'Post-sarcoidosis' fatigue: a psychoneuroimmunologic approach

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Exploring the incidence of fatigue after sarcoidosis, its severity and nature. Next we will try to associate fatigue with capacity to produce pro- and anti-inflammatory cytokines.Our secondary objective is testing the activity of the HPA-axis, the...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Adrenal gland disorders
Study type	Observational invasive

Summary

ID

NL-OMON30778

Source
ToetsingOnline

Brief title
'Post-sarcoidosis' fatigue

Condition

- Adrenal gland disorders
- Immune disorders NEC
- Respiratory disorders NEC

Synonym
Morbus Besnier Boeck Schaumann, Sarcoidosis

Research involving
Human

Sponsors and support

Primary sponsor: Sint Antonius Ziekenhuis
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: fatigue, pain, psychoneuroimmunology, sarcoidosis

Outcome measures

Primary outcome

Fatigue: measured with the CIS20-questionnaire. The cut-off point for severe fatigue is set at a score of 40 or more on the subscale Severity of Fatigue (subscale scores ranges from 8 to 56).

Measurements in serum: First Th1 / Th2 ratio will be determined. Secondly the ratio will be measured for the following cytokines: interferon (IFN)-g / IL-4.

Lastly, IL-1 and IL6 will be analysed in the supernatants. Method to be used: LUMINEX.

Secondary outcome

HPA-axis (cortisol, ACTH), autonomous responses (catecholaminen, bloodpressure, heartfrequency), psychologic characteristics (cynical hostility), pain complaints, function of neuroanatomical pain pathways (LEP) and sensitisation (GRK).

Study description

Background summary

Fatigue appears to be the most commonly reported complaint by part of the patients suffering from sarcoidosis. Not only during the active phase of this multi-systemic granulomatous disorder, but also when, clinically, no disease-activity can be found anymore, fatigue may persist. Also for pain, this seems the case. So far research has not offered reliable rates on incidence nor a plausible explanation for this fatigue nor for these pain complaints. Due to this lack there is no evidence based treatment to offer these patients.

Study objective

Exploring the incidence of fatigue after sarcoidosis, its severity and nature. Next we will try to associate fatigue with capacity to produce pro- and anti-inflammatory cytokines.
Our secondary objective is testing the activity of the HPA-axis, the autonomic response and psychological characteristics in order to find a correlation with fatigue.
In addition we will investigate pain complaints and test the functionality of the neuroanamtomic pain pathways. Lastly we will determinate the activity of GRK to assess possible sensitisation.

Study design

an observational, follow up study of a cohort of post-sarcoidosis patients. This cohort consists of patients who had their first broncho alveolaire lavage in the period 1998 - 2003
All patients will fill out the fatigue questionnaire (CIS-20) to estimate the incidence of fatigue. Next we will explore associations of fatigue with production of pro- and anti-inflammatory cytokines, psychological characteristics, the activity of the HPA-axis and the autonomous response.

Study burden and risks

Screening: physical examination, x-thorax, lungfunction test, urine- and bloodsampling
Study: 6 questionnaires; 1 anamnesis; muscle force tests; actometer (12 days); 1 Trier Social Stress Test (including an extra bloodsample), 1 physical examination (neurologist), 1 Laser Evoked Potentials test, 24h sleep diary (7 days).
Risk for all participants is minimal. Risk intravenous catheter is an haematoma. Risk of LEP is an irritated skin that resolves within days.

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

· Evidence on the presence of active sarcoidosis is absent, over the last 6 months:
- normal serum parameters (ACE, serum IL-2, calcium)
- röntgenogram/CTscan: normal or >= 2 yr. stable
- lungfuction: normal or >= 2 yr. stable (< 10% change of VC or FEV1, < 15%change of DLco)
· No clinical evidence of disease activity of previously involved organs
· Sarcoidosis is diagnosed based according to the latest ATS/ERS/WASOG statement on sarcoidosis, i.e.: histologic demonstration of noncaseating granulomas in combination with compatible clinical findings and exclusion of other causes of granuloma formation
· Capability of giving informed consent

Exclusion criteria

· Sarcoidosis presented as Löfgren*s syndrome
· Medication with corticosteroids or other immunosuppressive drugs over the last 6 months
· Antidepressiva
· Psychiatric diseases (major depression, schizophrenia, dementia, anorexia nervosa. bulimia nervosa)
· Sleep apnoea or narcolepsy or restess legs syndrome
· Any diagnosed disease or any significant abnormal and clinically relevant laboratory test that could possibly contribute to fatigue
(Hb, BSE, leukocytes and differentiation, Na, K, Ca, creatine, bicarbonate, AF, ALAT, creatine phosphokinase (CPK), glucose, total protein, protein spectrum, thyroid stimulating hormone (TSH), ferritine en urine)

· Body Mass Index (BMI): >= 45 or BMI<17
· Abuse of alcohol, drugs or other substance

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	04-07-2007
Enrollment:	75
Type:	Actual

Ethics review

Approved WMO

Date:	06-12-2006
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO

Date:	24-05-2007
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL14786.100.06