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The effect of muscle relaxant drugs on the larynx

Submission date	Recruitment status	[_] Prospectively registered
23/01/2004	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
23/01/2004	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
31/10/2019	Ear, Nose and Throat	[_] 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

Protocol serial number
RBF 96XX4

Study information

Scientific Title
The effect of muscle relaxant drugs on the larynx

Study objectives

Phase 1: to compare the degree of neuromuscular block at the larynx using video imaging and endotracheal tube cuff pressure changes.
Phase 2: to compare the onset, duration and recovery index of intubating doses of various commonly used relaxants a the vocal cords and adductor pollicis.
Phase 3: to extend the studies to include monitoring sites other than adductor pollicis (initially the orbicularis oculi and the diaphragm).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Primary study design
Interventional

Study design
Randomised crossover study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Ear, nose and throat diseases

Interventions
Phase I: The patients will be allocated randomly to one of four groups. Group one will have the adductor pollicis twitch reduced by 25%, group two 50%, group three 75% and group four 90%.
Phase II: Patients will be allocated randomly to receive one of five muscle relaxants which have been selected on the basis of their different onset characteristics: group 1 vecuronium 0.08 mg.kg-1; group 2 rocuronium 0.6 mg.kg-1; group 3 atracurium 0.45 mg.kg-1; group 4 suxamethonium 1.0 mg.kg-1; and group 5 mivacurium 0.16 mg.kg-1.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Interim and final reports for review by NHS Executive Trent

Key secondary outcome(s)
Not provided at time of registration

Completion date
31/01/1999

Eligibility

Key inclusion criteria
Phase 1: 40 patients will be studied in this randomised crossover study. All patients will be scheduled to undergo elective surgery which will require the use of nondepolarizing muscle relaxants.
Phase 2: American Society of Anesthesiologists (ASA) 1&2 patients will be studied initially. Inclusion and exclusion criteria and patient monitoring will be as for Phase 1. Patients will then be allocated randomly to receive one of five muscle relaxants (10 per group). If numbers prove insufficient, further patients will be recruited, in groups of 25 (5 per group).

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Not Specified

Key exclusion criteria
Any patient with a history of regurgitation, dyspepsia or neuromuscular disease or who is taking any medication that may interfere with neuromuscular function will be excluded.

Date of first enrolment
01/02/1997

Date of final enrolment
31/01/1999

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University Department of Anaesthesia
Nottingham
United Kingdom
NG7 2UH

Sponsor information

Organisation
NHS R&D Regional Programme Register - Department of Health (UK)

Funder(s)

Funder type
Government

Funder Name
NHS Executive Trent (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration