ISRCTN14024829 https://doi.org/10.1186/ISRCTN14024829

TARGET Trial

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

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

Contact name
Ms Lucy Ellis

Contact details
Clinical Trials and Evaluation Unit (CTEU)
Level 7, Queen's Building
Bristol Royal Infirmary
Marlborough Street
Bristol
United Kingdom
BS2 8HW
+44 (0)117 3422374
target-trial@bristol.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised parallel trial

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
Not available in web format, please use the 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
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 measure
Diagnostic accuracy of the PET-CT scan in the detection of pleural malignancy is determined using biposy results.

Secondary outcome measures
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

Overall study start date
01/06/2015

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 78; UK Sample Size: 78

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
England

Scotland

United Kingdom

Wales

Study participating centre
Bristol Royal Infirmary (Coordinating centre)
Clinical Trials and Evaluation Unit (CTEU)
Level 7, Queen's Building

Bristol Royal Infirmary
Marlborough Street
Bristol
United Kingdom
BS2 8HW

Study participating centre
Queen Elizabeth University Hospital
1345 Govan Road
Govan
United Kingdom
G51 4TF

Study participating centre
Gloucester Royal Hospital
Gloucestershire Hospitals NHS Foundation Trust
Great Western Road
Gloucester
United Kingdom
GL1 3NN

Study participating centre
Southmead Hospital
North Bristol NHS Trust
Southmead Road
Westbury-on-Trym
Bristol
United Kingdom
BS10 5NB

Study participating centre
Royal Gwent Hospital
Cardiff Road
Newport
United Kingdom
NP20 2UB

Study participating centre
Norfolk and Norwich University Hospital
Colney Lane
Norwich

United Kingdom
NR4 7UY

Study participating centre
Churchill Hospital
Oxford University Hospitals NHS Foundation Trust
Old Road
Headington
Oxford
United Kingdom
OX3 7LE

Study participating centre
Northern General Hospital
Sheffield Teaching Hospitals NHS Foundation Trust
Herries Road
Sheffield
South Yorkshire
Sheffield
United Kingdom
S5 7AU

Study participating centre
Royal Stoke University Hospital
Newcastle Road
Stoke-on-Trent
United Kingdom
ST4 6QG

Sponsor information

Organisation
North Bristol NHS Trust

Sponsor details
Trust Headquarters
Beckspool Road
Frenchay
Bristol

England
United Kingdom
B16 1JE

Sponsor type
Hospital/treatment centre

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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date
31/03/2020

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?
Protocol article	protocol	19/02/2018		Yes	No
HRA research summary			28/06/2023	No	No
Results article		01/02/2024	13/02/2024	Yes	No
Plain English results			02/08/2024	No	Yes