

# 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)

<b>Submission date</b> 15/11/2021	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 23/11/2021	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 08/10/2024	<b>Condition category</b> Respiratory	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

## 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

**Contact name**  
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## Additional identifiers

**EudraCT/CTIS number**  
Nil known

**IRAS number**

**ClinicalTrials.gov number**  
Nil known

**Secondary identifying numbers**  
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

**Secondary study design**

Case series

**Study setting(s)**

GP practice

**Study type(s)**

Quality of life

**Participant information sheet**

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

**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 measure**

Mortality measured using patient records at the end of the study

**Secondary outcome measures**

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

**Overall study start date**

17/03/2016

**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

## Age group

Adult

## Sex

Both

## Target number of participants

100

## 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

Rio de Janeiro

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# Sponsor information

## Organisation

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

**Sponsor details**

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**Sponsor type**

Research organisation

**Website**

<http://www.faperj.br/>

**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

**Publication and dissemination plan**

BMC Pulmonary Medicine

**Intention to publish date**

01/01/2026

**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?
<a href="#">Interim results article</a>	1-year quality of life results	01/03/2022	15/07/2022	Yes	No