Registry for advanced sarcoidosis (ReAS)

Published: 08-02-2017
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The purpose of the registry is to determine disease development of advanced and non-advanced sarcoidosis. In addition, the registry would note the other organ involvemen, treatment and quality of life.

Ethical review	Not approved
Status	Will not start
Health condition type	Lower respiratory tract disorders (excl obstruction and infection)
Study type	Observational non invasive

Summary

ID

NL-OMON45613

Source
ToetsingOnline

Brief title
ReAS

Condition

- Lower respiratory tract disorders (excl obstruction and infection)

Synonym
pulmonary sarcoidosis

Research involving
Human

Sponsors and support

Primary sponsor: Sint Antonius Ziekenhuis
Source(s) of monetary or material Support: eigen geld van de ILD-onderzoeksgroep

Intervention

Keyword: Clinical course, pulmonary sarcoidosis, Quality of life, Registry

Outcome measures

Primary outcome

Disease development of advanced and non-advanced sarcoidosis.

Secondary outcome

Quality of life for patients with advanced and non-advanced sarcoidosis as

assessed using questionairs

Study description

Background summary

A. Specific Aims: During the past 20 years, new treatments have been developed for sarcoidosis. Many of these treatments have been directed towards patients with advanced disease. However, the natural course of patients with advanced and non-advanced disease is not knoen. The purpose of the registry is to determine the development of sarcoidosis. In addition, the registry would note the other organ involvement and treatment used for these patients and the quality of life of patients.
B. Background and significance: The clinical outcome of sarcoidosis is variable. While over half of patients have resolution of their disease within two years of diagnosis, at least a quarter of patients will have chronic disease requiring therapy for more than five years. Certain manifestations of sarcoidosis are associated with chronic disease. These include pulmonary fibrosis, neurologic and cardiac disease, lupus pernio, and those requiring treatment.
The use of potent agents such as infliximab have proved useful in treating advanced sarcoidosis. This treatment regimen is associated with significant cost and requires careful monitoring. Other potent agents have also been used for advanced sarcoidosis, including adalimumab, rituximab, cyclophosphamide, and Acthar. This registry will determine diseae development in advanced and non-advanced patients, organ involvement, use of medication and quality of life via questionairs.

Study objective

The purpose of the registry is to determine disease development of advanced and non-advanced sarcoidosis. In addition, the registry would note the other organ involvemen, treatment and quality of life.

Study design

Observational study

Study burden and risks

The completion of the questionnaires may be time consuming but no other risks. There are no risks associated with participation. By being a subject in this study, a patient helps to gain insight in the clinical course of sarcoidosis. In time, this may improve the treatment of patients with sarcoidosis.

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

* Patients with diagnosis of sarcoidosis based on ATS/WASOG criteria 22
* Age * 18 years.
* Life expectancy of at least 2 years.
* Pulmonary function tests (spirometry) within one month of entry or willing to under pulmonary
function testing on the day of study enrollment
* Sarcoidosis as characterized as either advanced or non-advanced (see protocol for definition
of advanced disease)
* Subjects must be able to understand and be willing to sign the written informed consent form. A signed informed consent form must be appropriately obtained prior to the conduct of any trial-specific procedure.

Exclusion criteria

* Subjects with a medical disorder, condition, or history of such that would impair the subject*s
ability to participate or complete this study in the opinion of the investigator
* Inability to comply with the protocol and/or not willing or not available for follow-up assessments.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	100
Type:	Anticipated

Ethics review

Not approved

Date:	08-02-2017
Application type:	First submission
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	NL60192.100.17