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Prolonging muscle paralysis after surgery: a comparative age-matched study

Submission date
16/04/2017

Recruitment status
No longer recruiting

Registration date
02/06/2017

Overall study status
Completed

Last Edited
10/08/2017

Condition category
Nervous System Diseases

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

Plain English summary of protocol

Background and purpose of study
Neuromuscular blockade (NM) is a technique which involves interrupting nerve signals with medication in order to paralyse muscles. This technique is commonly used during surgery, as they can assist the effects of general anaesthesia (putting someone to sleep for an operation). Although this technique works very well, it can be associated with undesirable side effects, such as prolonged muscle paralysis after surgery (residual muscle paralysis). In some cases, this can lead to the muscles of the body not getting enough oxygen and difficulties with the airways. Currently, there is little research looking at residual muscle paralysis and age. The aim of this study is to find out how common residual muscle paralysis is in patients aged between 2 and 10 years, 18 and 64 years, and over 65 years.

Who can participate?
Patients aged between 2-10, 18-64 and 65+ years who have been scheduled for surgery under general anesthesia with NM.

What does the study involve?
Patients are assigned to one of three groups based on their age. During their surgery, patients undergo the same treatment with general anaesthesia and muscle relaxants. Every 15 minutes after surgery for the five hours they are in the recovery room, participants are monitored to find out what (if any) degree of muscle paralysis is present. After being discharged from the recovery room, patients are followed up every three hours until 24 hours after surgery.

What are the possible benefits and risks of participating?
All participants will benefit from regular monitoring of muscle paralysis as part of the study. There are no notable risks involved with participating.

Where is the study run from?
First Affiliated Hospital of Dalian Medical University (China)

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

Who is funding the study?
First Affiliated Hospital of Dalian Medical University (China)

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
KY2017

Study information

Scientific Title
Residual neuromuscular blockade following surgery and anesthesia: A prospective age-matched cohort study

Study objectives
40% of the patients in the age bracket 2-10 years and 65+ years cohort will develop postoperative residual neuromuscular blockade (TOF ratio 0.9).

Ethics approval required
Old ethics approval format

Ethics approval(s)

Human Research Ethics Committee of the First Affiliated Hospital of Dalian Medical University, 10/01/2017, ref: KY2017

Study design
Prospective observational cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Post-operative residual neuromuscular blockade

Interventions
Participants are allocated to one of three study cohorts based on their age (2-10 years, 18-64 years and 65+ years), which each undergo the following:

Neoromuscular monitoring
The same standard of general anesthesia protocol will be employed for all the study participants during the surgery. Management of muscle blockade will be standardized in all the three study groups. On admission at the post-anesthesia care unit (PACU), surface ECG electrodes for neuromuscular monitoring will be applied on the cleansed skin over the ulnar nerve close to the wrist. To determine quantitative train-of-four (TOF) ratio measurement in all study participants, the leads of train-of-four (TOF) Watch SX will be connected to the surface ECG electrode on the patient arm. The transducer of the TOF Watch-SX that measures the acceleration of the patients' muscles will be applied to the thumb of patients' hand on which the ECG surface electrode will be placed. Based on standard guidelines, the hand adapter will be applied to the anterior surface of the four fingers of the hand. Two serial TOF measurements at 15 minutes intervals will be obtained in all participants, averaged and documented. TOF ratios 0.7 and 0.8 will be defined as moderate neuromuscular block, while TOF ratio of less than 0.7 will be defined as severe residual neuromuscular block. Participants with various grades of TOF ratios (TOF ratio less than 0.7, 0.8 and 0.9) in each study cohort will be summed up and compared. In addition to TOF ratio data to be collected, study participants will be assessed at 15 minutes interval for clinical features of neuromuscular blockade on PACU admission. In this regard a structured examination sheet will be employed to capture data about whether or there is muscle weakness in various muscle groups.

Potential pulmonary complications associated with residual neuromuscular block
Arterial oxygen saturation (Sp02) will be continuously monitored through pulse oximetry in all study participants during PACU admission. While in PACU, study participants of each cohort will

be put on 5 litters face mask airway and oxygenation monitored continuously and data saved. This will enable investigators determine early signs of airway obstruction.

Duration of PACU Hospitalization
The influence of residual neuromuscular block on duration of PACU admission will assessed. Therefore, the time to discharge criteria and the actual discharge time will be recorded.

Duration of participant observation
The maximum duration of observation of patients in PACU will be 5 hours. After discharge from PACU, 3 hourly follow ups in the ward will be observed until the 24 hours postoperative phase elapsed. This will enable investigators detect residual neuromuscular block and its related pulmonary or respiratory complications that may occur on the ward.

Intervention Type
Procedure/Surgery

Primary outcome measure
Residual neuromuscular blockade (RNMB), defined as train-of-four (TOF) ratio of less than 0.9. Moderate (TOF ratio ≥ 0.7 but < 0.9) and severe (TOF ratio 0.7) PRNMB, is assessed 5 minutes to administration of cisatracurium at induction of general anesthesia, 1 minute interval after cisatracurium injection until 6 minutes and every 15 minutes in the postanesthetic care unit (PACU) until discharge.

Secondary outcome measures
1. Demographic and patient characteristics such as age, weight, sex and co-morbidities, airway obstruction, indication of surgery, anesthesia duration, time (minutes) to PACU discharge and respiratory complications during hospital admission and length of hospital admission (days)
2. Total crystalloids and colloids volume (mls), total cisatracurium (mg) and total neostigmine (mg)
3. Perioperative and PACU temperature () monitoring during perioperative and PACU periods
4. Peripheral oxygen saturation (SpO2) monitoring during perioperative and PACU periods
5. End tidal carbon dioxide (EtCO2) monitoring during perioperative and PACU periods
6. Heart rate, systolic, diastolic and mean arterial pressure (mmHg) monitoring during perioperative and PACU periods.
7. Bispectral index (BIS) monitoring perioperative and PACU periods

Overall study start date
05/12/2016

Completion date
30/12/2017

Eligibility

Key inclusion criteria
1. Patients with American Society of Anesthesiologists (ASA) physical status I-III scheduled to undergo elective surgery undergo general with muscle relaxants
2. Patients within the age groups 2-10, 18-64 and 65+ years

Participant type(s)
Patient

Age group
Mixed

Lower age limit
2 Years

Sex
Both

Target number of participants
79 in each cohort

Key exclusion criteria
1. Patients with muscular disorders
2. Patients with neurological deficit
3. Patient refusal to consent
4. Patients scheduled to undergo prolong surgical procedures
5. Patients with severe impaired liver and renal function
6. Infants under 2 years
7. Patients with asthma
8. Patients with diabetes mellitus

Date of first enrolment
01/05/2017

Date of final enrolment
30/10/2017

Locations

Countries of recruitment
China

Study participating centre
First Affiliated Hospital of Dalian Medical University
Department of Anesthesiology
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Sponsor information

Organisation

First Affiliated Hospital of Dalian Medical University

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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/055w74b96

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
First Affiliated Hospital of Dalian Medical University

Results and Publications

Publication and dissemination plan
A comprehensive report of the trial findings will be made available to the funder of the trial. The results of the trial will be published in a reputable clinical journal by December 2018.

Intention to publish date
31/12/2018

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Wen Qingping (yabasin@dmu.edu.cn)

IPD sharing plan summary
Available on request