ISRCTN13472721 https://doi.org/10.1186/ISRCTN13472721

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

Submission date 27/11/2014	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 28/11/2014	**Overall study status** Completed	
Last Edited 26/01/2024	**Condition category** Cancer	

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

Contact information

Type(s)
Public

Contact name
Ms Surinder Kaur

Contact details
Bristol Trials Centre (CTEU)
Bristol Medical School, University of Bristol
Level 7
Queen's Building
Bristol Royal Infirmary
Marlborough Street
Bristol
United Kingdom
BS2 8HW
+44 (0)117 342 2987
violet-study@bristol.ac.uk

Type(s)
Scientific

Contact name
Mr Eric Lim

Contact details
Academic Division of Thoracic Surgery
The Royal Brompton Hospital
Sydney Street
London
United Kingdom
SW3 6NP

Additional identifiers

ClinicalTrials.gov (NCT)
NCT03521375

Protocol serial number
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

Study type(s)
Treatment

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(s)
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.

Key secondary outcome(s))
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)

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

Healthy volunteers allowed

No

Age group
Adult

Sex
All

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
United Kingdom

England

Scotland

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)
Marton 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

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

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?
Results article	results	18/01/2022	27/01/2022	Yes	No
Results article		01/12/2022	19/12/2022	Yes	No
Protocol article	protocol	04/10/2019		Yes	No
HRA research summary			28/06/2023	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes