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Meso-ORIGINS: An observational study investigating the origins of mesothelioma

Submission date 11/08/2021	**Recruitment status** Recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 13/08/2021	**Overall study status** Ongoing	
Last Edited 21/08/2025	**Condition category** Cancer	

Plain English summary of protocol

Background and study aims
Mesothelioma is an incurable cancer of the lining of the lungs (the pleura), which is strongly associated with previous asbestos exposure. The factors that promote or permit mesothelioma evolution to develop many decades after exposure to asbestos dust are poorly understood, but mesothelioma may be preceded by benign (non-cancerous) inflammation of the pleura in some patients. The diagnosis of asbestos-associated benign pleural inflammation therefore provides a unique window of opportunity to study mesothelioma evolution.
We will study samples collected in patients with an initial benign pleural biopsy sample, in whom mesothelioma subsequently develops, and compare these with similar samples from patients that do not evolve in this way. To do this, the study will create a large cohort of matched 'benign /mesothelioma' and 'benign/no mesothelioma' tissue pairs. This information may help us and future researchers to design new, more effective treatments for mesothelioma.

Who can participate?
Patients with abnormalities of the pleura who have reported previous asbestos exposure may be eligible. There is no age or gender restriction on participation.

What does the study involve?
This study has 2 arms: Arm A and Arm B, and an MRI sub-study as part of Arm A (site dependent).

Arm A
Arm A will recruit asbestos-exposed participants with an initial benign pleural biopsy result. Participants will be followed up for 2 years following retrieval of their original biopsy for use in the study and collection of a sample of blood and exhaled breath. The breath sample will be collected using a special device that looks like a large inhaler. They will be asked to take deep breaths in and out during this test, which takes around 5 minutes to complete. The study will also request access to any additional scans or biopsies taken over the 2-year follow-up.

Arm A MRI sub-study:
The sub-study will recruit participants at participating sites who have already consented to be part of Arm A. Participants who choose to be part of the MRI sub-study will have an MRI performed within 14 days of study enrolment, in addition to the steps noted above.

Arm B:
Arm B will recruit asbestos-exposed participants who are going to have biopsies taken because a pleural abnormality has been found by their medical team (e.g. a pleural effusion (a collection of fluid around the lung) or a pleural mass (an area of thickening on the lining of the lung). Participants will have extra biopsy samples taken for study analyses during the biopsy procedure already planned, and samples of the drained pleural fluid will be taken. In addition, patients will be asked to give blood samples and exhaled breath. The breath sample will be collected using a special device that looks like a large inhaler. They will be asked to take deep breaths in and out during this test, which takes around 5 minutes to complete.

What are the possible benefits and risks of participating?
There is unlikely to be any direct benefit to participants taking part, but the results of this study could help us understand how mesothelioma develops and how to effectively diagnose and treat it. This has the potential to greatly improve the lives of patients in the future.
Biopsies come with small risks; however, these are safe, common procedures and complications are rare. The biopsies are done as part of routine care if a participant's doctor suspects that mesothelioma might be developing; therefore, being in the study would not increase any risks related to this.

Where is the study run from?
The study is being coordinated by the University of Glasgow, supported by Cancer Research UK Glasgow Clinical Trials Unit (based at the Beatson West of Scotland Cancer Centre in Glasgow) (UK)

When is the study starting and how long is it expected to run for?
August 2021 to August 2028

Who is funding the study?
Cancer Research UK

Who is the main contact?
Professor Kevin Blyth, Kevin.blyth@glasgow.ac.uk
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https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-study-to-find-out-more-about-mesothelioma-meso-origin

Study website
https://www.predictmeso.com/

Contact information

Type(s)
Public

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Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
291818

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
GN19ON232, CPMS 50562

Study information

Scientific Title
Meso-ORIGINS: Mesothelioma Observational study of RIsk prediction and Generation of paired benign-meso tissue samples, Including a Nested MRI Sub-study

Acronym
Meso-ORIGINS

Study objectives
Malignant pleural mesothelioma (MPM) is an incurable cancer of the lining of the lung, strongly associated with asbestos exposure, that develops after decades of benign pleural inflammation. It is not known what triggers the evolution from benign inflammation to MPM, or how best to treat the cancer to reverse or halt these processes.

