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High blood pressure in the lungs in patients with systemic sclerosis: a screening for diagnosis and follow-up to see how it behaves

Submission date
07/07/2021

Recruitment status
No longer recruiting

Registration date
08/07/2021

Overall study status
Completed

Last Edited
18/08/2023

Condition category
Skin and Connective Tissue Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[X] Individual participant data

Plain English summary of protocol

Background and study aims
Systemic sclerosis (SSc) is a rare autoimmune disease, caused by the immune system attacking the connective tissue under the skin and around internal organs and blood vessels. This causes scarring and thickening of the tissue in these areas.
Pulmonary hypertension is high blood pressure in the blood vessels that supply the lungs (pulmonary arteries). It's a serious condition that can damage the right side of the heart. The walls of the pulmonary arteries become thick and stiff, and cannot expand as well to allow blood through.
Pulmonary hypertension is the leading cause of death in systemic sclerosis (SSc) and affects up to 12% of all patients with SSc.
The aim of this study was to evaluate the diagnosis, profile, and prognosis of systemic sclerosis pulmonary hypertension (SSc-PH) diagnosed by systematic screening in a Brazilian population.

Who can participate?
Patients aged 18 years and above with SSc.

What does the study involve?
The study involves the performance of a systematic screening procedure for the diagnosis of systemic sclerosis-related pulmonary hypertension. Then, the study performed a three-year follow-up of the included patients. Patients with positive screening underwent right heart catheterization.

What are the possible benefits and risks of participating?
Potential benefits: patients who participate have the chance to receive an early diagnosis of pulmonary hypertension. This affords early treatment and may alleviate symptoms, improve quality of life. We speculate that early treatment could improve survival.
Potential risks: to confirm the diagnosis of pulmonary hypertension, the patients referred by the screening had to undergo right heart catheterization. This is an invasive haemodynamic procedure. Right heart catheterization has the risks of bleeding, heart arrhythmias, vessel perforation, allergic reaction to iodine contrast, heart failure and very rarely death.

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

When is the study starting and how long is it expected to run for?
June 2012 to July 2020

Who is funding the study?
Fundação Carlos Chagas Filho de Amparo à Pesquisa do Estado do Rio de Janeiro (Foundation to Sponsor Research in Rio de Janeiro) (Brazil)

Who is the main contact?
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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
CAAE16739013.4.0000.5259

Study information

Scientific Title
Pulmonary hypertension in systemic sclerosis: diagnosis by systematic screening and prognosis after a three-year follow-up

Study objectives
A systematic screening to achieve early diagnosis of systemic sclerosis-related pulmonary hypertension can be performed. The profile and prognosis of the patients diagnosed by this screening should be described.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 24/03/2013, Local ethics committee University Hospital Pedro Ernesto (Boulevard 28 de Setembro 77 Vila Isabel CePeM – Centro de Pesquisa Clínica Multiusuário – 2º andar/sala 28, prédio anexo ao Hospital Universitário Pedro Ernesto, Rio de Janeiro, Brazil; +55 21 2868-8253; cep@hupe.uerj.br), ref: 314.092

Study design
Single centre observational study

Primary study design
Observational

Study type(s)
Screening

Health condition(s) or problem(s) studied
Pulmonary hypertension related to systemic sclerosis

Interventions
All patients with systemic sclerosis in treatment at our referral centre were invited to be included between 01/07/2014 until 01/07/2017. Included patients underwent a systematic screening for pulmonary hypertension that included transthoracic echocardiography and the multiple tools required by the DETECT algorithm. Patients were referred to right heart catheterization if the screening was positive. The profile of the patients diagnosed by this screening was described. The prognosis was evaluated by a three-year follow-up.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Diagnosis of pulmonary hypertension at baseline (yes/no) measured using patient records

Key secondary outcome(s))
1. Survival measured using patient records at 3 years
2. Worsening of condition from baseline measured using patient records at 3 years

Completion date
01/07/2020

Eligibility

Key inclusion criteria

1. Aged ≥ 18 years
2.Systemic sclerosis diagnosis according to the 2013 European League Against Rheumatism and American College of Rheumatology criteria

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
65

Key exclusion criteria
1. Severe left ventricle dysfunction (left ventricular fraction ejection <55%)
2. Severe restrictive lung disease (forced vital capacity <40%)
3. Unwillingness to undergo right heart catheterization

Date of first enrolment
01/07/2014

Date of final enrolment
01/07/2017

Locations

Countries of recruitment
Brazil

Study participating centre
University Hospital Pedro Ernesto
Boulevard 28 de Setembro 77
Vila Isabel
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20551-030

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
Charity

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

Alternative Name(s)
Carlos Chagas Filho Foundation for Research Support in Rio de Janeiro, Research Support Foundation for the State of Rio de Janeiro, Fundação Carlos Chagas Filho de Amparo à Pesquisa do Estado do Rio de Janeiro FAPERJ, FAPERJ - Fundação Carlos Chagas Filho de Amparo à Pesquisa do Estado do Rio de Janeiro, FAPERJ

Funding Body Type
Government organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Brazil

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request: vilelavs@gmail.com
Type of data: demographic, screening tools, screening results, clinica, serum and immunological data, haemodynamic data. All datasets are on Excel sheets where anonymisation was made by replacing patients dentifications by numbers (codes). The criteria for the access to the data is to send e-mail for the main author with reasonable request. Data will be available as soon as requested by email (within one or two weeks). Once shared, data will be permanently available. As patient identifications are not disclosed in the sheets, consent from participants to share data was not obtained. There are no legal and ethical restrictions for this data sharing.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		29/07/2021	02/08/2021	Yes	No
Dataset			18/08/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes