ISRCTN11243396 https://doi.org/10.1186/ISRCTN11243396

A three year follow up study to assess the rate of death and other diseases in patients with a long-term condition where the airways of the lungs become widened, leading to a build-up of excess mucus that can make the lungs more vulnerable to infection (bronchiectasis)

Submission date 15/11/2021	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 23/11/2021	**Overall study status** Completed	
Last Edited 08/10/2024	**Condition category** Respiratory	

Plain English summary of protocol

Background and study aims
Bronchiectasis is a long-term condition where the airways of the lungs become widened, leading to a build-up of excess mucus that can make the lungs more vulnerable to infection. The most common symptoms of bronchiectasis include a persistent cough that usually brings up phlegm (sputum) shortness of breath.
This study aims to investigate the long-term risk factors and health outcomes for patients with bronchiectasis, over 3 years.

Who can participate?
Patients with bronchiectasis.

What does the study involve?
Participants complete a number of tests and questionnaires at the initial consultation and the patients are monitored over the next 3 years.

What are the possible benefits and risks of participating?
None

Where is the study run from?
Pedro Ernesto University Hospital (Brazil)

When is the study starting and how long is it expected to run for?
March 2016 to December 2024

Who is funding the study?
FAPERJ (Research Support Foundation of the State of Rio de Janeiro) (Brazil)

Who is the main contact?
Prof. Rogério Rufino, rrufino.uerj@gmail.com

Contact information

Type(s)
Public

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
RBR 61923316.1.0000.5259

Study information

Scientific Title
Mortality and comorbidities in patients with bronchiectasis over a three-year follow-up

Study objectives
Bronchiectasia has high mortality despite treatment

Ethics approval required
Old ethics approval format

Ethics approval(s)

Approved 17/11/2016, Research Ethics Committee of the Pedro Ernesto University Hospital (CePeM – Centro de Pesquisa Clínica Multiusuário – 2nd floor /room 28, Pedro Ernesto University Hospital, Rio de Janeiro, Brazil; +55. 21 2868-8253; cep@hupe.uerj.br), ref: 1,823,665

Study design
Prospective observational single-center cohort study

Primary study design
Observational

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Risk factors for mortality in patients with non-cystic fibrosis bronchiectasis

Interventions
Prospective cohort study comprising 120 adult patients with non-cystic fibrosis bronchiectasis regularly treated at the specialized outpatient clinic of a university hospital between January 2017 and June 2020. All patients had the diagnosis confirmed by high-resolution computed tomography. Demographic and clinical data, pulmonary function test, and Euro quality-of-life five-domain three-level questionnaire (EQ-5D-3L) were analyzed. Factors associated with death were determined using the Cox proportional hazard model.

Intervention Type
Behavioural

Primary outcome(s)
Mortality measured using patient records at the end of the study

Key secondary outcome(s))
Quality of life measured using Euro quality-of-life five-domain three-level questionnaire (EQ-5D-3L) at the initial consultation

Completion date
31/12/2024

Eligibility

Key inclusion criteria
Diagnosis of bronchiectasis confirmed by chest HRCT, evaluated by two radiologists and two pulmonologists

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
100

Key exclusion criteria
Cystic fibrosis

Date of first enrolment
01/02/2017

Date of final enrolment
31/12/2024

Locations

Countries of recruitment
Brazil

Study participating centre
Pedro Ernesto University Hospital
Avenida 28 de Setembro, 77 - Vila Isabel
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Sponsor information

Organisation
Fundação Carlos Chagas Filho de Amparo à Pesquisa do Estado do Rio de Janeiro

ROR
https://ror.org/03kk0s825

Funder(s)

Funder type
Government

Funder Name
Research Support Foundation of the State of Rio de Janeiro

Results and Publications

Individual participant data (IPD) sharing plan
All data generated or analysed during this study will be included in the subsequent results publication
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request (rrufino.uerj@gmail.com)

IPD sharing plan summary
Available on request, Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Interim results article	1-year quality of life results	01/03/2022	15/07/2022	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes