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ASSESS-meso: a long-term study looking at people with mesothelioma (cancer of the outer lining of the lung) that will gather information on symptoms, disease processes and factors that affect survival

Submission date 08/01/2018	**Recruitment status** Recruiting	[_] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 24/01/2018	**Overall study status** Ongoing	
Last Edited 07/02/2025	**Condition category** Cancer	

Plain English summary of protocol

Background and study aims
Mesothelioma is an aggressive cancer that usually affects the outside lining of the lung, but can also affect the lining of the heart or abdomen. It usually arises as a result of previous exposure to asbestos, often more than 40 years previously. Rates of mesothelioma diagnosis have increased steadily over the past decade, in the UK and worldwide, and are predicted to continue rising over the next 5-10 years. Unfortunately the average life-expectancy of a person diagnosed with mesothelioma is less than a year. This is because it is very difficult to treat, with only one chemotherapy treatment that has been shown to be effective. On average, this chemotherapy allows people to live approximately 3 months longer, although some people respond really well and go on to live for many months or even years. Unfortunately at the moment, we can't predict which people will be the ones to respond well to chemotherapy. Lots of new treatments are being developed for mesothelioma. There is more to learn about mesothelioma, specifically whether there are any patient characteristics, factors relating to the tumour or blood tests that predict which patients might live longer and reponses to chemotherapy. This may help make better treatment decisions for individual patients. This information is will be gathered by setting up a database (cohort) of patients with mesothelioma diagnosed at our hospital, and at other hospitals in the UK. The cohort will also be used as a resource for identifying patients who are suitable to participate in clinical trials. The aim of the study is to collect information about mesothelioma and the people who develop it, their symptoms, and how things change over time, whilst also screening participants for participation in clinical trials.

Who can participate?
Adults aged 18 and older who have mesothelioma

What does the study involve?
Participants in the study are followed up in accordance with usual clinical care (aiming to have

appointments every 3 months or so). At each visit routine clinical data is collected, such as what treatments participants have had since their last appointment and whether they are still draining fluid from their chest. Imaging, such as chest x-rays and ultrasound scans will be undertaken at every appointment. CT scans are done every 6 months. Blood tests are taken at every study appointment, and if participants have fluid in their chest, a sample of this may be taken and stored. Participants are also asked to complete a symptom score and a quality of life questionnaire at each appointment. Participants are followed up from the day they receive their diagnosis for their whole life, or until they withdraw from the study. If participants find it too tiring or difficult to come to appointments in hospital, they are offered a telephone follow up.

What are the possible benefits and risks of participating?
There is no direct benefit for people taking part in the study. The information they provide will help doctors learn more about mesothelioma and potentially help future patients diagnosed with this disease. In future we intend to use the study to screen people to see if they are eligible to participate in clinical trials. As this study does not include an intervention, there are few risks to taking part. The additional time taken to complete the study assessments and up to 4 extra blood tests per year are potential disadvantages. Participants may be asked to undergo up to 2 extra CT scans and up to 4 extra chest x-rays per year, which involves exposure to radiation. However, this is only a small amount, and is unlikely to cause any significant health problems.

Where is the study run from?
1. Southmead Hospital (UK)
2. Churchill Hospital (UK)
3. Musgrove Park Hospital (UK)

When is the study starting and how long is it expected to run for?
September 2016 to December 2028

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
Dr Anna Bibby (Scientific)

Contact information

Type(s)
Scientific

Contact name
Dr Anna Bibby

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
220360

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS 33514

Study information

Scientific Title
A prospective observational cohort study collecting data on demographics, symptoms and biomarkers in people with mesothelioma that will provide a resource for future trials

Acronym
ASSESS-meso

Study objectives
The aim of the study is to collect information about mesothelioma and the people who develop it, their symptoms, and how things change over time, whilst also screening participants for participation in clinical trials.

Ethics approval required
Old ethics approval format

Ethics approval(s)
South West - Central Bristol Research Ethics Committee, 14/03/2017, ref: 17/SW/0019

Study design
Observational; Design type: Cohort study

Primary study design
Observational

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Mesothelioma (cancer of the outer lining of the lung)

Interventions
This is an observational study, with no additional intervention above usual clinical care. Participants are followed up from the point of diagnosis until death or withdrawal from the study. Data is collected during routine clinical appointments, every three months as a minimum. There is the option to switch to telephone follow up if participants are no longer undergoing hospital follow up.

Patients who agree to join the cohort provide clinical information at the point of diagnosis, alongside samples of blood and pleural fluid for analysis. Additional blood and pleural fluid samples are kept, and stored anonymously, for further testing in the future. Participants then continue to be followed up in clinic, approximately every 3 months. At every clinic appointment, participants provide more information, for example about the severity of their current symptoms, which will be collected and added to the database. If possible, further samples of pleural fluid and blood are also be taken at these appointments. Participants continue to provide information for the cohort at every pleural clinic appointment for the rest of their life.

