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Ultrasound identification of the cricothyroid membrane

Submission date 21/03/2015	**Recruitment status** Stopped	[X] Prospectively registered [_] Protocol
Registration date 02/04/2015	**Overall study status** Stopped	[_] Statistical analysis plan [_] Results
Last Edited 12/03/2019	**Condition category** Respiratory	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol

Background and study aims

Air containing oxygen, normally passes in and out of our nose or mouth to the lungs during normal breathing. In the event of rare and life-threatening emergency, this passage may become blocked or obstructed, and an alternative route that bypasses the nose or mouth is needed. This can be done with a small cut or window made in the front of the neck (the cricothyroid membrane) overlying the windpipe. Without this life-saving procedure, the patient will be starved of oxygen and may come to serious harm, or die. This is a very rare event, and many doctors will never perform even one of these in their lifetime. Correctly locating this point on the neck can be difficult, especially when a patient is very overweight. The current way of finding this point is by feeling for landmarks on the neck with fingers, known as “palpation”. This is known to be more difficult when the patient is very overweight and the landmarks of the windpipe underneath the neck are less easy to feel. Another way to find this point on the neck is by using ultrasound. This is a machine that can produce an image or picture of tissues underneath the skin onto a screen, so that a trained doctor can see the correct spot to aim for, even if they may not be able to feel it by the finger method. Our study is going to look at which of these two techniques is more accurate.

Who can participate?

Anaesthetists working at University College London Hospital (UCLH).

What does the study involve?

Participants are randomly allocated into one of two groups. Those in group 1 are asked to locate the cricothyroid membrane using the finger "palpation" technique on an actor who is overweight. Those in group 2 are asked to locate the cricothyroid membrane using ultrasound on an actor who is overweight. Assessments are made as to how quickly and easily the membrane is located.

What are the possible benefits and risks of participating?

There are no specific benefits for the participants, though they will receive education on ultrasound guided interventions in the neck. There are no risks to participants.

Where is the study run from?

University College London Hospital (UK)

When is the study starting and how long is it expected to run for?
May 2016 to July 2016

Who is funding the study?
University College Hospital NHS Trust (UK)

Who is the main contact?
Dr Kirstie McPherson

Contact information

Type(s)
Scientific

Contact name
Dr Kirstie McPherson

ORCID ID
http://orcid.org/0000-0002-8366-4886

Contact details
Dept of Anaesthetics
UCLH
235 Euston Road
London
United Kingdom
NW1 2BU

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
KMP1

Study information

Scientific Title
Randomised control trial of ultrasound versus palpation-technique in identifying the cricothyroid membrane (CTM) in simulated can’t intubate, can’t ventilate scenario

Study objectives
The principle research question is which of two methods is more accurate at correctly identifying the spot on the neck, under which lies the windpipe. At this point a "cut" or window can be made accessing the windpipe, providing a route for air to pass down into the lungs, bypassing the nose

or mouth, where a blockage or obstruction lies. The first method relies on examining the neck with hands and fingers to locate this spot correctly, the second uses ultrasound, a machine that produces a picture or image of structures below the skin and invisible to the human eye. We will measure how accurate both methods are by randomly allocating anaesthetists to one of two groups (finger palpation and using ultrasound). We will ask them to find the correct point on the neck of an actor, marking this with "invisible ink". An experienced doctor will have marked this area beforehand (with invisible ink), enabling a measurement of how accurate and close to the expert's mark the subject has been using one of either techniques.

Ethics approval required
Old ethics approval format

Ethics approval(s)
On pre-review by ethics, it was decided that full ethical review was not required

Study design
Single-centre 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
Can't intubate, can't ventilate scenarios

Interventions
Doctors are randomly assigned to one of two groups.
Group 1: Participants are asked to locate the cricothyroid membrane using the finger "palpation" technique on an actor who is overweight
Group 2: Participants are asked to locate the cricothyroid membrane using ultrasound on an actor who is overweight

Intervention Type
Device

Primary outcome measure
Ease of identification of the cricothyroid membrane with ultrasound in a simulated CICV scenario.

Secondary outcome measures
Speed of identification of cricothyroid membrane using ultrasound

Overall study start date
01/05/2016

Completion date
01/07/2016

Reason abandoned (if study stopped)
Objectives no longer viable

Eligibility

Key inclusion criteria
Anaesthetists working at UCLH

Participant type(s)
Health professional

Age group
Adult

Sex
Both

Target number of participants
20

Key exclusion criteria
Unwilling to consent to taking part

Date of first enrolment
01/05/2016

Date of final enrolment
01/06/2016

Locations

Countries of recruitment
United Kingdom

Study participating centre
University College Hospital
235 Euston Rd

London
United Kingdom
-

Sponsor information

Organisation
University College Hospital NHS Trust (UK)

Sponsor details
235 Euston Rd
London
England
United Kingdom
WD6 3HH

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/042fqyp44

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
University College Hospital NHS Trust (UK)

Results and Publications

Publication and dissemination plan
We anticipate the results of the trial will be published in an international anaesthetic journal for dissemination of the lessons learned.

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Available on request