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Pathways through the nose in nasotracheal intubation: comparison of the Rae tube and the Reinforced tube

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Registration date 28/09/2007	**Overall study status** Completed	
Last Edited 12/10/2017	**Condition category** Surgery	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr JE Smith

Contact details
Anaesthetics
Selly Oak Hospital
Birmingham
United Kingdom
B29 6JD

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0265178910

Study information

Scientific Title
Pathways through the nose in nasotracheal intubation: comparison of the Rae tube and the Reinforced tube

Study objectives
1. When performing nasotracheal intubation under general anaesthesia, how frequently do Rae and Reinforced tubes pass through nasal pathway 1 and pathway 2?
2. Do reinforced nasal tubes pass through pathway 1 more frequently than Rae nasal tubes?
3. Is there less resistance to the advancement of the tube through pathway 1 or 2?
4. How many redirections of the tube are needed before the tube advances through pathway 1 or 2?
5. Is there a greater incidence of nosebleed when the tube passes through pathway 1 or 2?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

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
Surgery: Intubation

Interventions
Patients will be asked if they have any difficulty breathing through the nose. Only asymptomatic patients who report being able to breathe clearly through both nostrils will be invited to participate in the study.
Xylometazoline (a vasoconstrictor) will be applied to the nasal mucosa approximately thirty

minutes and then approximately 6 minutes before the induction of anaesthesia. Anaesthesia will be established with glycopyrrolate, fentanyl, propofol and atracurium and the patients lungs will be ventilated with oxygen and isoflurane until neuromuscular blockade is complete.

All nasotracheal intubations and all endoscopies will be performed by experienced anaesthetists (J. E. Smith or J. L. Tong). Firstly, each nostril will be examined systematically with a videoendoscope in order to select the most patent nostril for the intubation. Following anterior rhinoscopy, the fibrescope will be passed both underneath and alongside the inferior turbinate in each nostril and any resistance to the passage of the instrument along these pathways will be noted, The presence of any intranasal abnormalities will be documented. The most patent nostril (if any) will be selected for the nasal intubation. If the nostrils are considered to be equally patent, a random selection will be made. The fibrescope will be removed and patients will be randomised into two groups, the Rae nasal tube group or the Reinforced nasal tube group, by opening an opaque, sealed envelope.

Traditional nasotracheal intubation using the Macintosh laryngoscope will then be performed with the selected tube through the selected nostril, Size 7 mm and 6 mm lubricated tubes for males and females respectively will be used. The tracheal tube will be introduced via the nostril and directed along the floor of the nose, in an attempt to advance it along pathway 1. If undue resistance is encountered, the tube will be redirected slightly lower in the nasal cavity, but if undue resistance is still encountered, it will be redirected slightly higher, until a pathway is found that offers minimal resistance, The number and type of redirections required, if any, will be documented. The ease of navigability of the tube through the nose (no resistance, slight resistance or moderate resistance will be noted. If no clear pathway can be found, then an attempt will be made to intubate the other nostril, in the same way. If undue resistance is encountered in this nostril, then orotracheal intubation will be performed and the options for further management will be discussed with the surgeon. (The inability to intubate both nostrils in a patient with an otherwise normal airway is a recognised problem, but in clinical practice it is a very rare event. It may occur perhaps once in approximately 500 patients. The sequence of events described reflects normal clinical practice and is given in detail for completeness. In the great majority of such cases, the best option available is for the surgeon to perform the patients surgery with the orotracheal tube in situ).

When the tracheal intubation is completed, the anaesthetist will note whether epistaxis has occurred as he removes the Macintosh laryngoscope blade from the mouth. Ventilation will be re-established and the fibrescope will then be passed both above and below the tube into the nose for a distance of 1-1.5 cm and the pathway taken by the tube will be identified and documented. The patients surgical treatment will then proceed as normal. There is usually ample space above and below the tube to advance the 4 mm diameter fibrescope a short distance into the nose. However, if any difficulty is encountered in making this examination, it will be abandoned immediately and the patient withdrawn from the trial.

Videotape recordings of the two endoscopic procedures will be made following General Medical Council guidelines. The recordings will be analysed later by an otolaryngologist in order to confirm or refute the anaesthetic diagnoses. He will check whether the most patent nostril has been used and identify which pathway the tube has passed through. He will also attempt to identify any association between the observed nasal morphology and the pathway taken by the tube.

