

# Bronchiectasis observational cohort and biobank UK study

<b>Submission date</b> 18/06/2015	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 28/07/2017	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 28/07/2021	<b>Condition category</b> 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  
Philip.Mawson@newcastle.ac.uk

**Study website**  
www.bronch.ac.uk

## Contact information

**Type(s)**  
Public

**Contact name**  
Mr Phil Mawson

**Contact details**  
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Newcastle University  
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Newcastle upon Tyne  
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+44 (0)191 208 2422  
Phil.Mawson@newcastle.ac.uk

## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

**Secondary identifying numbers**  
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

## **Secondary study design**

Cohort study

## **Study setting(s)**

Hospital

## **Study type(s)**

Quality of life

## **Participant information sheet**

Currently not available in web format, please use the contact details to request a patient information sheet.

## **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 measure**

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

**Secondary outcome measures**

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

**Overall study start date**

01/11/2014

**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

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

2000

**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**

England

Northern Ireland

Scotland

United Kingdom

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

**Sponsor details**

Freeman Hospital  
Freeman Road  
High Heaton  
Newcastle upon Tyne  
England  
United Kingdom  
NE7 7DN

**Sponsor type**

Hospital/treatment centre

**Website**

<http://www.newcastle-hospitals.org.uk/index.aspx>

**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, 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

**Publication and dissemination plan**

Plans to publish data from this study in a series of high-impact, peer reviewed articles and to present data at national and international meetings. Results of the study will also be reported to the Sponsor and Funder and will be available, if deemed appropriate, on their web sites. All manuscripts, abstracts or other modes of presentation will be reviewed by the Scientific Steering Committee and Funder (as required) prior to submission. Individuals will not be identified from any study report. Participants will be informed about the study results at the end of the study, including a lay summary.

**Intention to publish date**

30/04/2028

**Individual participant data (IPD) sharing plan**



The datasets generated during and/or analysed during the current study will be stored in a publicly 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?
<a href="#">HRA research summary</a>			28/06/2023	No	No