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An observational study of patients with asbestos exposure and pleural disease to assess the feasibility of a future interventional trial where repeat biopsies are taken

Submission date
06/01/2022

Recruitment status
No longer recruiting

Registration date
08/02/2022

Overall study status
Completed

Last Edited
29/04/2025

Condition category
Cancer

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

Plain English summary of protocol

Background and study aims
Mesothelioma is a cancer most commonly affecting the tissue layers which line the lung and inside of the chest wall (the pleura). It most commonly presents with a collection of fluid surrounding the lung (pleural effusion). Mesothelioma is strongly associated with asbestos exposure, which causes intense inflammation of the pleura, but does not occur until many decades after exposure. Benign asbestos pleural effusion (BAPE) is a non-cancerous condition also associated with asbestos exposure and pleural effusion. However, about 12% of patients diagnosed with BAPE are later diagnosed with mesothelioma. It is not currently known what triggers the change from benign pleural inflammation to mesothelioma. The Meso-ORIGINS study aims to define this by performing 2 years of surveillance, collecting measurements from repeat pleural fluid and biopsy (tissue) samples, repeat blood tests and scans. The aim of this study is to determine whether it will be possible to recruit sufficient numbers of patients to Meso-ORIGINS and to work out whether it will possible to perform all of the repeat tests that might be helpful (including biopsies) and whether patients would agree to have these performed.

Who can participate?
Patients of any age with benign asbestos pleural disease

What does the study involve?
Participants will be followed up for 6 months. At 6 months they will have an ultrasound assessment to assess the feasibility of local anaesthetic thoracoscopy and ultrasound-guided biopsy. The participants will also complete a questionnaire to assess their response to various other surveillance strategies. The researchers will also collect data from online databases.

What are the possible benefits and risks of participating?
There are no risks to participants as this is an observational study only. There are no direct benefits to patients but the study results should help inform future management of patients with their condition.

Where is the study run from?
Queen Elizabeth University Hospital, Glasgow (UK)

When is the study starting and how long is it expected to run for?
November 2018 to February 2021

Who is funding the study?
1. June Hancock Mesothelioma Research Fund (UK)
2. Glasgow Clinical Research Facility (UK)
3. Investigator initiated and funded (UK)

Who is the main contact?
Prof. Kevin Blyth
Kevin.blyth@glasgow.ac.uk

https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-study-to-find-out-more-about-mesothelioma-meso-origins

Contact information

Type(s)
Principal investigator

Contact name
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Additional identifiers

Integrated Research Application System (IRAS)
253522

Central Portfolio Management System (CPMS)
41018

Protocol serial number
GN17ON341

Study information

Scientific Title
The Meso-ORIGINS feasibility study: an observational study investigating patients with non-malignant asbestos-associated pleural inflammation

Study objectives
The current feasibility study will address important areas of uncertainty regarding the current Meso-ORIGINS design, including the technical feasibility and patient acceptability of the proposed surveillance protocol (including repeat local anaesthetic thoracoscopy [LAT]) and the sample size estimate. Alternative strategies for surveillance for transformation to malignant pleural mesothelioma (MPM) will be explored including imaging, blood tests for biomarkers and breath tests.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 30/11/2018, South Central - Hampshire B Research Ethics Committee (Level 3, Block B, Whitefriars, Lewins Mead, Bristol, BS1 2NT, UK; +44 (0)2071048055; nrescommittee.southcentral-hampshireb@nhs.net), REC ref: 18/SC/0617

Primary study design
Observational

Study design
Observational study and retrospective cohort study

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Benign asbestos pleural disease and mesothelioma

Interventions
The trial will recruit patients with benign asbestos pleural disease and follow them up for 6 months. At 6 months the patients will have an ultrasound assessment to assess local anaesthetic thoracoscopy and ultrasound-guided biopsy feasibility. The patients will also complete a questionnaire to assess their response to various other surveillance strategies.

