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Comparing stereotactic ablative radiotherapy with surgery in patients with peripheral stage I non small cell lung cancer considered at higher risk of complications from surgical resection.

Submission date 04/02/2015	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 04/02/2015	**Overall study status** Completed	
Last Edited 31/05/2022	**Condition category** Cancer	

Plain English summary of protocol
http://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-study-of-stereotactic-ablative-radiotherapy-for-lung-cancer-sabrtooth

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
18037

Study information

Scientific Title
A study to determine the feasibility and acceptability of conducting a phase III randomised controll

Acronym
SABRTOOTH

Study objectives
This study aims to determine the feasibility and acceptability of performing a large-scale definitive randomised phase III trial comparing surgery with stereotactic ablative radiotherapy (SABR) for patients with peripheral Stage I non-small cell lung cancer (NSCLC) at higher risk from surgery in the UK.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NHS Health Research Authority, NRES Committee Yorkshire and The Humber - Leeds West, 22/09/2014, ref: 14/YH/1162

Study design
Both; Interventional and Observational; Design type: Treatment, Qualitative

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Topic: Cancer; Subtopic: Lung Cancer; Disease: Lung (non-small cell)

Interventions
Patients will receive either Surgery or SABR.

1. Surgery:
1.1. Aim of surgical resection is a R0 resection.

1.2. Both thoracotomy and VATS (Video Assisted Thoracoscopic Surgery) are acceptable.
1.3. For high risk patients, a VATS approach is preferred (but not mandatory)
1.4. Confirmation of N0 stage either by EBUS-TBNA or mediastinoscopy before lung resection is recommended for lymph nodes >1cm in axial diameter and/or positive on PET/CT.
1.5. Confirmation of diagnosis of Non-Small Cell Carcinoma of the primary tumour either pre-operatively by image guided biopsy or intra-operatively by Frozen Section examination is recommended for those cases without pre-operative histology but not mandatory.
1.6. Recommended procedure is an anatomical resection – either a lobectomy or an anatomical segmentectomy.
1.7. Sub-lobar or wedge resection is acceptable if an anatomical resection is not deemed safe.
1.8. Sampling of at least 3 lobe-specific N2 nodal stations is recommended, though for wedge resections lymph node sampling is not mandated as, due to patient specific factors, the duration of the anaesthetic may need to be minimised.
1.9. Post-op analgesia and chest tube management is as per local unit protocols.

2. Stereotactic Ablative Radiotherapy (SABR):
This will be primarily based on the accepted guidelines of the UK SABR consortium, with three dose schedules based on the location of the tumour. 4D-CT scanning is used to establish the extent of tumour motion due to respiration and cone beam CT/fiducial tracking to localise the target on the linear accelerator). Multiple beams >7 or VMAT ARC therapy can be used and doses are according to the position of the tumour.

There will be 21 months of recruitment followed by 6 months of additional follow-up. Follow up will be at 6weeks, 3 months, 6 months, 9 months, 12 months, 18 months and 24 months post treatment (or until 6 months after the final participant is randomised), there will also be a patient reported questionnaire at 15 months and 21 months post treatment. OS data will be captured at the end of the study for all participants via the National Cancer Data Repository (NCDR).

Intervention Type
Other

Primary outcome measure
Recruitment rate/month over months 7-21

Secondary outcome measures
N/A

Overall study start date
01/11/2014

Completion date
31/01/2017

Eligibility

Key inclusion criteria
Main study:
1. Histological and/or clinical and radiological diagnosis of NSCLC
2. Primary tumour characteristics:
2.1. Peripherally located tumour as defined in the RTOG 0236 study and UK SABR Consortium

