ISRCTN95525805 https://doi.org/10.1186/ISRCTN95525805

A cohort study to investigate whether radiolabelled lung nodule localisation and excision is a technically successful and reliable method for excision, in patients with small lung nodule.

Submission date
21/01/2016

Registration date
22/01/2016

Last Edited
07/05/2021

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-study-using-radioactive-labelling-to-help-remove-lung-nodules

Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Lung Nodule Study Protocol : Version 1.1, 26th Feb 2015

Study information

Scientific Title
A cohort study to investigate whether radiolabelled lung nodule localisation and excision is a technically successful and reliable method for excision, in patients with small lung nodule: a observational, prospective, pilot study

Acronym
Radio-labelled excision of lung nodules (RLELN)

Study objectives
Injection of small pulmonary nodules with radiolabelled material will improve accurate localisation, aid early resection of these nodules and will optimize patient management with resultant improved outcome.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee North West - Lancaster, 27/05/2015, ref: 15/NW/0369

Study design
Observational, prospective, pilot study

Primary study design
Observational

Secondary study design

Study setting(s)
Hospital

Study type(s)
Diagnostic

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
Lung cancer or lung nodules of indeterminate origin

Interventions
Patients with very small nodules not amenable to excision via VATS surgery will be offered the option of radionucleotide injection of their nodules with VATS resection performed on the same day as an alternative to thoracotomy.

Patients will be identified from lung cancer multi-disciplinary (MDT) meetings. These MDT meetings are already an integral part of the researchers thoracic surgery services. They meet these patients to discuss their options for the management of these lung nodules and convey them the decision of the MDT. Patient makes a choice and an informed consent is taken. This new treatment option will be discussed as part of their treatment options.

The procedure will entail an admission to hospital (as per routine practice for patients who are due to undergo surgery). All patients will sign an informed consent form. They will have an injection of radio labelled substance under local anaesthesia by a consultant radiologist in the CT scan room. This is the same technique which is employed for CT guided lung biopsies which is a well-established procedure and the radiology team are well experienced in its conduct.

After this procedure the patient will return to the ward and later that day they will come to theatres, have a general anaesthetic and undergo a minimally invasive excision (key hole surgery) of the nodule in question.

The researchers will use the same key hole surgical technique that they routinely employ for larger nodules excision which they are able to see and feel, but the difference will be that they will use intraoperative gamma probe to detect the exact location of the nodule within the lung tissues. The recovery period from this operation will be about 2-4 days.

Intervention Type
Procedure/Surgery

Primary outcome measure
Technical success of lung nodule excision., assessed via histological confirmation of complete excision of nodule

Secondary outcome measures
1. Postoperative complications
2. Length of hospital stay
3. Conversion to Thoracotomy

Overall study start date
10/12/2014

Completion date
02/02/2017

Eligibility

Key inclusion criteria
1. Patients more than 16 years of age
2. Nodules less than 15 mm in size
3. Perceived difficulty in localising and excision of the nodule during surgery

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
20

Total final enrolment
23

Key exclusion criteria
1. Patients less than 16 years of age
2. Ability to remove mass without radiolabelling
3. Anatomic location of nodule makes it technically difficult to CT guided radiolabelling
4. Patient not willing to undergo the procedure
5. Inability to consent to the operation
6. Pregnancy

Date of first enrolment
02/11/2015

Date of final enrolment
02/02/2017

Locations

Countries of recruitment

England

United Kingdom

Study participating centre
James Cook University Hospital UK
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Sponsor information

Organisation
James Cook University Hospital

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Sponsor type
Research organisation

ROR
https://ror.org/02vqh3346

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
James Cook University Hospital (UK)

Results and Publications

Publication and dissemination plan
The data from this study will be analysed and presented at national and International Meetings. The findings from the study will be published in peer reviewed journals.

Intention to publish date
01/11/2017

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Plain English results			07/05/2021	No	Yes
Results article		01/02/2018	07/05/2021	Yes	No
HRA research summary			28/06/2023	No	No