There is also a retrospective cohort arm to the study which will involve the collection of data from online databases. The following data will be recorded retrospectively for all eligible patients using local anaesthetic thoracoscopy, video-assisted thoracoscopic surgery (VATS) and image-guided biopsy databases and electronic health records at study centres (all data will be recorded in a linked anonymised format):
1. Demographics (age, gender, occupation, asbestos exposure)
2. Baseline clinical data:

2.1. X-ray and CT findings
2.2. Local anaesthetic thoracoscopy findings (date of procedure, views obtained, nature of abnormalities, number of biopsies, lung apposition post-procedure, whether pleurodesis or indwelling pleural catheter performed)
2.3. Histology results
2.4. Blood tests (neutrophils, lymphocytes, platelets, CRP, albumin, LDH, total protein)
2.5. Pleural fluid results (colour, cytology, LDH, albumin, glucose and total protein)
3. Follow-up data (any new pleural or mesothelioma diagnosis since initial biopsy)

Intervention Type
Mixed

Primary outcome(s)
Prospective arm:
Recruitment rate recorded as the number of eligible participants who consent to participate in the study by 12 months

Retrospective arm:
Number of eligible patients diagnosed with mesothelioma within 2 years of a diagnosis of BAPE divided by the total number of eligible patients, measured using electronic health records

Key secondary outcome(s)
Prospective arm:
Outcomes including hypothetical consent to surveillence strategies (blood tests, breath tests, CT scan, MRI scan, pleural fluid sampling, local anaesthetic thoracoscopy) and reasons if declining consent, assessed using patient questionnaires at study visit 2 (6 months after recruitment, or at study visit 1 if recruited more than 6 months following diagnosis)

Retrospective arm:
Logistic regression model for mesothelioma transition using patient baseline data from first presentation with pleural disease as predictors

Completion date
15/02/2021

Eligibility

Key inclusion criteria
1. History of asbestos exposure or compatible radiology, e.g. pleural plaques
2. Histological diagnosis compatible with benign asbestos pleural effusions (BAPE) including benign fibrinous pleurisy, non-specific pleuritis, atypical mesothelial proliferation
Plus for the prospective feasibility study only - histological diagnosis made at LAT
3. Informed written consent
4. Expected prognosis ≥6 months
5. No age range was specified prior to recruitment

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
39

Key exclusion criteria
1. Histological diagnosis of MPM or secondary pleural malignancy
2. Pleural infection, empyema or granulomatous pleuritis

Plus for the retrospective cohort study only:
<2 years follow-up completed at the point of enrolment

Date of first enrolment
01/01/2019

Date of final enrolment
01/01/2020

Locations

Countries of recruitment
United Kingdom

England

Scotland

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

Study participating centre
University Hospital of South Manchester NHS Foundation Trust
Wythenshawe Hospital
Southmoor Road
Wythenshawe
Manchester
United Kingdom
M23 9LT

Study participating centre
Churchill Hospital
Churchill Hospital
Old Road
Headington
Oxford
United Kingdom
OX3 7LE

Study participating centre
University Hospital Bristol
Bristol Royal Infirmary
Marlborough Street
Bristol
United Kingdom
BS2 8HW

Sponsor information

Organisation
NHS Greater Glasgow and Clyde

ROR
https://ror.org/05kdz4d87

Funder(s)

Funder type
Charity

Funder Name
June Hancock Mesothelioma Research Fund

Alternative Name(s)
JHMRF

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Funder Name
Glasgow Clinical Research Facility

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
Study data will be stored in the PREDICT-Meso database in a linked anonymised format. Information regarding data sharing options can be found on the PREDICT-Meso website (https://www.predictmeso.com) or via application to the PREDICT-Meso Project Manager (Alexandrea.Macpherson@glasgow.ac.uk). Consent for use of data in subsequent research was only obtained from patients in the prospective study, therefore only these data can be shared.

IPD sharing plan summary
Stored in non-publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	prospective observational data	08/08/2023	09/08/2023	Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	version 3.1	01/05/2019	04/02/2022	No	Yes
Protocol file	version 1.1	10/05/2019	04/02/2022	No	No