

# The effect of muscle relaxant drugs on the larynx

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

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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 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

### **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<sup>-1</sup>; group 2 rocuronium 0.6 mg.kg<sup>-1</sup>; group 3 atracurium 0.45 mg.kg<sup>-1</sup>; group 4 suxamethonium 1.0 mg.kg<sup>-1</sup>; and group 5 mivacurium 0.16 mg.kg<sup>-1</sup>.

### **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