Conventional bronchoscopy vs. endosonography: A randomized prospective clinical study for the diagnosis of sarcoidosis

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

Summary

ID

NL-OMON33798

Source
ToetsingOnline

Brief title
Diagnosing sarcoidosis: conventional bronchoscopy vs endosonography

Condition

- Immune disorders NEC
- Lower respiratory tract disorders (excl obstruction and infection)

Synonym
Besnier-Boeck disease, lekenterm nvt

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: EBUS-TBNA, EUS-FNA, Flexible bronchoscopy, Sarcoidosis

Outcome measures

Primary outcome

The sensitivity of endo-sonography vs. bronchoscopy in the detection of

non-caseating granulomas.

Secondary outcome

1. The role of a broncho-alveolar lavage (BAL) in addition to endo-sonography

and conventional bronchoscopy for diagnosing sarcoidosis.

2. Complications in both study arms.

3. Patient tolerance for both study arms.

Study description

Background summary

Sarcoidosis is the most prevalent interstitial lung disease in Western-Europe and the US. The disease is most prevalent in young adults. To set the final diagnosis of sarcoidosis, the following parameters need to be present:

1. A clinical and radiological suspicion of sarcoidosis
2. A tissue diagnosis of disease-specific non-caseating granulomas.
3. Exclusion of possible alternative diagnoses as lung cancer or tuberculosis.

Nowadays, a bronchoscopy with lung biopsies is advised to set a tissue

diagnosis of sarcoidosis. However, these biopsies are only diagnostic in 70% of the procedures and they are associated with a 3% risk of coughing up blood and a 4% risk of a lung collaps.

Since recently, a new diagnostic procedure has come available. This procedure, endo-sonography, makes it possible to biopsy lymph nodes in the chest under direct visualisation and has a diagnostic accuracy of 85%. The associated risk of complications appears to be small (<1%)

We consider the current standard for the diagnostics of sarcoidosis to be outdated, considering the clinical availability of endo-sonography. We expect that endo-sonography is more frequent diagnostic for a tissue diagnosis of sarcoidosis.
Also we hypothesize that this technique is safer and more preferred by patients.

Study objective

The study is a diagnostic study for the diagnostics of sarcoidosis, in where a new, endo-sonographic procedure is compared to the current, bronchoscopic method.
The objective is to assess the accuracy, safety and patient tolerance of endo-sonography against conventional bronchoscopy for the diagnosis of sarcoidosis.

Study design

For the detection of non-caseating granulomas, patients are randomized between endo-sonography and conventional bronchoscopy. In both study arms, a lung lavage (BAL) will be performed as well. Specific BAL outcomes can also contribute to the diagnosis of sarcoidosis.

After endo-sonography or bronchoscopy, the contribution of both methods for the detection of non-caseating granulomas and for the diagnosis of sarcoidosis will be evaluated.

After 6 months follow-up, all patients will be seen again by the treating physician.

Study burden and risks

Since all procedures are part of standard clinical care, the are no additional risks attached to the study.
Prior to the investigation, patients are informed about the risks of the procedures.

The patients are subjected to a small questionaire and a visual analogue scale (VAS) to determine the procedure demand for the patient. The VAS quantification and the questionaire will take approximately 10 minutes.

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 suspected pulmonary sarcoidosis (stage I/II) in whom a tissue diagnosis (presence of non-caseating granulomas) is indicated.

Exclusion criteria

No informed consent
Unable to undergo EUS/EBUS or bronchoscopy (e.g. esophageal strictures, respiratory insufficency)
Unable to participate in the follow -up
Contraindications for a lung or nodal biopsy (e.g. coagulopathy, thrombocytopenia)
Pregnancy
age under 18 years

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	30-03-2009
Enrollment:	140
Type:	Actual

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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	NL26316.058.08
Other	registratie volgt na goedkeuring protocol