

The effect of muscle relaxant drugs on the larynx

Submission date 23/01/2004	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 23/01/2004	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 31/10/2019	Condition category Ear, Nose and Throat	<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

Contact name
Dr Keith Girling

Contact details
University Department of Anaesthesia
Queens Medical Centre
Nottingham
United Kingdom
NG7 2UH
+44 (0)115 924 9924 Ext 42855
abc@email.com

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 at 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