Sarcoidosis and Fatigue: Influence of successive cardiopulmonary exercise testing on fatigue, ACE, cytokine response and acitivity pattern

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Immune disorders NEC
Study type	Observational invasive

Summary

ID

NL-OMON33379

Source
ToetsingOnline

Brief title
Sarcoidosis and fatigue

Condition

- Immune disorders NEC
- Respiratory disorders NEC

Synonym
Morbus Besnier Boeck (Schaumann), Sarcoidosis

Research involving
Human

Sponsors and support

Primary sponsor: Rijnstate Ziekenhuis
Source(s) of monetary or material Support: Ministerie van OC&W,Maatschap Longziekten Rijnstate ZH Arnhem en St. Antonius Ziekenhuis Nieuwegein

Intervention

Keyword: cytokine respons, exercise testing, fatigue, sarcoidosis

Outcome measures

Primary outcome

Recuperative capacity: Outcome on two maximal exercise tests (bicycle ergometer): comparing results of cardiovascular, pulmonary and aerobic capacity on two successive days.

Fatigue: State of fatigue (before and after exercise) will be evaluated by Visual Analogue Scales. Trend of fatigue (at the start of taking part in this study and after completing) will be measured with the CIS-20R-08-questionnaire.

Measurements in serum: Level of ACE, including genotype of patients for ACE and levels of cytokines will be determined (IL-6 and TNF-α before and after exercise).

Secondary outcome

Secondary objective is to find associations between exercise and patterns of sleep behaviour and acitivity, not only on basis of patient reports, but also objectified bij means of an accelerometer.

Study description

Background summary

Fatigue is an often reported complaint by patients suffering from sarcoidosis, especially during the onset and the active phase of this multi-systemic granulomatous disorder. However, when sarcoidosis patients are tested for cardiovascular, pulmonary, and aerobic capacity by means of exercise tests, the results of these tests are usually within normal limits. Nonetheless a lot of these patients state that after completing the exercise test they are totally exhausted. Their complaints are so severe that they cannot do their daily work the same and the next day(s).
This study examines if excessive complaints of fatigue in sarcoidosis patients after exercise can be objectified. It hypothesizes that the recuperative capacity in sarcoidosis is decreased, probably due to an increase in levels of ACE and cytokines in blood, as result of the disease. Until now this particular phenomenon of exhaustion after exercise has never been studied before in sarcoidosis patients.

Study objective

This study will investigate fatigue after exercise in sarcoidosis patients. It will determine the severity of their fatigue, the recuperative capacity after maximal exertion (bicycle ergometer) and the levels of ACE and cytokines (before and after exercise) in these patients. Results in sarcoidosis patients will be compared to results of a control group of healthy volunteers.
Our secondary objective is to find associations with sleep behaviour and activity pattern.

Study design

This study is a pilotstudy to instigate a prospective observational study.

Study burden and risks

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Participants will visit the hospital on 3 days: 2 times successively to complete the exercise test and a 3rd time to collect a last blood sample. In addition they are asked to keep a sleep- and activity diary, and to wear an actometer during a period of 14 days.
The aerobic capacity during the exercise test is registered by means of a combined sensor for CO2 en SaO2 measurement (TOSCA 500 Monitoring System), which is applied to the ear lobe. This has a tremendous benefit because it is obviously not invasive (there is no arterial line needed). The only risks of the study comprises a haematoma as result of venous bloodsampling.
This study could give insight in pathways of fatigue during a systemic disease. Fatigued sarcoidosis patients might benefit from this study if physical factors can be found that can explain their exhaustion after exercise. This information is not only helpful in their private life, but can also clarify their incapacity to work. In this respect it could be used in labour disputes in

which a lot of these sarcoidosis patients are involved. If a relationship between fatigue and cytokine levels can be established, in the future patients may benefit from anticytokine therapy.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Sarcoidosis
diagnosis confirmed within 1 year before inclusion
18 years and older
informed consent
see protocol section 4.2

Exclusion criteria

corticosteroid use, cardiovasculair comorbidity
see protocol section 4.3

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-01-2010
Enrollment:	30
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO

Date:	08-09-2009
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL28093.091.09