ISRCTN11036029 https://doi.org/10.1186/ISRCTN11036029

# Comparison of two ultrasound techniques in identifying the cricothyroid membrane in patients with abnormal necks

**Submission date**
23/01/2017

**Recruitment status**
No longer recruiting

**Registration date**
31/01/2017

**Overall study status**
Completed

**Last Edited**
06/10/2022

**Condition category**
Signs and Symptoms

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

## Plain English summary of protocol

Background and study aims
The cricothyroid membrane (CTM) is a band of tissue located at the front of the neck, which can be used to access the airways to provide oxygen. In patients who cannot be intubated (having a tube passed through their mouth into their lungs to provide breathing support), inserting the tube through the front of the neck is recommended (cricothyroidotomy). Locating the CTM is vital for placing the tube in the right place is vital, however the traditional technique of “feeling” where it is is not always accurate. Ultrasound is a technique which uses the way sound waves bounce off different types of tissue inside the body to produce a picture on a screen of the inside of the body. The use of ultrasound in locating the CTM could help improve accuracy, especially when a patient has some kind of neck deformity. The aim of this study is to find out whether using ultrasound is able to improve the rate of accuracy in locating the CTM in anesthesiology trainees.

Who can participate?
The participants of this study are trainee anesthesiologists (doctors who specialize in anesthetizing people), and the study is performed on one healthy volunteer, two patients with neck deformaties.

What does the study involve?
Three patients take part in this study, one who is healthy and two who have neck abnormalities. The participants of this study (trainee anesthesiologists) perform the standard technique of using fingers to feel the neck and using two ultrasound techniques to scan the front of the neck, in order to located the CTM. At the start of the study, the healthy patient is used to help “train” the participants in the different techniques. They then perform each technique of each patient with neck abnormalities in a random order. The time taken to perform each assessment is recorded, and at the end of the study, the accuracy of the assessments is calculated.

What are the possible benefits and risks of participating?
There are no direct benefits to the patients taking part. The anesthesiologists may benefit from receiving training of identifying the cricothyroid membrane using the ultrasound which would be

useful in their when they are working with patients with neck deformities. There are no risks involved for anyone taking part.

Where is the study run from?
Royal Surrey County Hospital NHS Trust (UK)

When is the study starting and how long is it expected to run for?
January 2016 to December 2017

Who is funding the study?
National Institute of Academic Anaesthesia (UK)

Who is the main contact?
Dr Chia Kuan Yeow
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# Contact information

### Type(s)
Public

### Contact name
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# Additional identifiers

### EudraCT/CTIS number

### IRAS number

### ClinicalTrials.gov number

### Secondary identifying numbers
32960

# Study information

### Scientific Title
Comparison of sagittal versus transverse ultrasound techniques in identifying the cricothyroid membrane in subjects with neck pathology: A diagnostic accuracy study

## Study objectives
The aim of this study is to compare both ultrasound technique and also the landmark technique the time and accuracy in identifying the cricothyroid membrane in subjects with neck pathologies.

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
London Central Research Ethics Committee, 06/12/2016, ref: 16/LO/2068

## Study design
Randomised; Both; Design type: Process of Care, Imaging, Case-controlled study

## 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
Specialty: Anaesthesia, perioperative medicine and pain management, Primary sub-specialty: Anaesthesia, Perioperative Medicine and Pain Management; UKCRC code/ Disease: Respiratory/ Other diseases of upper respiratory tract

## Interventions
Three subjects are to be recruited. The first subject is a healthy adult subject with normal BMI as the ‘training’ subject. The other two subjects are adults with neck pathology who is otherwise medically stable as the ‘study’ subjects. The ‘study’ subjects with neck pathology would ideally be patients who have a deviated trachea or neck mobility issues (e.g. post radiotherapy or surgery) that is known by the head & neck surgeons in RSCH. Subjects will be lying supine with the neck extended. The borders of the cricothyroid membrane will be demarcated with an invisible UV pen by a Consultant Radiologist and a transparent dressing applied over the front of the neck. The demarcated line will only be visible when exposed to UV light.

Participants (anaesthetists from the anaesthetic department) will provide written consent before completing a pre-study questionnaire. Training will be provided to all participants in identifying the cricothyroid membrane with both ultrasound techniques on the ‘training’ subject.

All participants will be required to complete the assessments on both 'study' subjects and will be randomized to a subject to start with. Participants (anaesthetists) perform three interventions of each subject (1 'training' subject and 2 'study' subjects).

1. Landmark technique: It is a touch technique with fingers on the subject's front of neck.
2. Transverse ultrasound technique: Using the ultrasound probe in the transverse plane (out of plane) on the subject's front of neck.
3. Sagittal ultrasound technique: Using the ultrasound probe in the sagittal plane (in plane) on the subject's front of neck.

Each anaesthetist would have assessed both 'study' subjects with all three techniques by the end of the study.

Each participant should take no longer than 30 minutes to complete the training and assessments. On completing the study, participants will be asked to complete a post-study questionnaire.

### Intervention Type
Other

### Primary outcome measure
Time taken in successful identification of the cricothyroid membrane with each technique is measured in seconds throughout the performance of each technique.

### Secondary outcome measures
1. Accuracy in identifying the cricothyroid membrane with each technique is assessed by comparing results to subject status immediately after each technique is performed (the borders of the cricothyroid membrane has been pre-marked with UV pen)
2. Confidence in identification of the cricothyroid membrane with each technique is measured using a numerical rating scale from 1-10 immediately before and after performing all 3 techniques on all 3 subjects
3. Ease of learning and performing techniques is assessed by a post-study questionnaire designed for the purpose of this study immediately after performing all 3 techniques on all 3 subjects

### Overall study start date
01/01/2016

### Completion date
31/12/2017

## Eligibility

### Key inclusion criteria
Training subjects (n = 1):
1. Between the ages of 18-80 years old either male or female
2. Able to give informed consent
3. Healthy volunteer

Study subjects (n = 2):
1. Between the ages of 18-80 years old either male or female

2. Able to give informed consent
3. Has neck pathology/ previous neck surgery or irradiation

Research Participants (n = 45):
1. Anaesthetic trainees (ST3 and above), NCCG and consultants proficient in handling the ultrasound either for vascular access or regional anaesthesia.
2. Between the ages of 18-80 years old either male or female
3. Able to give informed consent

### Participant type(s)
Patient

### Age group
Adult

### Lower age limit
18 Years

### Upper age limit
80 Years

### Sex
Both

### Target number of participants
Planned Sample Size: 48; UK Sample Size: 48

### Key exclusion criteria
Training subjects (n1):
1. Have neck pathology
2. Previous neck surgery or irradiation.
3. Medically unstable
4. Unable to tolerate lying flat or extending the neck for a prolonged period of time

Study subjects (n2):
1. Medically unstable
2. Unable to tolerate lying flat or extending the neck for a prolonged period of time

Research Participants (n45):
Have used the ultrasound in identifying the cricothyroid membrane within the past 1 year.

### Date of first enrolment
01/02/2017

### Date of final enrolment
31/03/2017

## Locations

### Countries of recruitment

England

United Kingdom

**Study participating centre**
**Royal Surrey County Hospital NHS Trust**
Egerton Road
Guildford
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GU2 7XX

# Sponsor information

**Organisation**
Royal Surrey County Hospital NHS Foundation Trust

**Sponsor details**
Department of Research, Development & Innovations
Leggett Building
Daphne Jackson Road
Guildford
England
United Kingdom
GU2 7XX

**Sponsor type**
Hospital/treatment centre

**ROR**
https://ror.org/050bd8661

# Funder(s)

**Funder type**
Research organisation

**Funder Name**
National Institute of Academic Anaesthesia

# Results and Publications

## Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal. Intend to publish by one year after overall trial end date.

## Intention to publish date
31/12/2019

## Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

## IPD sharing plan summary
Other

## Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Basic results | | 07/01/2019 | 15/01/2019 | No | No |
| Abstract results | | | 17/08/2022 | No | No |
| Poster results | | | 17/08/2022 | No | No |
| Protocol file | version 4 | 12/08/2016 | 06/10/2022 | No | No |
| HRA research summary | | | 28/06/2023 | No | No |