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The Tulip GT airway versus Guedel with facemask airway

Submission date	Recruitment status	[_] Prospectively registered
25/03/2015	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
13/04/2015	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
09/08/2017	Respiratory	

Plain English summary of protocol

Background and study aims
Airway management is poorly achieved by para-medic and inexperienced medical staff. The aim of this study is to find out whether users perform better with a new device (Tulip GT airway) or a conventional mask (Guedel with facemask airway)? This new device may have a place in out-of-hospital and in-hospital resuscitation.

Who can participate?
Inexperienced users annually trained with Basic Life Support skills (BLS).
Adults patients undergoing scheduled surgery.

What does the study involve?
A group of 60 inexperienced users who are trained in BLS skills are introduced to a new airway device that has already been tested on manikins and in other studies. All patients undergoing surgery will be allocated to one device and then to the other.

What are the possible benefits and risks of participating?
The potential benefits of the new device are ease of use, secure, hands free, has a steep learning curve and cost. Neither device protects the airway from aspiration of stomach contents but all patients are undergoing elective surgery and anyone with this risk is excluded from the study.

Where is the study run from?
North West London Hospitals NHS Trust (UK)

When is the study starting and how long is it expected to run for?
From April 2013 to July 2017.

Who is funding the study?
North West London Hospitals NHS Trust (UK)

Who is the main contact?
Dr Peter Neville

Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
The Tulip GT airway versus Guedel with facemask airway: a randomised crossover clinical study using inexperienced users in anaesthetised patients

Study objectives
Is the Tulip airway easier to use and does it provide better ventilation for unconscious patients when compared to the Guedel with facemask ventilation when used by inexperienced users?
60 inexperienced users (with Basic Life Support BLS skills) will manage the airway on 60 anaesthetised patients

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee London, 11/11/2011, 11/LO/1400

Study design
Single-centre randomised cross over study

Primary study design

Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet

Health condition(s) or problem(s) studied
Airway management in the community and by para-medical staff is widely accepted as poor. Good airway management is fundamental to a safe outcome.

Interventions
Two different airway devices are being tested. The most common in use is the facemask. A new device (Tulip airway) works better in manikins. Ventilation parameters are measured using both devices in unconscious (anaesthetised) consented patients. The subjects are inexperienced users with BLS skills.

Intervention Type
Device

Primary outcome measure
Parameters measured are tidal volume, peak inspiratory pressure, end-tidal carbon dioxide. Three breaths are recorded.
After anaesthesia is induced in the patient, the depth of anaesthesia is deepened until the patient has total jaw relaxation. The consultant anaesthetist doing the study confirms that the airway is manageable and that the patient can be ventilated and ventilates the patient 3 times and measures the ventilatory parameters of tidal volume, airway pressure and end tidal carbon dioxide. The inexperienced user then ventilates the patient using both devices in a randomised order. The first 3 breaths that are achieved with each device are measured using the same end-points as the consultant. The inexperienced user is given 60 seconds to achieve ventilation. The study is abandoned if there is patient compromise.
The exact time points are 3 breaths within 60 seconds oaf attempting ventilation.

Secondary outcome measures
Ease of use and airway preference by the inexperienced user is assessed.

Overall study start date
01/04/2013

Completion date
01/07/2015

Eligibility

Key inclusion criteria
All users must have had BLS training within the last year.
All patients must be 18-70 years old, ASA 1 or 2, scheduled surgery with no risk factors for regurgitation.

Participant type(s)
Mixed

Age group
Adult

Lower age limit
18 Years

Upper age limit
70 Years

Sex
Both

Target number of participants
60 users + 60 patients

Key exclusion criteria
1. Risk of regurgitation
2. Vomiting
3. ASA status greater than 2

Date of first enrolment
01/04/2014

Date of final enrolment
01/04/2015

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Northwick Park Hospital
Watford Road
Middlesex
Harrow
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HA1 3UJ

Sponsor information

Organisation
North West London Hospitals NHS Trust

Sponsor details
Watford Road
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/04cntmc13

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
North West London Hospitals NHS Trust

Results and Publications

Publication and dissemination plan
The journal Anaesthesia (AAGBI) in 2015

Intention to publish date
01/05/2015

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/03/2016		Yes	No