Meso-ORIGINS aims to generate a large prospective cohort of asbestos-exposed patients with benign initial biopsies matched to subsequent samples acquired at mesothelioma evolution. These samples will be used in downstream pre-clinical work packages to define the biology driving mesothelioma evolution; to define new drug targets; and in the validation of pre-clinical models.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 11/11/2021, West of Scotland Research Ethics Committee 4 (West of Scotland Research Ethics Service, Ward 11, Dykebar Hospital, Grahamston Road, Paisley, PA2 7DE, UK; +44 (0)141 314 0212; WoSREC4@ggc.scot.nhs.uk), ref: 21/Ws/0120

Study design
Multi-centre prospective observational study incorporating a cross-sectional MRI sub-study

Primary study design
Observational

Secondary study design
Longitudinal study

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
Not available in web format, please use contact details to request participant information sheet

Health condition(s) or problem(s) studied
Patients with benign asbestos-associated pleural disease and patients with suspected mesothelioma

Interventions
Arm A will follow patients up over a 2-year period following an initial benign pleural biopsy. All patients will have their initial pleural biopsies retrieved and banked and all will have baseline risk assessment, including data, blood and exhaled breath sample collection. Participants will provide consent for any subsequent tissue samples to be banked, including any taken because of suspected Mesothelioma during the 2-year follow-up period. MRI sub-study participants will have an additional MRI scan as part of their baseline assessment.

Arm B will recruit patients with suspected mesothelioma and ask for consent to take additional pleural biopsies, a blood sample (added 14/07/2022), and a breath sample (added 21/08/2025).

Removed 21/08/2025: Participants with benign follow-up may be asked to consent to repeat biopsy sampling.

Intervention Type
Mixed

Primary outcome measure
Number of patients in Arm A diagnosed with malignant pleural mesothelioma based on histological confirmation in tissue biopsies at any point from study registration to completion of 2 years follow-up

Secondary outcome measures
1. Results of a multiomic risk classifier based on radiomics based on perfusion MRI early contrast enhancement, proteomic assay to be confirmed, exhaled breath metabolomics by gas chromatography-mass spectrometry at baseline in Arm A
2. Number of patients in the Arm B with histologically confirmed malignant pleural mesothelioma following thoracoscopy

Overall study start date
12/08/2021

Completion date
31/08/2028

Eligibility

Key inclusion criteria
Arm A:
1. History of asbestos exposure or imaging compatible with this (e.g., pleural plaques)
2. Any form of pleural biopsy within the last 1 year showing evidence of associated pleural inflammation (e.g., benign fibrinous pleurisy, non-specific pleuritis, atypical mesothelial proliferation)
3. Informed written consent (to at least banking of previous and future pleural tissue samples)

Arm A MRI sub-study:
1. Registered to Arm A
2. Informed written consent

Arm B:
1. Suspected pleural malignancy, defined by a unilateral pleural effusion or mass
2. History of asbestos exposure or typical radiological features, e.g., pleural plaques
3. Sufficient fitness for thoracoscopy (LAT or VATS are permissible)
4. Informed written consent

Added 21/08/2025:
Arm A and B:
≥16 years of age

Participant type(s)
Patient

Age group
Adult

Lower age limit
16 Years

Sex
Both

Target number of participants
600

Key exclusion criteria
Arm A:
1. Any cytologically or histologically confirmed pleural malignancy
2. Any pleural infection including TB
3. Granulomatous pleural inflammation
4. Any specific pleuritis (e.g., RA)
5. Previous pleurodesis

Arm A MRI sub-study:
1. Any contraindication to MRI, e.g., claustrophobia, pregnancy, metallic foreign body, pacemaker /implant
2. Allergy to gadolinium contrast
3. eGFR <30 ml/min

Arm B:
1. Current or recent (within the last 3 months) intercostal chest drain
2. Previous pleurodesis

Date of first enrolment
16/06/2022

Date of final enrolment
31/08/2026

Locations

Countries of recruitment
England

Scotland

United Kingdom

Wales

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

Study participating centre
University Hospitals Plymouth NHS Trust
Derriford Hospital
Derriford Road
Derriford
Plymouth
United Kingdom
PL6 8DH

Study participating centre
Royal Gwent Hospital
Aneurin Bevan University Health Board
Cardiff Road
Newport
United Kingdom
NP20 2UB

Study participating centre
Churchill Hospital
Oxford Respiratory Trials Unit (ORTU)
The University of Oxford
Oxford Centre for Respiratory Medicine
Oxford
United Kingdom
OX3 7LE

Study participating centre
Musgrove Park Hospital (taunton)
Musgrove Park Hospital
Taunton
United Kingdom
TA1 5DA

Study participating centre
Southmead Hospital
Southmead Road
Westbury-on-trym
Bristol
United Kingdom
BS10 5NB

Study participating centre
Wythenshawe Hospital
Southmoor Road
Wythenshawe
Manchester
United Kingdom
M23 9LT

Study participating centre
Northumbria Specialist Emergency Care Hospital
North Tyneside General Hospital
Rake Lane
North Shields
United Kingdom
NE29 8NH

Study participating centre
Glasgow Royal Infirmary
NHS Greater Glasgow and Clyde
84 Castle Street
Glasgow
United Kingdom
G4 0SF

Study participating centre
Gartnavel General Hospital
1053 Great Western Road
Glasgow
United Kingdom
G12 0YN

Study participating centre

Royal Lancaster Infirmary
Ashton Road
Lancaster
United Kingdom
LA1 4RP

Study participating centre
Salford Royal
Stott Lane
Salford
United Kingdom
M6 8HD

Study participating centre
Aberdeen Royal Infirmary
Foresterhill Road
Aberdeen
United Kingdom
AB25 2ZN

Study participating centre
Victoria Hospital (blackpool)
Whinney Heys Road
Blackpool
United Kingdom
FY3 8NR

Study participating centre
Ninewells Hospital
Ninewells Avenue
Dundee
United Kingdom
DD1 9SY

Study participating centre
Raigmore Hospital
Old Perth Rd
Inverness
United Kingdom
IV2 3UJ

Study participating centre
Kettering General Hospital Laboratory
Kettering General Hospital
Rothwell Road
Kettering
United Kingdom
NN16 8UZ

Study participating centre
Western General Hospital
Crewe Road South
Edinburgh
Lothian
United Kingdom
EH4 2XU

Study participating centre
Royal Papworth Hospital NHS Foundation Trust
Papworth Road
Cambridge Biomedical Campus
Cambridge
United Kingdom
CB2 0AY

Study participating centre
Glenfield General Hospital
Groby Road
Leicester
United Kingdom
LE3 9QP

Study participating centre
Furness General Hospital
Dalton Lane
Barrow-in-furness
United Kingdom
LA14 4LF

Study participating centre

The Grange University Hospital
Caerleon Road
Cwmbran
United Kingdom
NP44 8YN

Study participating centre
Royal Devon and Exeter Hospital
Royal Devon & Exeter Hospital
Barrack Road
Exeter
United Kingdom
EX2 5DW

Study participating centre
Golden Jubilee National Hospital
Agamemnon Street
Clydebank
United Kingdom
G81 4DY

Study participating centre
University Hospital Monklands
Monkscourt Avenue
Airdrie
United Kingdom
ML6 0JS

Study participating centre
Freeman Hospital
Freeman Road
High Heaton
Newcastle upon Tyne
United Kingdom
NE7 7DN

Study participating centre
St Woolos Hospital
131 Stow Hill

Newport
United Kingdom
NP20 4SZ

Study participating centre
University Hospital of North Tees
Hardwick Road
Stockton-on-tees
United Kingdom
TS19 8PE

Study participating centre
Northern General Hospital
Herries Road
Sheffield
United Kingdom
S5 7AU

Study participating centre
South Tyneside District Hospital
Harton Lane
South Shields
United Kingdom
NE34 0PL

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

Sponsor information

Organisation
NHS Greater Glasgow and Clyde

Sponsor details

Research & Innovation Department
Admin Building, Level 2
Gartnavel Royal Hospital
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G12 0XH
+44 (0)141 314 4001
liz-anne.lewsley3@nhs.scot

Sponsor type
Hospital/treatment centre

Website
http://www.nhsggc.org.uk/

ROR
https://ror.org/05kdz4d87

Funder(s)

Funder type
Charity

Funder Name
Cancer Research UK

Alternative Name(s)
CR_UK, Cancer Research UK - London, CRUK

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Results will be published in peer-reviewed clinical and scientific journals, and presented at local, national and international scientific meetings. In addition, results will be published on the

PREDICT-Meso website (https://www.predictmeso.com/) and the PREDICT-Meso Twitter (https://twitter.com/PREDICT_Meso) and Bluesky (https://bsky.app/profile/predict-meso.bsky.social). We will utilise our established relationships with the Scottish Mesothelioma Network, Macmillan Cancer Support and Mesothelioma UK and their websites, social media, newsletters and events, to inform patients and participants of study results.

Intention to publish date
01/02/2028

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from the PREDICT-Meso Research Tissue Bank (REC approval 21/WS/011). Please contact alexandrea.macpherson@glasgow.ac.uk for details on the data available and application process. Patient consent will be obtained that allows storage in the Research Tissue Bank and appropriate sharing of samples and data with the mesothelioma research community. A copy of the PREDICT-Meso Research Tissue Bank Governance, Collection and Access policy can be made available upon request. This covers access criteria; what data will be shared including with whom, for what types of analyses, and by what mechanism comments on data anonymisation, any ethical or legal restrictions).

IPD sharing plan summary
Available on request