The trial will establish, for the first time, the frequency (with 95% confidence intervals) with which the Rae and Reinforced tubes pass through the preferred nasal pathway. With regard to the comparison of the two types of tube, the null hypothesis is that there is no difference in the

frequency with which they pass through pathway I and pathway 2. The alternative hypothesis is that there is a difference, that one tube passes though pathway I significantly more frequently than the other tube.

In order to assess the value of the Reinforced tube in nasal intubation with regard to its passing or not passing through the preferred pathway, it is essential to have a concurrent comparison, a control group, who receive another commonly used tube under identical conditions. Without a control group, it is impossible to make an objective evaluation of a potential new treatment recommendation. It is essential to avoid researcher bias as much as possible in this type of trial. Unfortunately, it is not possible for the operator to be blinded with regard to the type of tube being used. He will, however, be blind to the results of his interventions until the endoscopic examination is made.

Patients will not be exposed to any increased risk if they agree to participate in the research. Traditional nasal intubation using the Macintosh laryngoscope is the commonest way to effect nasal intubation in the UK and throughout the world. Patient safety will be increased by the performance of a preliminary nasendoscopy to select the most patent nostril for the intubation. This will minimise the risk of intubation trauma. The endoscopic assessment of the pathway taken by the tube, will not be of any direct benefit to the patient but will add no more than approximately one minute to their anaesthetic time. There is usually ample space above and below the tube to advance the 4 mm diameter fibrescope approximately 1-1.5 cm into the nose. However, if any difficulty is encountered in making this examination, it will be abandoned immediately and the patient withdrawn from the trial.

The surgical and nursing staff have been consulted during the design of the investigation and have given their support.
The broad timetable of the study is as follows:
Preparation time - 6 months
Collecting data - 6 months

Intervention Type
Procedure/Surgery

Phase
Not Specified

Primary outcome measure
Proportion of Rae and Reinforced tubes advancing through the nose in pathway 1 and pathway

Secondary outcome measures
1. Resistance to the advancement of the tube through pathways 1 or 2.
2. Number of redirections of the tube needed before the tube advances through pathway 1 or 2
3. Incidence of nosebleed when the tube passes through pathway 1 or 2

Overall study start date
20/03/2006

Completion date
20/03/2007

Eligibility

Key inclusion criteria
The patients involved will be scheduled for elective surgery on maxillofacial operating lists. Patients admitted to the hospital on the day before surgery, or earlier, will be visited on their ward at least 24 hours before the planned surgery. It is not possible to adopt this approach in day-surgery patients (who are admitted on the day of surgery). It is important to ensure that these patients have sufficient time to consider whether they wish to be involved and also to give them an opportunity to discuss the research proposal with relatives or friends. The initial approach to these patients will therefore be by an invitation letter. This letter, accompanied by the Research Participant Information Sheet, will be sent to the patient with the admission documentation, approximately 2 to 3 weeks before admission. Patients will be recruited following clinical history taking and medical examination, Patients classified ASA 1 or 2, with no significant undercurrent illness, with inclusion criteria present and exclusion criteria absent, will be invited to consider participating in the trial. A full explanation will be given by the investigators and questions answered.

Inclusion criteria:
1. Patients in whom nasotracheal intubation is an essential part of their anaesthetic management. (It is not ethical to perform a potentially traumatic nasotracheal intubation unless it is required to facilitate the planned surgery).
2. ASA physical status 1 or 2 (Only patients who present no increased anaesthetic risks will be studied).
3. Aged 16 and over
4. Undergoing elective surgery (emergency surgery is associated with increased anaesthetic risks).
5. Asymptomatic patients who report being able to breathe clearly through the nose (if the patient has any significant nasal pathology e.g. nasal obstruction associated with septal deviation or sinusitis, then the pathway through the nose, taken by the tube, may be abnormal).
6. Able and willing to give informed written consent.

Participant type(s)
Patient

Age group
Adult

Lower age limit
16 Years

Sex
Not Specified

Target number of participants
74

Key exclusion criteria
1. Morbid obesity
2. Oesophageal reflux
3. A history of nasal trauma or obstruction

4. Having a bleeding diathesis
5. Taking anticoagulant drugs
6. Patients expected to present difficult intubation will not be studied

Date of first enrolment
20/03/2006

Date of final enrolment
20/03/2007

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Selly Oak Hospital
Birmingham
United Kingdom
B29 6JD

Sponsor information

Organisation
Record Provided by the NHSTCT Register - 2007 Update - Department of Health

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.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Government

Funder Name
University Hospital Birmingham NHS Trust (UK), NHS R&D Support Funding

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