

Cardiopulmonary exercise testing and stress echocardiography as screening methods to detect pulmonary hypertension in patients with connective tissue diseases (CTD)

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| Submission date 16/01/2009 | Recruitment status No longer recruiting | <input checked="" type="checkbox"/> Prospectively registered |
| Registration date 27/02/2009 | Overall study status Completed | <input type="checkbox"/> Protocol |
| Last Edited 27/02/2009 | Condition category Musculoskeletal Diseases | <input type="checkbox"/> Statistical analysis plan |
| | | <input type="checkbox"/> Results |
| | | <input type="checkbox"/> Individual participant data |
| | | <input type="checkbox"/> Record updated in last year |

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
01-09

Study information

Scientific Title

Cardiopulmonary exercise testing and stress echocardiography as screening methods to detect pulmonary hypertension in patients with connective tissue diseases (CTD): an observational study

Study objectives

1. Cardiopulmonary exercise testing (CPET) and stress echocardiography provide reliable measures to characterise severity stages of patients with connective tissue diseases (CTD) and pulmonary hypertension (PH)
2. CPET and stress echocardiography provide reliable measures for early detection of PH in CTD
3. CPET and stress echocardiography correlates to established severity measures of dyspnoea (World Health Organization [WHO] classification) in patients with CTD and PH

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics Committee of the Ernst Moritz Arndt University of Greifswald, pending as of 16/01/2009.

Study design

Observational cross-sectional study

Primary study design

Observational

Study type(s)

Diagnostic

Health condition(s) or problem(s) studied

Pulmonary hypertension in patients with connective tissue diseases (CTD)

Interventions

Patients affected by different forms of CDT will be included in the study. All patients will undergo CPET as well as stress echocardiography to detect secondary PH. Based on general disease characteristics and CPET results a diagnostic value will be assessed to provide a prospective measure for the early detection of PH in CDT. Second, it will attempted to assess a severity classification based on CPET and stress echocardiography.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Exercise capacity

Key secondary outcome(s)

No secondary outcome measures

Completion date

31/05/2010

Eligibility

Key inclusion criteria

1. Adults ≥ 18 years, both males and females
2. Patients with all forms of CTD

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

1. Contraindications for CPET according to current guidelines
2. Congestive heart failure
3. Coronary heart disease
4. Myocardial infarction within the last 6 months
5. Pulmonary diseases other than CTD
6. Primary myopathy

Date of first enrolment

01/06/2009

Date of final enrolment

31/05/2010

Locations

Countries of recruitment

Germany

Study participating centre

F.-Loeffler-Strasse 23a

Greifswald

Germany

17475

Sponsor information

Organisation

Actelion (Germany)

ROR

<https://ror.org/03572ah39>

Funder(s)

Funder type

Industry

Funder Name

Actelion (Germany)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration