

Case series to evaluate the use of the VivaSight double lumen tube

Submission date 03/03/2013	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 10/06/2013	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 21/01/2019	Condition category Surgery	☐ Individual participant data

Plain English summary of protocol

Background and study aims

The majority of the chest surgeries, at Guys Hospital tertiary referral centre, require lung isolation. This is generally achieved by insertion of a breathing tube called a double lumen endotracheal tube (DLT). In order to confirm correct positioning of the DLT, it is recommended to use flexible fiberoptic bronchoscopes (tubes inserted to see the inside of the lung). These tubes have to be cleaned and disinfected after each use. They are also fragile and are prone to damage particularly during passage within the double lumen tube.

VivaSight™-DL (ETView Medical Ltd) double lumen tubes are manufactured as single use double lumen tubes with an integrated high resolution camera which provides real time images. The aim of this is to reduce the need for bronchoscopy (a procedure to see the airways) to confirm correct tube positioning and to enhance early recognition of tube displacement. This study aims to assess how well VivaSight DLT works.

Who can participate?

Adult female patients (age 18 years or over), due to undergo chest surgery requiring lung isolation, can participate in this study.

What does the study involve?

The patient will be given a general anaesthetic and a muscle relaxant. The VivaSight DLT will then be inserted into the patient. The time taken to insert the tube and to isolate the lung will be studied. We will also be looking for any incidental airway defects.

What are the possible benefits and risks of participating?

The VivaSight DLT is virtually identical to the standard DLT used at Guys Hospital and will be inserted by an experienced consultant. The benefits of this study will be for future patients, to enable continuous viewing of the airway and enhance placement of the tube. It is possible that using the VivaSight tube may cause sore throat, hoarseness, swallowing difficulties, coughing, difficulty breathing and damage to teeth. An uncommon side effect can be damage to the windpipe. All of these side effects, however, can occur after any general anesthetic for chest surgery.

Where is the study run from?

The study will be run at Guys Hospital in the thoracic theatres.

When is the study starting and long is it expected to run for?

The study starts in June 2013 and is expected to run for 3 months.

Who is funding the study?

The VivaSight DLTs are being provided by the manufacturing company free of charge.

Who is the main contact?

Dr Cheng Ong, cheng.ong@gstt.nhs.uk

Dr Caroline Dean, cally_dean@hotmail.com

Contact information

Type(s)

Scientific

Contact name

Dr Cheng Ong

Contact details

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SE1 9RT

Additional identifiers

Protocol serial number

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Study information

Scientific Title

Case series: Double-lumen tracheal intubation using VivaSight DLT

Study objectives

Case series to assess and quantify the timing required to isolate lungs, and the ease of intubation, using the VivaSight™ double lumen tube (DLT).

Ethics approval required

Old ethics approval format

Ethics approval(s)

Proportionate Review Sub-Committee, 25/03/2013, ref: 13/NW/0204.

Study design

Observational case series

Primary study design

Observational

Study type(s)

Screening

Health condition(s) or problem(s) studied

Female patients undergoing thoracic surgery requiring lung isolation

Interventions

The use of the VivaSight DLT, which will be inserted once the patient is under a general anaesthetic and has been administered a muscle relaxant.

Intervention Type

Procedure/Surgery

Phase

Not Applicable

Primary outcome(s)

1. Quantify time to successful intubation and separation of lungs using VivaSight™-DL
2. Quantify failure or number of attempts until successful lung separation
3. Quantify complications

Key secondary outcome(s)

No secondary outcome measures

Completion date

01/07/2013

Eligibility

Key inclusion criteria

1. Female patients, age 18-99 years
2. Thoracic surgery requiring left sided 37 fr Double lumen tube
3. American Society of Anaesthesiologists (ASA) categories 1-3

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

99 years

Sex

Female

Key exclusion criteria

1. Age less than 18 years
2. ASA category 4
3. Known or predicted difficult airway
4. Require rapid sequence induction or another anaesthetic technique deviating from that outlined in the protocol

Date of first enrolment

01/05/2013

Date of final enrolment

01/07/2013

Locations**Countries of recruitment**

United Kingdom

England

Study participating centre

Guys Hospital

London

United Kingdom

SE1 9RT

Sponsor information**Organisation**

Guy's and St Thomas' Foundation NHS Trust (UK)

ROR

<https://ror.org/00j161312>

Funder(s)

Funder type

Industry

Funder Name

VivaSight DLT will be provided by the manufacturing company ETVView Medical Ltd. free of charge. No further funding is required for this case series.

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/04/2016	21/01/2019	Yes	No
HRA research summary			28/06/2023	No	No