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Muscle relaxants for rapid sequence intubation

Submission date 16/09/2015	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol
Registration date 04/12/2015	**Overall study status** Completed	[ ] Statistical analysis plan [ ] Results
Last Edited 04/12/2015	**Condition category** Digestive System	[ ] Individual participant data [ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Rapid sequence intubation (RSI) is an important medical procedure used in emergency situations. The procedure involves rapidly inserting a flexible tube into the windpipe (trachea) through the mouth. This helps to keep the airways open and can be used to provide artificial respiration (helping to breathe). This is particularly useful for patients in danger of vomiting (regurgitation) and breathing the vomit into the airway (aspiration) such as in cases of bowel obstruction (when the intestines are blocked). In order to aid the RSI procedure medications are used to help relax the muscles in the face and throat (muscle relaxants). The most commonly used muscle relaxant is succinylcholine, as it works and wears off very quickly. In the body, movement of muscles is caused by a chemical messenger called acetylcholine, which binds to receptors causing nervous impulses to be fired into muscles triggering contraction. Succinylcholine is known as a depolarising muscle relaxant, which means that it binds to the acetylcholine receptors, causing them to fire nervous impulses making muscles contact and then relax. They then block the receptors, depolarising the connection, meaning that it cannot “re-set” and re-fire. Unfortunately, succinylcholine can cause a number of undesirable side effects such as affecting blood pressure, causing muscle pain and prolonged paralysis. Rocuronium is a non-depolarising muscle relaxant which works by blocking the acetylcholine receptors so that the muscles remain relaxed. Rocuronium has far fewer side effects than succinylcholine, and so it could be a viable alternative to succinylcholine. The aim of this study is to find out compare how effective rocuronium and succinylcholine are at relaxing muscles for RSI.

Who can participate?
Adults with bowel obstruction classified as having mild to severe systemic (affecting the entire body) disease.

What does the study involve?
Patients are randomly allocated into one of two groups, who will receive a different muscle relaxant. After being prepared, participants in the first group receive succinylcholine and participants in the second group receive rocuronium. Within 60 second of being given the muscle relaxants, patients are intubated using the RSI procedure. During intubation, the ease of the procedure is evaluated, based on jaw and muscle relaxation, movement of the vocal cords, movement and coughing.

What are the possible benefits and risks of participating?
There are no notable benefits of participating in the study. Risks of participating include the general risks that accompany the procedure such as pain, bleeding or swelling, as well as general risks of the drugs that are given.

Where is the study run from?
University Medical Centre Maribor (Slovenia)

When is the study starting and how long is it expected to run for?
December 2013 to June 2016

Who is funding the study?
University Medical Centre Maribor (Slovenia)

Who is the main contact?
Mrs Lidija Perša

Contact information

Type(s)
Public

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
104/10/13

Study information

Scientific Title
Rocuronium versus succinylcholine for rapid sequence intubation in patients with bowel obstruction

Study objectives

We expect to have as good intubating conditions in patients who are going to receive rocuronium as in patients who are going to receive succinylcholine in our study.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Commission of the Republic of Slovenia for Medical Ethics, 29/10/2013, ref: 104/10/13

Study design
Single-centre randomised parallel trial interventional study

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Hospital

Study type(s)
Not Specified

Participant information sheet

Health condition(s) or problem(s) studied
Bowel obstruction

Interventions
We are going to include patients with bowel obstruction who need an urgent operation. They are going to be divided in two groups using a random number generator. The patients are going to be prepared and intubated using rapid sequence intubation protocol. The first group is going to receive succinylcholine (1,5 mg/kg) and the second rocuronium (1,2 mg/kg). All drugs are going to be applied by the peripheral vein. The intubation is going to be performed 60 seconds after the application of muscular relaxant; muscular relaxation is going to be measured at the same time. We are going to evaluate the intubation conditions using grading system (the position and movement of the vocal cords, jaw relaxation and laryngoscopy resistance, coughing and movement).

Intervention Type
Drug

Drug/device/biological/vaccine name(s)
Rocuronium, succinylcholine

Primary outcome measure
Quality of vocal cords visualisation is determined during the laryngoscopy 60 seconds after the muscular relaxant application using the visual scale (evaluating the position of vocal cords - whether are they adduced, in the midlle position or abduced at the time of laryngoscopy).

Secondary outcome measures
1. Potassium and mioglobin serum level measured five minutes before and after the RSI
2. Heart rate measured one minute before and after the RSI
3. Blood pressure measured one minute before and after the RSI

Overall study start date
01/12/2013

Completion date
30/06/2016

Eligibility

Key inclusion criteria
1. Patient with bowel obstruction
2. Aged 18 years or over
3. Graded 2 and 3 on ASA Physical Status Classification System

Participant type(s)
Patient

Age group
Mixed

Lower age limit
18 Years

Sex
Both

Target number of participants
60

Key exclusion criteria
1. Patients with known allergy for rocuronium or succinylcholine
2. Patients with increased potassium level
3. Patients with cronic or acute renal failure
4. Patients with whom difficulties with vocal cords visualisation and tracheal intubation are expected

Date of first enrolment
01/12/2013

Date of final enrolment
30/06/2016

Locations

Countries of recruitment

Slovenia

Study participating centre
University Medical centre Maribor
Ljubljanska ulica 5
Maribor
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Sponsor information

Organisation
University Medical Centre Maribor

Sponsor details
Ljubljanska ulica 5
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Sponsor type
Hospital/treatment centre

Website
www.ukc-mb.si

ROR
https://ror.org/02rjj7s91

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
University Medical Centre Maribor

Results and Publications

Publication and dissemination plan
Publication in a peer reviewed journal.

Intention to publish date
30/06/2016

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration