

The McGrath® MAC videolaryngoscope for nasal intubation

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		<input type="checkbox"/> Protocol
Registration date 07/10/2014	Overall study status Stopped	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 31/08/2016	Condition category Surgery	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Laryngoscopes are commonly used to help place a tube into a patients windpipe (a nasotracheal tube) after they have gone to sleep so that the anaesthetist can protect the airway and keep them safe during their procedure. Sometimes when the anaesthetist introduces the tube it needs to be directed with additional help by a pair of blunt forceps placed into the mouth to hold the tube and place it in the right position. These forceps are regularly used items (Magills forceps). We believe that using one laryngoscope called the McGrath Video laryngoscope in preference to the Macintosh laryngoscope may reduce the chances of having to use Magills forceps. This may reduce the chances of damage to teeth, sore throat and also the cost of the equipment, decreasing chances of complications and allowing savings to be diverted to other areas where patients will benefit.

Who can participate?

Patients whose operation requires that they have a nasotracheal tube placed into the windpipe will be asked to take part.

What does the study involve?

Patients will be brought to theatre as normal on the day of operation and into the anaesthetic room as normal. The anaesthetic procedure will be the same regardless of participation in the study. The only difference will be that the anaesthetist will be randomly allocated to use either the Macintosh laryngoscope or the McGrath Video laryngoscope. After the operation the anaesthetist will ask the patient if they have a sore throat - sore throat is a common side effect of anaesthesia and in general one in ten people will have a mild sore throat for a day or two after anaesthesia.

What are the possible benefits and risks of participating?

We do not believe that there will be any increased risk to those who take part in the study other than that normally associated with the surgery and anaesthetic.

Where is the study run from?

Institute of Neurological Science and Maxillofacial Surgery, Southern General Hospital, Glasgow, UK.

When is the study starting and how long is it expected to run for?
October 2014 to September 2015.

Who is funding the study?

1. The Department of Neuroanaesthetics Fund
2. Aircraft Medical (UK)

Who is the main contact?

Dr Simon P Young
spydoc@gmail.com

Contact information

Type(s)

Scientific

Contact name

Dr Simon P. Young

Contact details

Department of Neuroanaesthetics
Institute of Neurological Sciences
Southern General Hospital
1345 Govan Road
Glasgow
United Kingdom
G51 4TF
+44 (0) 141 201 1989
spydoc@gmail.com

Additional identifiers

Protocol serial number

N/A

Study information

Scientific Title

A randomised comparative trial of MacIntosh direct laryngoscopy versus the McGrath® MAC videolaryngoscope

Study objectives

Nasotracheal intubation is employed extensively for oromaxillofacial surgery (OMFS) procedures involving the mandible and intra-oral pathology. Prolonged or repeated attempts, particularly when associated with use of intra-airway adjuncts to aid intubation, can be associated with adverse outcomes. Videolaryngoscopes (VL) could potentially lend themselves well to correct first-time, adjunct-free placement of nasally introduced tracheal tubes (TT), particularly when mouth opening may be limited and the airway may be soiled with blood.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Research and Development Management Office; NHS Greater Glasgow and Clyde - approval pending

Study design

Prospective single-blind randomised comparative trial of the McGrath® MAC VL versus a standard Macintosh DL to intubate the trachea via the nasal route in OMFS patients

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Oromaxillofacial surgery (OMFS) procedures involving the mandible and intra-oral pathology, requiring nasotracheal intubation: primarily trauma, also abscesses and tumours

Interventions

Patients presenting with OMFS trauma will form the bulk of the research population. By necessity these patients may be taken to theatre on the day of admission we would therefore anticipate waiving the normal 24-hour time to consider participation option. A patient information sheet (PIS), patient interview with a GCP-trained clinical researcher, and consent form (CF) will be delivered to each patient participant. They will be given at least two hours to consider their participation in the study.

The Sealed Envelope website will be used to generate a randomisation sequence for the study. Patients will be randomised to two groups: one to undergo nasotracheal intubation by Macintosh direct laryngoscopy (DL), the other to undergo nasotracheal intubation by McGrath MAC videolaryngoscopy (VL).

Intervention Type

Procedure/Surgery

Phase

Not Applicable

Primary outcome(s)

Use of the McGills forceps as an aid to intubation this is used as a surrogate for difficulty in positioning the tracheal tube, and subsequent airway tissue trauma. This will be known immediately by the laryngoscopist.

Key secondary outcome(s)

1. Number of attempts at laryngoscopy
2. Number of attempts at tracheal tube passage
3. Failures/cross-overs to McGrath® MAC or other rescue technique, including patient wake-up
4. Cormack Lehane classification (CLC) and percentage of glottic opening (POGO)
5. Ease of TT insertion/any hold-up

6. Dental trauma requiring OMFS referral

7. Airway soft tissue (soft palate/tonsillar pillars) requiring ENT/OMFS referral

These secondary outcome measures will all be known immediately, again by the laryngoscopist.

8. Incidence of sore throat. will be known after the patient's operation, either from questioning in the recovery room, or later on the ward. In all cases, this will be known within 24 hours.

Completion date

30/09/2015

Reason abandoned (if study stopped)

Insufficient clinical time.

Eligibility

Key inclusion criteria

1. Adults with capacity undergoing general anaesthesia

2. Nasotracheal intubation planned, as agreed by both the anaesthetist and surgeon involved in the patients care, with administration of a neuromuscular blocking drug prior to intubation

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. Planned fiberoptic intubation or surgical airway

2. Manual inline stabilization required, or an external cervical fixation device (e.g. Halo)

Date of first enrolment

01/10/2014

Date of final enrolment

30/09/2015

Locations

Countries of recruitment

United Kingdom

Scotland

Study participating centre
Department of Neuroanaesthetics
Glasgow
United Kingdom
G51 4TF

Sponsor information

Organisation
NHS Greater Glasgow and Clyde (UK)

ROR
<https://ror.org/05kdz4d87>

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
NHS Greater Glasgow and Clyde (UK) - Department of Neuroanaesthetics Fund (ref no: NEUROGAS001)

Funder Name
Aircraft Medical (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration