

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	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 22/01/2016	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 07/05/2021	Condition category Cancer	☐ 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)

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Additional identifiers

Protocol serial number

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

Primary study design

Observational

Study design

Observational, prospective, pilot study

Study type(s)

Diagnostic

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 radionuclide 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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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**

United Kingdom

England

Study participating centre

James Cook University Hospital UK

Marlon Road

Middlesbrough

United Kingdom

TS4 3BW

Sponsor information

Organisation

James Cook University Hospital

ROR

<https://ror.org/02vqh3346>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

James Cook University Hospital (UK)

Results and Publications

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?
Results article		01/02/2018	07/05/2021	Yes	No
HRA research summary			28/06/2023	No	No
Plain English results			07/05/2021	No	Yes