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Sugammadex to prevent complications after general anesthesia in the elderly

Submission date
11/12/2019

Recruitment status
No longer recruiting

Registration date
27/01/2020

Overall study status
Completed

Last Edited
27/01/2020

Condition category
Surgery

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

Plain English summary of protocol

Background and study aims
Elderly patients are very sensitive to complications after general anesthesia connected with residual action of relaxants. The aim of this study is to evaluate the use of sugammadex to prevent residual curarization in people over 65 years of age. The scale of residual curarization and the effect of the new medication on the incidence of critical respiratory events in elderly people is still to be investigated. The relationship between residual neuromuscular blockade and the incidence of postoperative cognitive dysfunction in people over 65 years of age is not known yet. The aim of the project is to increase the safety of the use of neuromuscular-blocking drugs and to prevent respiratory complications.

Who can participate?
Patients over 65 years of age who are scheduled for elective surgery

What does the study involve?
Lung function and mental status are assessed one day before the surgery and one day after the surgery. The patients are anaesthetized by a number of anaesthesiologists. Each medical doctor decides on their own whether to use neuromonitoring or not. One measurement is taken during recovery from anaesthesia. The anesthesiologist providing anaesthesia decides on administration of sugammadex during recovery from anaesthesia or neostigmine.

What are the possible benefits and risks of participating?
Benefits include increasing safety of the perioperative period in elderly patients. There are no potential risks to the patients except for possible allergic reaction to the administered drugs.

Where is the study run from?
M. Kopernik Provincial Multispeciality Centre of Oncology and Traumatology (Poland)

When is the study starting and how long is it expected to run for?
January 2014 to August 2019

Who is funding the study?
Medical University of Lodz (Poland)

Who is the main contact?
Dr Piotr Pietraszewski
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
2019-004843-56

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
RNN/704/10/KB

Study information

Scientific Title
Sugammadex to prevent residual neuromuscular block and other complications after general anesthesia in the elderly

Study objectives
The study is planned to concern a new medication called sugammadex constituting an antidote to some non-depolarizing neuromuscular-blocking drugs. The aim of the study was to evaluate the use of sugammadex to prevent residual curarization in people over 65 years of age. The applicant would like to investigate the scale of residual curarization, while assessing the effect of the new medication on the incidence of critical respiratory events in elderly people. The applicant would like to assess the relationship between residual neuromuscular blockade and the incidence of postoperative cognitive dysfunction (MMSE variable) in people over 65 years of age.

The aim of the project is to increase the safety of the use of neuromuscular-blocking drugs and to prevent respiratory complications.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 02/02/2014 by Local Bioethical Committee of the Medical University in Lodz (ul Zeligowskiego 7/9, 90-752 Lodz; Tel: +48 (0)785911601; Email: bioetyka@umed.lodz.pl), ref: RNN /704/10/KB

Study design
Observational cross-sectional cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet
Not available in web format

Health condition(s) or problem(s) studied
Post-operative residual curarisation and its impact on respiratory function after anesthesia and possible postoperative pulmonary complications

Interventions
Overall, 351 patients aged 65-91 years were examined. Patients were anaesthetised at the M. Kopernik Provincial Multispeciality Centre of Oncology and Traumatology in Lodz. Spirometry and MMSE (Mini-Mental State Examination) were performed in patients one day before the surgery and one day postoperatively. The patients were anaesthetized by a number of anaesthesiologists. Each medical doctor decided on their own whether to use neuromonitoring or not. One measurement was taken during recovery from anaesthesia. Anesthesiologist providing anaesthesia decided of administration of 2 mg/kg of sugammadex during recovery from anaesthesia or 2 mg of neostigmine iv.

Intervention Type
Drug

Phase
Not Applicable

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

Primary outcome measure
Post-operative residual curarisation, assessed using neuromuscular accelerometry after sugammadex or neostygmine injection after GA in elderly. After the immobilization of the hand, the ulnar nerve was stimulated to provoke the contraction of the adductor muscle of the thumb, and the response was recorded and measured using a piezoelectric acceleration transducer. The TOF mode is the most appropriate for the monitoring of the reversal of effects induced by nondepolarizing muscle relaxants. Each patient whose TOF was lower than 0.9 is considered to have risk of post operation residual curarisation.

Secondary outcome measures
1. Respiratory efficacy after GA in elderly, assessed by spirometry at one day before surgery and one hour after discharge from the PACU. The principles of the procedure will be explained to the patient, and then the test will be done using a portable handheld spirometer (Spirobank, MIR) with digital disposable turbines. The patient will be seated, and a clip is placed on his/her nose to close the nostrils. The patient breath calmly and hold the mouthpiece with the teeth. When instructed, the patient take a deep breath in, and then exhale as hard as he/she can. The test was repeated three times and the highest value was recorded. FEV1 and FVC is measured and evaluated
2. Mental status assessed using MMSE test (Mini-Mental State Examination) by an anaesthetist one day before surgery and in the morning within 24 h after surgery. The test consists of 30 questions, and examines orientation to time and place, registration, attention, calculation, recall, language, and ability to follow simple commands, including writing and drawing. Each answer is scored. The maximum total score is 30 points. Scores in the range of 27-30 points indicate normal cognition. Scores 24-26 points may indicate cognitive impairment. Scores of 19-23 points indicate mild impairment, and scores 11-18 points moderate cognitive impairment. Scores 10 or fewer points indicate severe impairment

Overall study start date
01/01/2014

Completion date
01/08/2019

Eligibility

Key inclusion criteria
1. Physical status ASA class I-III
2. Patients verbally responsive and maintaining logical communication, understanding and responding to commands
3. Patients without pain disabling cooperation. Patients who were not under the clear influence of narcotic analgesics, psychotropic drugs, or in deep sedation
4. Patients scheduled for elective surgery
5. Patients scheduled for general surgery, endocrinology surgery, vascular surgery, trauma surgery, urological or oncological surgery
6. Neurosurgery and thoracic surgery patients were excluded from the study due to the expected difficulty in interpreting the results

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
351

Total final enrolment
351

Key exclusion criteria
Does not meet inclusion criteria or lack of consent

Date of first enrolment
02/01/2015

Date of final enrolment
22/12/2018

Locations

Countries of recruitment
Poland

Study participating centre
M. Kopernik Provincial Multispeciality Centre of Oncology and Traumatology
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Sponsor type
University/education

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Funder(s)

Funder type
University/education

Funder Name
Uniwersytet Medyczny w Lodzi

Alternative Name(s)
Medical University of Lódz, Medical University of Łódź, UMED, MUL

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
Poland

Results and Publications

Publication and dissemination plan
Publish in medical journals

Intention to publish date
01/01/2020

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Pior Pietraszewski MD (piotrpserwus@wp.pl).

IPD sharing plan summary
Available on request