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TARGET Trial

Submission date 27/01/2016	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 27/01/2016	**Overall study status** Completed	
Last Edited 02/08/2024	**Condition category** Cancer	

Plain English summary of protocol
https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-looking-at-pet-ct-targeted-biopsy-to-diagnose-cancer-of-the-covering-of-the-lungs-target-0

Contact information

Type(s)
Public

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Additional identifiers

Protocol serial number
19364

Study information

Scientific Title

Randomised controlled trial to compare the diagnostic yield of Positron Emission Tomography Computerised Tomography (PET- CT) targeted pleural biopsy versus CT--guided pleural biopsy in suspected pleural malignancy

Acronym
TARGET

Study objectives
The aim of this study is to investigate if PET-CT targeted biopsies are more likely to give a diagnostic biopsy compared to a second CT guided biopsy in patients who are suspected of having pleural malignancy who have already had one non-diagnostic biopsy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
South West - Exeter Research Ethics Committee, 15/07/2015, 15/SW/0156

Study design
Randomised; Interventional; Design type: Diagnosis

Primary study design
Interventional

Study type(s)
Diagnostic

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

Interventions
Participants are randomly allocated to one of two groups.

Intervention group: Participants will undergo a PET-CT scan prior to their CT guided biopsy. The PET-CT images and reports will be made available to the biopsy performing radiologists, ahead of the scheduled biopsy date.

Control group: Participants will undergo a CT guided biopsy alone.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Diagnostic accuracy of the PET-CT scan in the detection of pleural malignancy is determined using biposy results.

Key secondary outcome(s))
1. Diagnostic delay
2. Number of hospital attendances
3. Number of invasive pleural procedures

4. Survival
5. Costs associated with health related resource use
6. Mesothelin levels

Completion date
30/09/2019

Eligibility

Key inclusion criteria
Current participant inclusion criteria as of 17/11/2017:
Participants may be eligible for the study if ALL the following apply:
1. Pleural thickening on CT suspicious for pleural malignancy
2. Have had any form of pleural biopsy in the last 12 months (either by thoracoscopy or under radiological guidance) which was non-diagnostic for cancer
3. Lung Cancer/mesothelioma MDT decision to perform further CT-guided biopsy to pursue a diagnosis

Previous participant inclusion criteria:
1. Aged 18 years or over
2. Pleural thickening on CT suspicious for malignancy
3. Have had any for of pleural biopsy in the last 6 months (either by thoracoscopy or under radiological guidance) which was non-diagnostic for cancer
4. Lung Cancer/Mesothelioma Multidisciplinary team (MDT) decision to perform further CT guided biopsy to pursue a diagnosis

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
Current exclusion criteria as of 17/11/2017:
Participants may not enter study if ANY of the following apply:
1. Unsuitable for a CT guided biopsy – inability to co-operate, lie still for the duration of the biopsy, uncorrectable coagulopathy, inability to tolerate a pneumothorax, severe underlying lung disease (patients with an FEV1 < 35% assessed using simple spirometry, see section 5.3.1)
2. Unable to give written informed consent
3. Pregnancy or lactation
4. Age <18 years

5. Pleural thickening not amenable to a radiologically guided biopsy
6. Talc pleurodesis in the previous 6 months

Previous exclusion criteria:
1. Unsuitable for CT guided biopsy - inability to co-operate, lie still for the duration of the biopsy, uncorrectable coagulopathy, inability to tolerate a pneumothorax, severe underlying lung disease (patients with an FEV1 <35% assessed using simple spirometry)
2. Unable to give written informed consent
3. Pregnancy or lactation
4. Aged under 18 years
5. Pleural thickening not amenable to Tru-cut biopsy
6. Prior Talc pleurodesis

Date of first enrolment
10/11/2015

Date of final enrolment
30/09/2018

Locations

Countries of recruitment
United Kingdom

England

Scotland

Wales

Study participating centre
Bristol Royal Infirmary (Coordinating centre)
Clinical Trials and Evaluation Unit (CTEU)
Level 7, Queen's Building
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Study participating centre
Queen Elizabeth University Hospital
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Study participating centre
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GL1 3NN

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NP20 2UB

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NR4 7UY

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OX3 7LE

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Study participating centre
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Sponsor information

Organisation
North Bristol NHS Trust

ROR
https://ror.org/036x6gt55

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/02/2024	13/02/2024	Yes	No
Protocol article	protocol	19/02/2018		Yes	No
HRA research summary			28/06/2023	No	No
Plain English results			02/08/2024	No	Yes