

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

<b>Submission date</b> 03/03/2013	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 10/06/2013	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 21/01/2019	<b>Condition category</b> Surgery	<input type="checkbox"/> 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

Guys Hospital  
Great Maze Pond  
London  
United Kingdom  
SE1 9RT

## Additional identifiers

### Protocol serial number

1

## 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?
<a href="#">Results article</a>	results	01/04/2016	21/01/2019	Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No