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

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

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
Dr Alexandrea MacPherson, Alexandrea.MacPherson@glasgow.ac.uk

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

Contact information

Type(s)

Public

Contact name

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Type(s)

Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Integrated Research Application System (IRAS)

291818

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

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

Study type(s)

Other

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(s)

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

Key secondary outcome(s))

- 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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

16 years

Sex

All

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

United Kingdom

England

Scotland

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 & Exeter Hospital Poval Devon & 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

ROR

https://ror.org/05kdz4d87

Funder(s)

Funder type

Charity

Funder Name

Cancer Research UK

Alternative Name(s)

CR_UK, Cancer Research UK - London, Cancer Research UK (CRUK), CRUK

Funding Body Type

Private sector organisation

Funding Body Subtype

Other non-profit organizations

Location

United Kingdom

Results and Publications

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes