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The McGrath® MAC videolaryngoscope for nasal intubation

Submission date
26/08/2014

Recruitment status
Stopped

Registration date
07/10/2014

Overall study status
Stopped

Last Edited
31/08/2016

Condition category
Surgery

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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 measure
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.

Secondary outcome measures
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.

Overall study start date
01/10/2014

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

Age group
Adult

Sex
Both

Target number of participants
110

Key exclusion criteria

1. Planned fibreoptic 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
Scotland

United Kingdom

Study participating centre
Department of Neuroanaesthetics
Glasgow
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Sponsor information

Organisation
NHS Greater Glasgow and Clyde (UK)

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Sponsor type
Hospital/treatment centre

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

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