

# 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

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| <b>Submission date</b><br>08/01/2018   | <b>Recruitment status</b><br>Recruiting | <input type="checkbox"/> Prospectively registered<br><input checked="" type="checkbox"/> Protocol                       |
| <b>Registration date</b><br>24/01/2018 | <b>Overall study status</b><br>Ongoing  | <input type="checkbox"/> Statistical analysis plan<br><input type="checkbox"/> Results                                  |
| <b>Last Edited</b><br>07/02/2025       | <b>Condition category</b><br>Cancer     | <input type="checkbox"/> Individual participant data<br><input checked="" type="checkbox"/> Record updated in last year |

## 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 responses 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

**ORCID ID**

<http://orcid.org/0000-0001-7386-7754>

**Contact details**

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Bristol Medical School  
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BS10 5NB  
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## **Additional identifiers**

### **EudraCT/CTIS number**

Nil known

### **IRAS number**

220360

### **ClinicalTrials.gov number**

Nil known

### **Secondary identifying numbers**

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

### **Secondary study design**

Case-control study

### **Study setting(s)**

Hospital

## **Study type(s)**

Treatment

## **Participant information sheet**

See additional files

## **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 measure**

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

## **Secondary outcome measures**

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

**Overall study start date**

01/09/2016

**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

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

Planned Sample Size: 700; UK Sample Size: 700

**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**

England

Scotland

United Kingdom

**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

### Sponsor details

3rd Floor  
Learning & Research Building  
Southmead Hospital  
Bristol  
England  
United Kingdom  
BS10 5NB

### 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

Publication in a peer reviewed journal is planned for 2028. In addition results will be disseminated to the scientific community via presentation at conferences. Patients, participants and carers will be kept informed via presentation at patient conferences, and newsletters such as the British Lung Foundation and Mesothelioma UK. Publication of the study protocol in a peer-reviewed journal is planned in the next year.

### Intention to publish date

01/06/2018

### 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? |
|---|---|--------------|------------|----------------|-----------------|
| <a href="#">Participant information sheet</a> | version v2.3  |              | 01/04/2019 | No             | Yes             |
| <a href="#">Protocol article</a>              |   | 10/11/2022   | 11/11/2022 | Yes            | No              |
| <a href="#">HRA research summary</a>          |   |              | 28/06/2023 | No             | No              |
| <a href="#">Interim results article</a>       | Pre-specified interim analysis (baseline characteristics), conducted when recruitment reached 25% of target | 27/12/2023   | 08/01/2024 | Yes            | No              |
| <a href="#">Protocol file</a>                 | version 1.9   | 14/12/2023   | 24/01/2025 | No             | No              |