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

Submission date
16/01/2009

Recruitment status
No longer recruiting

Registration date
27/02/2009

Overall study status
Completed

Last Edited
27/02/2009

Condition category
Musculoskeletal Diseases

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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Cross-section survey

Study setting(s)
Hospital

Study type(s)
Diagnostic

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

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 measure
Exercise capacity

Secondary outcome measures
No secondary outcome measures

Overall study start date
01/06/2009

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
100

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. Pulomonary 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)

Sponsor details
Munzinger Str. 1
Freiburg
Germany
79111

Sponsor type
Industry

Website
http://www.actelion.com

ROR
https://ror.org/03572ah39

Funder(s)

Funder type
Industry

Funder Name
Actelion (Germany)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration