Identification of multiple potential triggers in sarcoidosis patients

Published: 03-09-2014
Last updated: 21-04-2024

To determine the prevalence of mycobacterial, propionibacterial and beryllium, aluminium and zirconium sensitized patients within a well-defined Dutch cohort of biopsy proven sarcoidosis patients.New clinico-pathological phenotypes within the group...

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

Summary

ID

NL-OMON44530

Source
ToetsingOnline

Brief title
Triggers in Sarcoidosis

Condition

- Autoimmune disorders
- Bronchial disorders (excl neoplasms)

Synonym
M. Besnier-Boeck-Schaumann, Sarcoidosis

Research involving
Human

Sponsors and support

Primary sponsor: Sint Antonius Ziekenhuis
Source(s) of monetary or material Support: ZonMW

Intervention

Keyword: IGRA, Immunology, Sarcoidosis, Triggers

Outcome measures

Primary outcome

To determine the prevalence of sensitization against mycobacteria,

propionibacteria and metals including beryllium, aluminium and zirconium in

sarcoidosis patients

Secondary outcome

Compare the classical lymphocyte proliferation test with the interferon gamma

release assay

Study description

Background summary

Sarcoidosis is a systemic disorder of unknown etiology. The majority of patients is between 20 and 40 years of age. In general the disease has a favourable course, with spontaneous remission in 70% of patients within 3 years from diagnosis. In the remaining group of patients, the disease can become chronic, and will be fatal in approximately 5% of patients. An important characteristic of the disease are non-caseating granulomas. So far, the cause of the disease is unknown. Many potential organic/anorganic substances or microorganisms have been suggested to trigger sarcoidosis such as aluminium, beryllium, zirconium, mycobacteria and propionibacteria.

Long term exposure to beryllium can cause berylliosis, which is difficult to distinguish from sarcoidosis. It has already been demonstrated in several studies that some berylliosis patients were initial incorrectly diagnosed with sarcoidosis. An interesting hypothesis might be that berylliosis is a type of sarcoidosis in which the inducing antigen is known. The estimated mortality of berylliosis is 25%, which is far higher compared to sarcoidosis. In The Netherlands, no information is available about the eventual prevalence of berylliosis among the group of sarcoidosis patients.

Currently, no curative treatment is available for sarcoidosis. Routine testing

for possible triggers in sarcoidosis is not daily clinical practice. However, published data suggest that possible triggers could be identified in 74% of patients. Conformation of these data in Dutch patients can lead the way for randomized controlled trials in distinct subgroups of patients assessing the efficacy of antimycobacterial or antipropionbacterial treatment. If sensitization for metals in sarcoidosis patients can be determined, avoiding exposure is an important extra therapeutic option in treating their disease.

Study objective

To determine the prevalence of mycobacterial, propionibacterial and beryllium, aluminium and zirconium sensitized patients within a well-defined Dutch cohort of biopsy proven sarcoidosis patients.
New clinico-pathological phenotypes within the group of sarcoidosis patients will be defined, using the data on sensitization in combination with a 4 year follow up in order to define the Clinical Outcome Score (COS) after 2 and 4 years of follow up.

In addition, a comparison will be made between the classic lymphocyte proliferation test and interferon gamma release assay in detecting metal sensitization

Study design

Retrospective and prospective cohort study

Study burden and risks

Burden and risks are minimal due to the fact that vein puncture is the only invasive proceidure during the study.

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

Biopsy proven diagnosis of Sarcoidosis

Exclusion criteria

none

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:	Recruitment stopped
Start date (anticipated):	17-05-2016
Enrollment:	1114
Type:	Actual

Ethics review

Approved WMO Date:	03-09-2014
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	25-04-2016
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	10-05-2017
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	NL49563.100.14