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Comparison of two types of treatment which cause short acting muscle relaxation to determine which treatment allows patients to resume normal breathing in the shortest period of time

Submission date 30/09/2009	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 14/10/2009	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 07/03/2017	**Condition category** Surgery	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
09005RM-CS

Study information

Scientific Title
Time to resumption of spontaneous respiration in patients administered either suxamethonium or rocuronium followed by sugammadex: a randomised double-blind controlled trial

Study objectives
There is no differece in the time to resumption of breathing or incidence of desaturation in patients receiving either suxamethonium or rocuronium followed by one of two doses of sugammadex.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Scotland A Research Ethics Committee, 24/08/2009, ref: 09/MRE00/29

Study design
Randomised controlled double-blind trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Routine general anaesthesia

Interventions
After pre-oxygenation, patients will be randomised to one of three groups for the administration of either: suxamethonium 1 mg/kg, rocuronium 1 mg/kg followed by sugammadex 10 mg/kg or rocuronium 1 mg/kg followed by sugammadex 16 mg/kg. Sugammadex will be administered 3 minutes after rocuronium; 0.9% saline will be administered at this time in the suxamethonium group to maintain blinding.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Suxamethonium, rocuronium, sugammadex

Primary outcome measure
Length of time to resumption of spontaneous ventilation as indicated by visible diaphragmatic movement or decrease in oxygen saturation to less than or equal to 90% before onset of spontaneous ventilation

Secondary outcome measures
1. Frequency of desaturation to less than or equal to 90%
2. Length of time to movement of reservoir bag
3. Length of time to first capnographic evidence of ventilation
4. Incidence of adverse events in all groups

Overall study start date
01/09/2009

Completion date
01/02/2010

Eligibility

Key inclusion criteria
1. American Society of Anaesthesiologists (ASA) class I - III
2. Patients able to give written informed consent
3. Patients requiring general anaesthesia
4. Patients aged 18 - 65 years, either sex

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Both

Target number of participants

90 patients - 30 randomised to each group

Key exclusion criteria
1. History of dementia or difficulty in providing informed consent
2. Patients with chronic obstructive pulmonary disease (COPD)
3. Patients with a history of ischaemic heart disease (IHD)
4. Patients with a haemoglobin concentration of less than 10 g/dl
5. Patients with a history of known difficulty in intubation or with an anticipated challenging airway
6. Pregnancy
7. Patients with a history of allergy to any of the medications used in the study

Date of first enrolment
01/09/2009

Date of final enrolment
01/02/2010

Locations

Countries of recruitment
Northern Ireland

United Kingdom

Study participating centre
Queen's University Belfast
Belfast
United Kingdom
BT12 6BJ

Sponsor information

Organisation
Belfast Health and Social Care Trust (UK)

Sponsor details
Grosvenor Road
Belfast
Northern Ireland
United Kingdom
BT12 6BJ

Sponsor type
Hospital/treatment centre

Website
http://www.belfasttrust.hscni.net

ROR
https://ror.org/02tdmfk69

Funder(s)

Funder type
Government

Funder Name
Belfast Health and Social Care Trust (UK) (ref: 09005RM-CS)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration