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The effect of muscle relaxant drugs on the larynx

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

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
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

Study design
Randomised crossover study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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 measure
Interim and final reports for review by NHS Executive Trent

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/02/1997

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

Age group
Not Specified

Sex
Not Specified

Target number of participants
40

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
England

United Kingdom

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)

Sponsor details
The Department of Health
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL
+44 (0)20 7307 2622
dhmail@doh.gsi.org.uk

Sponsor type
Government

Website
http://www.doh.gov.uk

Funder(s)

Funder type
Government

Funder Name
NHS Executive Trent (UK)

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