

Bronchiectasis observational cohort and biobank UK study

Submission date 18/06/2015	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 28/07/2017	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 28/07/2021	Condition category Respiratory	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Bronchiectasis is a long-term rare condition where the airways are abnormally widened (called bronchial dilatation), resulting in the build-up of mucus that can cause infection in the lungs. Symptoms include a persistent cough and breathlessness. There is a need to know more about how to treat bronchiectasis and how many patients there are in the UK with this condition. This study involves recording information about patients that are diagnosed with bronchiectasis and storing it in a registry. Currently there are very few drugs or treatments that are proven to work for bronchiectasis because very few clinical trials have been performed. The data collected in the registry will help us to evaluate how well treatments work and help to design better clinical trials by understanding more about the disease.

Who can participate?

Adults aged at 18 and older with bronchiectasis.

What does the study involve?

This study stores simple information about each participant, such as their age, the results of blood tests and x-rays and the treatments that they have or are receiving. This will help us to understand the impact of bronchiectasis on each participant, and on healthcare in the UK. Those asking for a data analysis to be conducted on the database may include doctors, university researchers and companies including the pharmaceutical industry. Participants that are willing to take part in clinical trials in the future are also identified and their contact details stored on file. Participants are asked to consent to the study period where funding is already identified namely a study duration of 36 months. The overall principle of the study is to collate data from routinely collected investigations as recommended in care guidelines with participants then followed up at least once a year.

What are the possible benefits and risks of participating?

There are no direct benefits or risks with participating.

Where is the study run from?

A number of NHS sites (at least 9) in the UK.

When is the study starting and how long is it expected to run for?
November 2014 to April 2027 (updated 28/07/2021, previously: October 2021)

Who is funding the study?
Medical Research Council (UK) & COPD Foundation (USA)

Who is the main contact?
Mr Phil Mawson
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Contact information

Type(s)
Public

Contact name
Mr Phil Mawson

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Additional identifiers

Protocol serial number
7378

Study information

Scientific Title
Bronchiectasis multi-centre observational cohort and biobank UK study

Acronym
BronchUK

Study objectives
The United Kingdom Bronchiectasis Registry (BronchUK) is a national research database and biobank of adults with bronchiectasis. The aim is to facilitate clinical trials and academic research studies in order to improve our understanding of what causes bronchiectasis and to find better, more effective treatments for people with this condition

Ethics approval required
Old ethics approval format

Ethics approval(s)

NRES Committee North East - Newcastle & North Tyneside 1, 17/07/2015, ref: 15/NE/0172

Study design

Multi-centre observational cohort study

Primary study design

Observational

Study type(s)

Quality of life

Health condition(s) or problem(s) studied

Adults resident in the UK with bronchiectasis

Interventions

This is an observational study. No interventions are undertaken as part of the study itself.

Once consented, participants have data extraction undertaken from their clinical notes. The data fields required include demographics, routine haematology, biochemistry and bronchiectasis aetiological investigations as per the UK Bronchiectasis guidelines (such as immunoglobulin levels and in selected cases Cystic fibrosis gene testing).

Data on age, gender, medications, past medical history and past test results relevant to bronchiectasis (such as CT scans, microbiology and immune tests) is collected. This information is recorded in a secure computer database, independent from the research team, which is held on a secure NHS-hosted computer system at the Farr Institute, Dundee. A series of questionnaires are completed annually which records how bronchiectasis affects patients' quality of life. These questionnaires include (Qol-B, EQ5D and SGRQ). At each visit, 40 millilitres (8 teaspoons) of blood and a sample of sputum (where possible) are taken with the intention to be used for future studies to understand aspects of bronchiectasis, inflammation, genetics and infections.

It is planned to use the biobank as the basis for future clinical research. However, such studies will be the subject of separate requests for approvals, with distinct protocols. The registry may be used to help recruitment into future clinical trials. Potential participants are identified by case-note review and attendance at outpatient clinics. All aetiologies or suspected aetiologies of bronchiectasis are eligible for entry into the observational cohort. It is preferred that the recruitment at each centre is based on a consecutive sample to avoid recruitment bias.

Intervention Type

Other

Primary outcome(s)

Develop and implement a cross sectional multi-centre observational cohort and biobank.

Key secondary outcome(s)

1. To evaluate and further define clinical outcomes longitudinally
2. To biobank serum and DNA from the cohort
3. To follow up entrants assessing mortality and morbidity

Completion date

30/04/2027

Eligibility

Key inclusion criteria

1. Participant has capacity to provide written informed consent
2. Aged 18 years or over
3. Clinical and radiological diagnosis of bronchiectasis (documented) as defined by historical evidence of bronchiectasis on Computerised Tomographic (CT) scanning. Either CT or High resolution CT scanning (HRCT) is acceptable.
4. English speaking / access to interpreter (ability to complete quality of life questionnaires)
5. Exacerbation frequency – no lower threshold
6. Any suspected aetiological cause of bronchiectasis (except cystic fibrosis)

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

1. Cognitive impairment
2. Non-English speaking/ unable to access interpreter
3. Terminal illness not related to bronchiectasis
4. Aged <18 years
5. Bronchiectasis is not main or co-dominant respiratory disease
6. Lung transplantation for previous bronchiectasis
7. Inability to attend yearly clinical follow up

Date of first enrolment

01/08/2015

Date of final enrolment

30/04/2022

Locations

Countries of recruitment

United Kingdom

England

Northern Ireland

Scotland

Wales

Study participating centre

Newcastle upon Tyne Hospitals NHS Foundation Trust

Freeman Hospital, Freeman Road, High Heaton

Newcastle upon Tyne

United Kingdom

NE7 7DN

Study participating centre

Royal Brompton and Harefield NHS Foundation Trust

Royal Brompton Hospital

Sydney Street

London

United Kingdom

SW3 6NP

Study participating centre

Southampton University Hospitals NHS Trust

Southampton General Hospital

Tremona Road

Hampshire

Southampton

United Kingdom

SO16 6YD

Study participating centre

Papworth Hospital NHS Foundation Trust

Papworth

Everard

Cambridgeshire

Cambridge

United Kingdom

CB23 3RE

Study participating centre

University College London Hospitals NHS Foundation Trust
250 Euston Road
London
United Kingdom
NW1 2PG

Study participating centre
University Hospital Birmingham NHS Foundation Trust
Queen Elizabeth Hospital Birmingham
Mindelsohn Way
Edgbaston
Birmingham
United Kingdom
B15 2GW

Study participating centre
Cardiff and Vale University Hospital of Wales
Address Eastern Avenue
Cardiff
United Kingdom
CF14 4XW

Study participating centre
Royal Infirmary of Edinburgh NHS Lothian
Royal Infirmary of Edinburgh
51 Little France Crescent
Old Dalkeith Road
Edinburgh
United Kingdom
EH16 4SA

Study participating centre
Belfast Health and Social Care Trust
Belfast City Hospital
51 Lisburn Road
Belfast
United Kingdom
BT9 7AB

Sponsor information

Organisation

The Newcastle upon Tyne Hospitals NHS Foundation Trust

ROR

<https://ror.org/05p40t847>

Funder(s)**Funder type**

Research council

Funder Name

Medical Research Council

Alternative Name(s)

Medical Research Council (United Kingdom), UK Medical Research Council, Medical Research Committee and Advisory Council, MRC

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Funder Name

COPD Foundation

Alternative Name(s)

Chronic Obstructive Pulmonary Disease Foundation

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

United States of America

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be stored in a publically available repository provided and hosted by the Health Information Centre (HIC), University of Dundee (<https://www.dundee.ac.uk/hic/>). The overall principle of the study is that it collates data from routinely collected investigations as recommended in care guidelines with participants then followed up at least annually. Data are collected on paper Case Report Form (CRF) then entered by the appropriate staff (as per each site's delegation log) on a secure, electronic clinical database system provided and hosted by the Health Information Centre (HIC), University of Dundee (<https://www.dundee.ac.uk/hic/>).

Patient identifiable information leave the site always remaining contained within the secure NHS N3 network. Identifiable data will never be released to researchers. Identifiable information will be held on a system independent to the research team by a trusted third party in The Health Information Centre (HIC). HIC will host the combined dataset and use identifiable data sets to link to health data sets such as the Office for National Statistics. The BronchUK data sets, once linked to other data sets, will then be anonymised before being released to researchers. The analysis can only be performed in a HIC hosted data "safe haven". Once the analysis is complete within the safe haven the data analysis outputs can only be exported from the safe haven after HIC have reconfirmed there are no identifiable data. No researcher will be able to access identifiable data at any point and there are two control points to ensure none is released. This follows the HIC governance framework effectively used in the past (see <https://medicine.dundee.ac.uk/data-security-confidentiality>).

Data are handled, computerised and stored in accordance with the Data Protection Act 1998 or relevant update. Participants are asked at baseline to agree to linking of their data based records with the Office for National Statistics and Hospital Episode Statistics. This ensures that we can capture mortality and healthcare usage as robustly as possible.

IPD sharing plan summary

Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes