Forced oscillation technique: a novel method to monitor sarcoidosis

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1. Determine the value of FOT for sarcoidosis evolution and response to therapy.2. Evaluate patients* experience with FOT.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Lower respiratory tract disorders (excl obstruction and infection)
Study type	Observational non invasive

Summary

ID

NL-OMON56906

Source
ToetsingOnline

Brief title
FLAIR study

Condition

- Lower respiratory tract disorders (excl obstruction and infection)

Synonym
interstitial lung disease, sarcoidosis

Research involving
Human

Sponsors and support

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

Intervention

Keyword: interstitial lungdisease, lung resistance, oscillometry

Outcome measures

Primary outcome

FOT-parameters:

• Respiratory resistance (Rrs)

• Airway resistance (Raw)

• Respiratory reactance (Xrs)

• Resonance frequency (Fres)

• Reactance area (AX)

Compared to regular examinations:

- Spirometry

- Diffusion capacity

- Body box

- HRCT

- Clinical parameters

Secondary outcome

• Evaluation form for patients:

o VAS cough

o VAS dyspnea

o VAS comfort

o General procedure rating and feedback

• Evaluation form for pulmonary function laboratory technician

o Duration of the procedure

o Was it possible to perform pulmonary function tests and/or FOT?

* No: why not?

• Cough

• Dyspnea

• Energy

* Yes:

• rate the quality: bad - mediocre - sufficient - good

• Number of attempts

• Variance between multiple measurements

• Medical conclusion based on pulmonary function

Study description

Background summary

Sarcoidosis is usually present in lungs and lymph nodes. The severity of pulmonary sarcoidosis ranges from unexpectedly found radiographic irregularities in patients showing no symptoms to a persistent, advancing condition that is refractory to treatment. After diagnosis, longitudinal surveillance is recommended. Surveillance should be most intensive during the first 2 years after presentation to determine prognosis and the need for therapy. Initial follow-up every 6 months is considered accurate, but more frequent evaluations at every 3-6 months are recommended for patients with pulmonary sarcoidosis scadding stages II-IV. In addition, all patients should be monitored for at least 3 years after discontinuation of treatment. Monitoring is performed with clinical evaluation, chest radiography and pulmonary function tests. Decrease in forced vital capacity (FVC) assessed by spirometry is the simplest and most accurate marker reflecting the stage of pulmonary sarcoidosis. In addition, a reduced diffusing capacity for carbon monoxide (DLCO) reflects the dilated alveolar-arterial gradient during exercise. These methods are time-consuming, require experienced lung-function technicians and patients that are able to follow-up their instructions for forced breathing.

Forced oscillation technique (FOT) is a promising new method providing information about lung mechanics during spontaneous breathing. Pulmonary sarcoidosis is associated with reduced pulmonary compliance and airway obstruction. Compared to conventional pulmonary function tests, the FOT has some clear advantages: no age restrictions, spontaneous breathing of only 20 seconds, less cooperation required, less influence of instructions, more sensitive in early stages of small airways disease and can detect changes in the airways when spirometry is still normal. FOT may be particularly useful in identifying restrictive, obstructive, or mixed lung function defects. FOT has gained increasing interest since recent updates of technical standards and improved devices. Studies of FOT in patients with sarcoidosis are scarce and suggest an advantage of FOT compared to conventional pulmonary function tests. However, no follow-up data are available that would support accurate monitoring of the course of sarcoidosis. Therefore, we will investigate the use of FOT in patients with pulmonary sarcoidosis during follow-up to determine its accuracy for monitoring disease progression and therapy effects.

Study objective

1. Determine the value of FOT for sarcoidosis evolution and response to therapy.
2. Evaluate patients* experience with FOT.

Study design

The research will be a prospective cohort study, conducted at the ILD Centre of Excellence of the St. Antonius Hospital in Nieuwegein. The subject visits the hospital as planned according to regular care. Interested patients with sarcoidosis, who visit the hospital for at least one lung function test or an HRCT-scan, will be screened and approached for participation in this study. In addition to their regular tests, they will perform a FOT measurement. These ameasurements are taken repeatedly during hospital visits for desease progression monitoring. Patients participating in this study will be followed until the end of this study, for up to 3 years.

Study burden and risks

The burden and risk of the research is considered negligible.

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 sarcoidosis

Exclusion criteria

age < 18 years
Pregnancy
Breast feeding

Study design

Design

Study type: Observational non invasive
Masking: Open (masking not used)

Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	06-09-2024
Enrollment:	170
Type:	Actual

Medical products/devices used

Generic name:	Airwave Oscillometry Device - Tremoflo
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	19-07-2024
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	NL86195.100.24