# **TARGET Trial**

Submission date 27/01/2016	<b>Recruitment status</b> No longer recruiting	<ul><li>Prospectively registered</li><li>Protocol</li></ul>
Registration date 27/01/2016	Overall study status Completed	<ul><li>Statistical analysis plan</li><li>[X] Results</li></ul>
<b>Last Edited</b> 02/08/2024	<b>Condition category</b> 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

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#### Contact details

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## 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?
<u>Protocol article</u>	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