guidelines. This states that the tumour must be more than 2cm in axial diameter from a major airway = “No Fly Zone”. This includes the trachea, carina, right and left main bronchus and extends to the bifurcation of the right upper, right middle, right lower, left upper and left lower lobe bronchioles (See diagram below).
2.2. Maximal axial diameter ≤ 5 cm measured on lung windows on computed tomography.
3. No evidence of hilar or mediastinal lymph nodes involvement. Any hilar or mediastinal lymph nodes that are either PET positive or >1cm in axial dimension must be sampled by mediastinoscopy, endo-bronchial ultrasound or oesophageal endoscopic ultrasound and demonstrate negative cytology and/or pathology.
4. Local lung cancer MDT consensus opinion that patient is considered suitable for either surgical resection or SABR treatment and also to be at higher risk of complications from surgical resection.
5. Age ≥ 18
6. Female patients must satisfy the investigator that they are either not of childbearing potential or not pregnant (i.e. be willing to undergo a pregnancy test within 72hrs of surgery or day 1 of SABR treatment),.
7. Able and willing to provide written informed consent.
Qualitative sub-study:
1. Approached to consider entry into the SABRTooth trial
2. Decided against participation in the SABRTooth trial/ dropped out after randomisation but before treatment
3. Willing and able to comply with requirements of this study protocol
4. Written informed consent obtained to participate in this study

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 54; UK Sample Size: 54

Total final enrolment
24

Key exclusion criteria
Main study:
1. Previous radiotherapy within the planned treatment volume
2. History of clinically significant diffuse interstitial lung disease
3. Any history of concurrent or previous invasive malignancy that in the opinion of the investigator could impact on trial outcomes
4. Clinical or radiological evidence of metastatic spread
5. History of psychiatric or addictive disorder or other medical condition that, in the opinion of the investigator, would preclude the patient from meeting the trial requirements

6. Previous systemic therapies, including targeted and experimental treatments, for their current lung cancer diagnosis.
Qualitative sub¬study:
1. Decline participation in this study
2. Unable to comply with requirements of this study protocol

Date of first enrolment
01/07/2015

Date of final enrolment
31/01/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
St James's University Hospital (lead centre)
Leeds
United Kingdom
LS9 7TF

Study participating centre
Bradford Teaching Hospitals NHS Foundation Trust
Bradford
United Kingdom
BD9 6RJ

Study participating centre
The James Cook University Hospital
Middlesbrough
United Kingdom
TS4 3BW

Study participating centre
NHS Nottingham University Hospitals
Nottingham
United Kingdom
NG5 1PB

Study participating centre
Wythenshawe Hospital
Manchester
United Kingdom
M23 9LT

Study participating centre
The Christie NHS Trust
Manchester
United Kingdom
M20 4BX

Sponsor information

Organisation
Leeds Teaching Hospitals NHS Trust

Sponsor details
Research & Development
34 Hyde Terrace
Leeds
England
United Kingdom
LS2 9LN

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/00v4dac24

Funder(s)

Funder type
Government

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
To maintain the scientific integrity of the trial, data will not be released prior to the first publication of the analysis of the primary endpoint, either for trial publication or oral presentation purposes, without the permission of the TSC.

Intention to publish date

Individual participant data (IPD) sharing plan
De-identified individual participant data datasets generated and/or analysed during the current study will be available upon request from the Clinical Trials Research Unit, University of Leeds (contact CTRU-DataAccess@leeds.ac.uk in the first instance). Data will be made available at the end of the trial, i.e. usually when all primary and secondary endpoints have been met and all key analyses are complete. Data will remain available from then on for as long as CTRU retains the data.

CTRU makes data available by a 'controlled access' approach. Data will only be released for legitimate secondary research purposes, where the Chief Investigator, Sponsor and CTRU agree that the proposed use has scientific value and will be carried out to a high standard (in terms of scientific rigour and information governance and security), and that there are resources available to satisfy the request. Data will only be released in line with participants' consent, all applicable laws relating to data protection and confidentiality, and any contractual obligations to which the CTRU is subject. No individual participant data will be released before an appropriate agreement is in place setting out the conditions of release. The agreement will govern data retention, usually stipulating that data recipients must delete their copy of the data at the end of the planned project.

The CTRU encourages a collaborative approach to data sharing, and believe it is best practice for researchers who generated datasets to be involved in subsequent uses of those datasets. Recipients of trial data for secondary research will also receive data dictionaries, copies of key trial documents and any other information required to understand and reuse the released datasets.

The conditions of release for aggregate data may differ from those applying to individual participant data. Requests for aggregate data should also be sent to the above email address to discuss and agree suitable requirements for release.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	01/12/2016		Yes	No
Results article		12/11/2020	17/05/2022	Yes	No
HRA research summary			28/06/2023	No	No