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

Submission date
03/03/2013

Recruitment status
No longer recruiting

Registration date
10/06/2013

Overall study status
Completed

Last Edited
21/01/2019

Condition category
Surgery

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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 fibreoptic 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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-Committeee, 25/03/2013, ref: 13/NW/0204.

Study design
Observational case series

Primary study design
Observational

Secondary study design
Non randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Screening

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
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 measure
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

Secondary outcome measures
No secondary outcome measures

Overall study start date
01/05/2013

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 Anaestesiologists (ASA) categories 1-3

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
99 Years

Sex
Female

Target number of participants
8

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
England

United Kingdom

Study participating centre
Guys Hospital
London

United Kingdom
SE1 9RT

Sponsor information

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

Sponsor details
c/o Ms Karen Ignatian
R&D Department
16th Floor Tower Wing
Great Maze Pond
London
England
United Kingdom
SE1 9RT

Sponsor type
Hospital/treatment centre

Website
http://www.guysandstthomas.nhs.uk

ROR
https://ror.org/00j161312

Funder(s)

Funder type
Industry

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

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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