

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 14/10/2009	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 07/03/2017	Condition category Surgery	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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 difference 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