratory	☐ 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 anaesthesia) 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?
Dr Hatem Elmoutaz
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Contact information

Type(s)
Scientific

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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

Primary study design

Interventional

Study design

Randomised parallel trial

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Upper age limit

50 Years

Sex

All

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

ROR
<https://ror.org/05pn4yv70>

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

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