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Investigating whether prolonged antibiotics can prevent permanent Pseudomonas infection in bronchiectasis

Submission date 06/11/2025	**Recruitment status** Recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 23/01/2026	**Overall study status** Ongoing	
Last Edited 14/04/2026	**Condition category** Respiratory	

Plain English summary of protocol

Background and study aims
Bronchiectasis is a lung disease that causes people to suffer from cough and chest infections. A bacteria called Pseudomonas causes lung infection in people with bronchiectasis. Pseudomonas is resistant to most antibiotic tablets and often needs to be treated with antibiotic injections. It causes permanent infection of the lungs that is difficult to clear even if patients taking several courses of antibiotics. Patients with Pseudomonas infection have more flare ups of the condition where symptoms get worse and more antibiotic treatments are needed.
As Pseudomonas infections are difficult for patients, preventing them from happening would be better than treating them once they become permanent. We want to conduct a trial to find out if it is possible to prevent a person with bronchiectasis being permanently infected with Pseudomonas by giving antibiotic treatment early on in the infection.

Who can participate?
Patients aged 16 years and over with bronchiectasis and Pseudomonas infection

What does the study involve?
The trial will involve randomly assigning half of the patients to a treatment with a combination of antibiotics given by mouth or through a drip, followed by antibiotic treatment through a nebulizer machine for 3 months, while half of the patients will not receive this treatment. We will measure whether giving this treatment reduces the number of flare-ups of bronchiectasis. The main outcome of the study will be exacerbations over 24 months follow-up. We will also measure whether sputum samples become negative for Pseudomonas by asking participants to give sputum samples for testing, and we will test whether the number of people admitted to hospital is reduced, whether patients feel better using symptom questionnaires and whether there were side effects from the antibiotics. We will also collect data to know if the treatment is cost-effective, meaning that the costs saved by preventing infections outweigh the costs of the treatment.

What are the possible benefits and risks of participating?
This trial will help doctors to know the best way to manage these pseudomonas infections in the

future and will inform future medical guidelines. No additional risk as participants will receive either symptomatic treatment or exacerbation treatment, both of which will be prescribed as per British Thoracic Society Guidelines.

Where is the study run from?
University of Dundee (UK)

When is the study starting and how long is it expected to run for?
November 2025 to June 2030

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

Who is the main contact?
1. Dr Gillian Martin, ESCAPE-TM@dundee.ac.uk
2. Prof. James Chalmers, j.chalmers@dundee.ac.uk

Contact information

Type(s)
Public, Scientific

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Additional identifiers

Integrated Research Application System (IRAS)
1011311

Protocol serial number
1-060-25

Study information

Scientific Title
Exacerbation and Symptom Control After Pseudomonas Eradication Treatment in Adult Bronchiectasis: a multicentre randomized controlled trial (ESCAPE)

Acronym
ESCAPE

Study objectives
Primary objectives:
To evaluate the effect of P. aeruginosa eradication treatment compared with standard care excluding inhaled antibiotics on rate of exacerbations

Secondary objectives:
1. To evaluate the cost-effectiveness of P. aeruginosa eradication treatment compared with standard care
2. To evaluate the effect of P. aeruginosa eradication treatment compared with standard care excluding inhaled antibiotics on eradication of aeruginosa, hospitalisation, quality of life, reinfection rates, antibiotic use, antibiotic resistance, healthcare usage, death, adherence to treatment, safety and use of long-term inhaled antibiotic treatment

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 06/01/2026, North East - Tyne & Wear South Research Ethics Committee (NHSBT Newcastle Blood Donor Centre Holland Drive, Newcastle upon Tyne, NE2 4NQ, United Kingdom; -; tyneandwearsouth.rec@hra.nhs.uk), ref: 25/NE/0214

Study design
Open randomized controlled parallel-group trial

Primary study design
Interventional

Study type(s)
Efficacy, Safety

Health condition(s) or problem(s) studied
Bronchiectasis

Interventions
Participants will be assigned in a 1:1 ratio to receive eradication treatment plus background therapy or background therapy only. Participants will be allocated to an arm using a minimisation algorithm, with factors for centre, long-term use of macrolides, and first isolation vs new isolation following previous clearance.

Intervention: P. aeruginosa eradication treatment consisting of systemic antibiotics (either oral or intravenous as clinically indicated) alongside or followed by inhaled anti-pseudomonal antibiotics for 3 months, in addition to background therapy.

Comparator: Background therapy only.

The intervention treatment will be prescribed as per British Thoracic Guidelines and following local clinician decision and usual practice. In the British Thoracic Guidelines, P. aeruginosa eradication treatment is defined as first line treatment with the oral antibiotic ciprofloxacin 500 mg or 750 mg twice a day for 2 weeks. Second line treatment of IV antipseudomonal beta-lactam ± an IV aminoglycoside for 2 weeks. This would be followed by a 3-month course of a nebulised antipseudomonal antibiotic. The protocol defines the eradication treatment options.

Background therapy may consist of their existing bronchiectasis treatments such as airway clearance, bronchodilators, long term macrolide treatment or other symptomatic therapies e.g mucoactive drugs. Background therapy also includes administration of antibiotics if patients have symptoms of an exacerbation.

Intervention Type
Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)
Ciprofloxacin, piperacillin, tazobactam, ceftazidime, meropenem, aztreonam, ceftolozane, gentamicin, tobramycin, amikacin, fosfomycin, levofloxacin, colomycin

Primary outcome(s)
Frequency of pulmonary exacerbations (EMBARC definition) from day 0 to week 104

Key secondary outcome(s))
1. Cost-effectiveness of P. aeruginosa eradication treatment compared with standard care, measured from day 0 to week 104 using:
1.1. Frequency of pulmonary exacerbations (EMBARC definition)
1.2. Incremental cost per exacerbation prevented
1.3. Incremental cost per quality adjusted life year (QALY) gained
2. Frequency of P. aeruginosa isolation in sputum samples measured using sputum microbiology at day 0, weeks 12, 52, 104
3. Hospitalisations for severe exacerbations recorded using medical records from day 0 to week 104
4. Quality of life measured using the Quality of Life-Bronchiectasis (QOL-B) respiratory symptom scale, Chronic Airways Assessment Test (CAAT) and EQ-5D-5L on day 0, weeks 12, 52, 104 and the Bronchiectasis Exacerbation and Symptom Tool (BEST) diary daily day 0 to week 104
5. Time to reinfection (isolation of P. aeruginosa after a first negative sputum sample) from Day

0 to week 104
6. Total days of antibiotic use recorded using prescribing medical records from Day 0 to week 104
7. P. aeruginosa antibiotic resistance measured using sputum microbiology at day 0, weeks 12, 52, 104
8. All-cause healthcare contacts recorded using medical records from day 0 to week 104
9. All-cause mortality recorded using medical records from day 0 to week 104
10. Treatment adherence recorded using patient report from day 0 to week 104
11. Frequency of adverse events (AEs) and serious adverse events (SAEs) recorded using medical records & participant reporting from day 0 to week 104
12. Time to commencement of long term inhaled antibiotic treatment recorded using prescribing medical records from day 0 to week 104

Exploratory Objectives:
P. aeruginosa abundance measured by molecular laboratory tests at day 0, weeks 12, 52, 104

Completion date
30/06/2030

Eligibility

Key inclusion criteria
1. Adults (18 years or older)
2. Able to provide informed consent.
3. Capable of complying with all trial procedures and of completing the trial, in the opinion of the investigator.
4. Bronchiectasis, confirmed by computed tomography (CT), showing bronchiectasis in 1 or more lobes (a historical radiology report or report from the investigator confirming bronchiectasis is sufficient for enrolment) and the appropriate clinical syndrome (symptoms of cough, sputum production and/or respiratory tract infections).
5. Able to be prescribed one of the inhaled antibiotics defined in the intervention arm, in the opinion of the investigator.
6. P. aeruginosa infection confirmed by:
6.1. New isolation of P. aeruginosa, defined as the first documented sputum or other respiratory tract sample e.g. bronchoalveolar lavage samples) positive for P. aeruginosa within the 6 months prior to randomisation
OR
6.2. New isolation of P. aeruginosa, within the 6 months prior to randomisation, following previous clearance of P. aeruginosa defined as a minimum of 12 months without a positive P. aeruginosa culture and at least 2 intervening cultures negative for P. aeruginosa.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
100 years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Current treatment with inhaled antibiotics or treatment with inhaled antibiotics within the previous 6 months
2. Chronic P. aeruginosa infection defined as isolation of P. aeruginosa persistently in sputum, or the absence of negative sputum samples for P. aeruginosa so that inclusion criteria (6) above cannot be met
3. Cystic fibrosis
4. Use of any investigational drugs within five times of the elimination half-life after the last dose or within 30 days, whichever is longer. Current enrolment in non-interventional, observational studies will be allowed
5. Currently pregnant or breastfeeding
6. Unstable comorbidities (e.g., cardiovascular disease, active malignancy) which in the opinion of the investigator would make participation in the trial not in the participant's best interest
7. Estimate eGFR <30 or abnormal liver function tests that in the opinion of the investigator make antibiotic treatment inappropriate (note that the trial is designed to be pragmatic and embedded within normal practice therefore testing is at the discretion of the managing clinician)
8. A strong preference, either from the managing clinician or the participant, for one of the two trial arms such that in the opinion of the investigator adherence to the trial protocol would not be possible.

Date of first enrolment
09/03/2026

Date of final enrolment
31/05/2028

Locations

Countries of recruitment
United Kingdom

England

Northern Ireland

Scotland

Wales

Study participating centre
Ninewells Hospital
Ninewells Avenue
Dundee
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DD1 9SY

Study participating centre
University Hospital of North Tees
Hardwick Road
Stockton-on-tees
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Study participating centre
University Hospital Southampton
Tremona Road
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SO16 6YD

Study participating centre
Kings Mill Hospital
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NG17 4JL

Study participating centre
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Manchester
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M23 9LT

Study participating centre
Prince Philip Hospital
Bryngwyn Mawr
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SA14 8QF

Study participating centre
University of Greater Manchester Medical School
Barnes Drive (Off Redgate Way), Farnworth
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England
BL4 0HW

Study participating centre
University Hospital Hairmyres
Eaglesham Road
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Scotland
G75 8RG

Study participating centre
Bristol Royal Infirmary
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England
BS2 8HW

Study participating centre
Antrim Area Hospital
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Antrim
Northern Ireland
BT41 2RL

Study participating centre
Royal Gwent Hospital
Cardiff Road
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NP20 2UB

Study participating centre

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CA2 7HY

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Royal Papworth Hospital
Papworth Road
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Cambridge
England
CB2 0AY

Study participating centre
Royal Sussex County Hospital
Eastern Road
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BN2 5BE

Study participating centre
University Hospitals Coventry and Warwickshire NHS Trust
Walsgrave General Hospital
Clifford Bridge Road
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England
CV2 2DX

Study participating centre
Victoria Hospital
Hayfield Road
Kirkcaldy
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KY2 5AH

Study participating centre
Liverpool Heart and Chest Hospital
Thomas Drive

Liverpool
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L14 3PE

Study participating centre
South Tyneside District Hospital
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Study participating centre
Kings College Hospital
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London
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SE5 8AB

Sponsor information

Organisation
University of Dundee

ROR
https://ror.org/03h2bxq36

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care 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 and/or analysed during the current study will be available upon request from the Chief Investigator (Prof. James Chalmers, j.chalmers@dundee.ac.uk).

Access to collated participant data will be restricted to the CI and appropriate delegated trial staff. In the event that data are shared with collaborators or groups wishing to undertake further analysis, collaborators will not have access to personal identifiable details other than those held on the EDC system. Pseudonymised participant data will also be available to interested parties after publication of the final report upon reasonable written request to the CI and subsequent approval. The transfer of data to collaborators or for use in further research will be as described in the Clinical Research Agreement. Published results will not contain any personal data that could allow identification of individual participants. Trial consent includes consent for the use of data in future research.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 2	20/12/2025	10/02/2026	No	No