Intervention Type
Other

Primary outcome(s)
Survival is measured as time from diagnosis to death (or censored at the point of withdrawal from the study) at every study visit.

Key secondary outcome(s))
1. Disease progression, assessed on CT scans using modified RECIST criteria at baseline and every 6 months
2. Change in serum mesothelin from baseline, assessed on blood tests taken at baseline and every 3 months
3. Patient reported symptom scores for breathlessness, chest pain and sweats, measured using visual analogue scales at baseline and every 3 months.
4. Patient reported quality of life, assessed using the EQ-5D-5L questionnaire, at baseline and every 3 months.
5. Pleurodesis rates assessed using pleural catheter drainage diaries, chest x-ray and thoracic ultrasound every 3 months. Pleurodesis is defined as "less than 50ml of pleural fluid drained on 3 or more successive drainages, with no evidence of residual fluid on chest x-ray or ultrasound".
6. Health services utilisation, assessed from patient history and hospital records every 3 months.

In addition data will be collected on confounding factors including:
1. Patient characteristics e.g. age, sex, presence of comorbidities, performance status - collected at baseline from patient history & medical records
2. Tumour variables e.g. histological type, disease site - collected at baseline from medical records
3. Treatment factors e.g. chemotherapy, radiotherapy, participation in clinical trials - collected at baseline and every 3 months based on patient history 7 medical records

Completion date
31/12/2028

Eligibility

Key inclusion criteria
1. Histological, cytological or clinico-pathological diagnosis of mesothelioma, confirmed at MDT
2. Willing and able to comply with study follow up assessments (including at least 1 appointment at a study recruiting centre if identified at a PIC)
3. Has capacity, as defined by the 2005 Mental Capacity Act

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Age < 18 years old
2. Unable to give written informed consent
3. Declines ongoing hospital follow up

Date of first enrolment
01/07/2017

Date of final enrolment
30/06/2027

Locations

Countries of recruitment
United Kingdom

England

Scotland

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

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

Study participating centre
Musgrove Park Hospital
Taunton & Somerset NHS Foundation Trust
Taunton
United Kingdom
TA1 5DA

Study participating centre
Greater Glasgow and Clyde
Gartnavel Royal Hospital
1055 Great Western Road
Glasgow
United Kingdom
G12 0XH

Study participating centre
Sherwood Forest Hospitals NHS Foundation Trust
Kings Mill Hospital
Mansfield Road
Sutton-in-ashfield
United Kingdom
NG17 4JL

Study participating centre
Velindre Cancer Centre
Velindre Road
Cardiff
United Kingdom
CF14 2TL

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

Study participating centre
Clatterbridge Cancer Centre
Clatterbridge Hospital
Clatterbridge Road
Wirral
United Kingdom
CH63 4JY

Study participating centre
Gloucestershire Hospitals NHS Foundation Trust
Cheltenham General Hospital
Sandford Road
Cheltenham
United Kingdom
GL53 7AN

Study participating centre
Sheffield Teaching Hospitals
Pegasus House, 4th Floor
463a Glossop Road
Sheffield
United Kingdom
S10 2QD

Study participating centre
NHS Highland
Reay House
17 Old Edinburgh Road
Inverness
United Kingdom
IV2 3HG

Study participating centre

University Hospitals of Morecambe Bay NHS Foundation Trust
Westmorland General Hospital
Burton Road
Kendal
United Kingdom
LA9 7RG

Study participating centre
Basildon Hospital
Nethermayne
Basildon
United Kingdom
SS16 5NL

Study participating centre
Broomfield Hospital
Court Road
Broomfield
Chelmsford
United Kingdom
CM1 7ET

Study participating centre
Southend University Hospital
Prittlewell Chase
Westcliff-on-sea
United Kingdom
SS0 0RY

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

Sponsor information

Organisation

North Bristol NHS Trust Research & Innovation Department

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

Individual participant data (IPD) sharing plan
The datasets generated during the current study will be available upon request from Dr Anna Bibby (anna.bibby@bristol.ac.uk) from December 2028 for 10 years. Pseudonymised patient-level data will be provided as Excel or STATA files for analysis in ethically approved research studies. Individual participant consent has been obtained for this type of data sharing.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		10/11/2022	11/11/2022	Yes	No
HRA research summary			28/06/2023	No	No
Interim results article	Pre-specified interim analysis (baseline characteristics), conducted when recruitment reached 25% of target	27/12/2023	08/01/2024	Yes	No

Participant information sheet	version v2.3		01/04/2019	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file	version 1.9	14/12/2023	24/01/2025	No	No