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Bronchiectasis observational cohort and biobank UK study

Submission date	Recruitment status	[ ] Prospectively registered
18/06/2015	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
28/07/2017	Ongoing	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
28/07/2021	Respiratory	[ ] 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

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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 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