

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 23/11/2021	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 08/10/2024	Condition category 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 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

Prof Rogerio Rufino

ORCID ID

<https://orcid.org/0000-0002-5071-6045>

Contact details

Avenida 28 de Setembro, 77 - second floor - Pulmonology Service
Rio de Janeiro
Brazil
20551030
+55.21.986255240
rrufino.uerj@gmail.com

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

Rio de Janeiro

Brazil

20551030

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