

Video-assisted thoracoscopic lobectomy (VATS) versus conventional Open Lobectomy for lung cancer

Submission date 27/11/2014	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 28/11/2014	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 26/01/2024	Condition category Cancer	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

<https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-comparing-keyhole-surgery-with-open-surgery-for-people-with-lung-cancer-violet>

Study website

<https://bristoltrialscentre.blogs.bristol.ac.uk/details-of-studies/violet/>

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

NCT03521375

Secondary identifying numbers

HTA 13/04/03

Study information**Scientific Title**

Video-assisted thoracoscopic lobectomy versus conventional Open LobEcTomy for lung cancer: a multi-centre randomised controlled trial with an internal pilot

Acronym

VIOLET

Study objectives

VIOLET is an interventional study to evaluate the effectiveness, cost effectiveness and acceptability of VATS vs open surgery for early stage lung cancer. The hypothesis is that VATS surgery is superior to open surgery with respect to self-reported physical function 5 weeks after randomisation (approx. 1 month after surgery).

More details can be found at <http://www.nets.nihr.ac.uk/projects/hta/130403>

Ethics approval required

Old ethics approval format

Ethics approval(s)

NRES Committee London - Dulwich, 07/01/2015, ref: 14/LO/2129

Study design

Pragmatic multi-centre parallel-group randomised controlled trial with an internal pilot phase (phase 1)

Primary study design

Interventional

Secondary study design

Randomised parallel trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet**Health condition(s) or problem(s) studied**

Lung cancer (stage cT1a-2b N0-1 M0)

Interventions

Trial participants will be randomised to lobectomy via VATS or open surgery in a 1:1 ratio.

Video-assisted thoracoscopic surgery (VATS):

VATS lobectomy is undertaken through one to four keyhole incisions without rib spreading. The use of 'rib spreading' is prohibited as this is the key intra-operative manoeuvre which disrupts tissues and causes pain (and is used in open surgery). The procedure is performed with videoscopic visualisation without direct vision. The hilar structures are dissected, stapled and divided. Endoscopic ligation of pulmonary arterial branches may be performed.

Open surgery:

Conventional open surgery is undertaken through a single incision +/- rib resection and with rib spreading. The operation is performed under direct vision with isolation of the hilar structures (vein, artery and bronchus) which are dissected, ligated and divided in sequence and the lobe of lung resected. The procedures may be undertaken using ligatures, over sewing or with staplers.

Lymph node management is undertaken in accordance with the International Association of the Study of Lung Cancer (IASLC) recommendations where a minimal of six nodes/stations are removed, of which three are from the mediastinum that includes the subcarinal station.

Added 02/04/2019:

VIOLET has an embedded sub-study which aims to determine if the presence of molecular residual disease detected in blood samples taken at pre-defined time points after surgery is associated with early cancer recurrence. Consenting participants will have blood drawn at baseline (pre-surgery) and at 5 weeks, 6 months, 12 months, 18 months, 24 months, 36 months, 48 months, and 60 months (post-surgery). The blood results of those patients whose cancer returns will be compared to the blood results of those patients who remain cancer-free. The sub-study will continue after recruitment to the main study has finished.

Intervention Type

Procedure/Surgery

Primary outcome measure

The primary endpoint is self-reported physical function (QLQ-C30) at 5 weeks post randomisation. Physical function has been chosen because it is a patient-centred outcome that will reflect the anticipated earlier recovery with video-assisted surgery and has been used in other minimal access surgery trials. The primary endpoint has been chosen to be 5 weeks (1 month post-surgery) to capture the early benefits of minimal access surgery on recovery.

Secondary outcome measures

Current secondary outcome measures as of 08/01/2019:

1. Time from surgery to hospital discharge
2. Adverse health events
3. Proportion and time to uptake of adjuvant treatment
4. Proportion of patients upstaged to pN2 disease after the procedure
5. Overall and disease-free survival to 1 year
6. Proportion of patients who undergo complete resection during the procedure
7. Proportion of patients who experience prolonged incision pain (defined as the need of analgesia > 5 weeks after surgery)
8. Generic and disease-specific HRQoL: EORTC QLQ-C30, QLQ-LC13 and EQ5D to 1 year (measured at 2 week, 5 weeks, 3 months, 6 months and 1-year post randomisation)
9. Resource use to 1 year (measured for the duration of post-operative hospital stay until discharge, and at 2 weeks, 5 weeks, 3 months, 6 months and 1-year post randomisation)

Previous secondary outcome measures:

1. Time from surgery to hospital discharge
2. Adverse health events
3. Proportion and time to uptake of adjuvant treatment
4. Proportion of patients upstaged to pN2 disease after the procedure
5. Overall and disease-free survival to 1 year
6. Proportion of patients who undergo complete resection during the procedure
7. Proportion of patients who experience prolonged incision pain (defined as the need of analgesia > 6 weeks after surgery)
8. Generic and disease-specific HRQoL: EORTC QLQ-C30, QLQ-LC13 and EQ5D to 1 year (measured at 2 week, 5 weeks, 3 months, 6 months and 1-year post randomisation)
9. Resource use to 1 year (measured for the duration of post-operative hospital stay until discharge, and at 2 weeks, 5 weeks, 3 months, 6 months and 1-year post randomisation)

Overall study start date

01/01/2015

Completion date

01/09/2020

Eligibility

Key inclusion criteria

Current participant inclusion criteria as of 08/01/2019:

1. Adults aged ≥ 16 years of age
2. Able to give written consent, undergoing either:
 - 2.1. Lobectomy or bilobectomy for treatment of known or suspected primary lung cancer beyond lobar orifice* in TNM8 stage cT1-3 (by size criteria, equivalent to TNM7 stage cT1a-2b) or cT3 (by virtue of 2 nodules in the same lobe), N0-1 and M0 or

- 2.2. Undergoing frozen section biopsy with the intention to proceed with lobectomy or bilobectomy if primary lung cancer with a peripheral tumour beyond a lobar orifice* in TNM8 stage cT1-3 (by size criteria, equivalent to TNM7 stage cT1a-2b) or cT3 (by virtue of 2 nodules in the same lobe), N0-1 and M0 is confirmed
3. Disease suitable for both minimal access (VATS) and open surgery

Previous participant inclusion criteria:

1. Adults aged ≥ 16 years of age
2. Able to give written consent, undergoing either:
 - 2.1. Lobectomy for treatment of known or suspected primary lung cancer beyond lobular orifice in stage cT1a-2b N0-1 M0 or
 - 2.2. Undergoing frozen section biopsy with the intention to proceed with lobectomy if primary lung cancer with a peripheral tumour beyond a lobular orifice in stage cT1a-2b N0-1 M0 is confirmed
3. Disease suitable for both minimal access (VATS) and open surgery

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

498 (Phase 1: 162, Phase 2: 338)

Total final enrolment

503

Key exclusion criteria

1. Adults lacking capacity to consent
2. Previous malignancy that influences life expectancy
3. Patients in whom a pneumonectomy or non-anatomic resection (e.g. wedge dissection) is planned
4. Patients with a serious concomitant disorder that would compromise patient safety during surgery
5. Planned robotic surgery

Date of first enrolment

01/07/2015

Date of final enrolment

01/03/2019

Locations

Countries of recruitment

England

Scotland

United Kingdom

Study participating centre

Royal Brompton Hospital

Sydney Street

London

United Kingdom

SW3 6NP

Study participating centre

Harefield Hospital

Hill End Road

Harefield

United Kingdom

UB9 6JH

Study participating centre

Bristol Royal Infirmary

Upper Maudlin Street

Bristol

United Kingdom

BS2 8HW

Study participating centre

Liverpool Heart & Chest Hospital

Thomas Drive

Liverpool

United Kingdom

L14 3PE

Study participating centre

James Cook University Hospital (Middlesbrough)

Marlon Road

Middlesbrough

United Kingdom

TS4 3BW

Study participating centre

Oxford University Hospitals - Churchill Hospital

Headley Way

Oxford

United Kingdom

OX3 9DU

Study participating centre

Hull and East Yorkshire Hospitals NHS Trust

Castle Road

Cottingham

United Kingdom

HU16 5JQ

Study participating centre

University Hospitals Birmingham NHS Foundation Trust

Bordesley Green East

Birmingham

United Kingdom

B9 5SS

Study participating centre

Royal Infirmary of Edinburgh

Little France Crescent

Edinburgh

United Kingdom

EH16 4SU

Sponsor information

Organisation

Royal Brompton & Harefield NHS Foundation Trust

Sponsor details

Research Office

Chelsea Wing

Sydney Street

London

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Sponsor type

Hospital/treatment centre

ROR

<https://ror.org/02218z997>

Funder(s)

Funder type

Not defined

Funder Name

National Institute for Health Research

Alternative Name(s)

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

Publication and dissemination plan

A full report will be written for the HTA and the findings will be written-up as methodology papers for conference presentation, and publication in peer-reviewed journals. Many aspects of the feasibility work will inform surgical RCTs in general and these will be reported at methodology meetings. We will also link with lung cancer clinical studies groups. Social media will be used to disseminate and publicise the trial via a website, facebook and twitter streams. The PPI group that work with the Respiratory Biomedical Research Unit at the Brompton Hospital will help identify how we can best publicise the findings.

Intention to publish date

31/01/2022

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Eric Lim (violet-study@bristol.ac.uk). Data will not be made available for sharing until after publication of the main results of the study. Thereafter, anonymised

individual patient data will be made available for secondary research, conditional on assurance from the secondary researcher that the proposed use of the data is compliant with the MRC Policy on Data Sharing regarding scientific quality, ethical requirements and value for money. A minimum requirement with respect to scientific quality will be a publicly available pre-specified protocol describing the purpose, methods and analysis of the secondary research, e.g. a protocol for a Cochrane systematic review. The second file containing patient identifiers would be made available for record linkage or a similar purpose, subject to confirmation that the secondary research protocol has been approved by a UK REC or other similar, approved ethics review body. These identifiers will not be shared with a third party.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	04/10/2019		Yes	No
Results article	results	18/01/2022	27/01/2022	Yes	No
Results article		01/12/2022	19/12/2022	Yes	No
HRA research summary			28/06/2023	No	No