High-definition videobronchoscopy with optical enhancement for the diagnosis of endobronchial sarcoidosis: a pilot study

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In this study we aim to assess: 1.the diagnostic yield of endobronchial biopsy taken during HD videobronchoscopy in a large study population;2. the prevalence, visual pattern and specificity (for the detection of granulomas) of airway abnormalities...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Bronchial disorders (excl neoplasms)
Study type	Observational invasive

Summary

ID

NL-OMON51157

Source
ToetsingOnline

Brief title
Enhance Sarcoid Study

Condition

- Bronchial disorders (excl neoplasms)

Synonym
Besnier Boeck disease, Saroïdosis

Research involving
Human

Sponsors and support

Primary sponsor: Fondazione Policlinico Universitario Agostino Gemelli IRCCS
Source(s) of monetary or material Support: material and logistic support by Pentax Medical,Pentax Medical

Intervention

Keyword: High-definition videobronchoscopy, Optical enhancement, Sarcoidosis

Outcome measures

Primary outcome

Diagnostic yield of endobronchial biopsy guided by HD videobronchoscopy for the detection of granulomas

Secondary outcome

- Prevalence of airway abnormalities in patients with suspected sarcoidosis at HD bronchoscopy

- Prevalence of different patterns of airway abnormalities in patients with suspected sarcoidosis at HD videobronchoscopy

- Specificity for the detection of granulomas of the above 6 different patterns of airway abnormalities identified during HD bronchoscopy

- The interobserver agreement for the identification of the above 6 predefined patterns of airway abnormalities.

- Diagnostic yield for the detection of endobronchial granulomas according to clinical, radiological and endoscopic findings.

The association between the following findings and the diagnostic yield of EBBs will be assessed: sex; ethnicity; sarcoidosis stage (I-IV); presence versus absence of endobronchial abnormalities at HD bronchoscopy; pattern of airway abnormality at HD bronchoscopy.

Study description

Background summary

Sarcoidosis is a systemic disease of unknown etiology that can be diagnosed in the presence of a compatible clinical picture and a pathological finding of non-necrotizing epithelial granulomas in one of the affected organs.
Since sarcoidosis is a pathology with thoracic involvement (bronchi, lung parenchyma and/or intrathoracic lymph nodes) almost always present, bronchoscopy and bronchoscopic sampling methods (endobronchial and transbronchial biopsies, bronchioloalveolar lavage, conventional transbronchial and/or ultrasound-guided fine needle aspirations ultrasound-guided transesophageal) are almost always used for the pathological confirmation of clinical suspicion of sarcoidosis.
Endobronchial biopsies, one of the simplest and safest sampling procedures to perform, with a diagnostic yield varying between 18% and 71%, always increases the diagnostic success of bronchoscopy in sarcoidosis when associated with other sampling procedures.
Predictors of succesfull endobronchial biopsies in sarcoidosis are associated with the African-American race and the presence of bronchial mucosal changes visible during bronchoscopy. However, even in the absence of alterations of the bronchial mucosa, in approximately 37% of the cases, it is possible to find the presence of non-necrotizing granulomas on endobronchial biopsies performed on apparently normal mucosa. This presupposes a microscopic involvement of the bronchial mucosa, not visible or not clearly visible on standard bronchoscopy, in a non-negligible percentage of patients with sarcoidosis. Consequently, an imaging method that helps identify bronchial mucosal involvement when present but not clearly visible with standard bronchoscopy, could increase the diagnostic yield of endobronchial biopsies. This is an advantage since this approach is less invasive than other lung parenchymal procedures (transbronchial biopsies), and less expensive than lymph node sampling procedures (EBUS-TBNA, EUS-B-FNA).
In recent years, the new high definition (HD) video bronchoscopes have become commercially available which, compared to standard bronchoscopes, offer a much higher image definition and, combined with the new video processors, allow for "real-time" methods to "post-processing* of the image which are particularly useful to study bronchial vascularization (i-scan technology).

Our hypothesis is that HD video bronchoscopy could help identify bronchial involvement of sarcoidosis before it is clearly visible on standard bronchoscopy.

Study objective

In this study we aim to assess:
1.the diagnostic yield of endobronchial biopsy taken during HD videobronchoscopy in a large study population;
2. the prevalence, visual pattern and specificity (for the detection of

granulomas) of airway abnormalities seen during HD + OE videobronchoscopy in patients with suspected sarcoidosis.

Study design

prospective, multicenter, observational cohort study

Study burden and risks

Bronchoscopy and the endobronchial sampoling methods to be preformed in the current study are routinely performed in clinical practice for the diagnosis of sarcoidosis and are considered safe, but every procedure has its risks. There is a small chance of infection and bleeding when taking biopsies. The risk for these complications when participating in the study is comparable to the standard procedure.

The bronchoscopic procedure can take a few minutes longer because short video recordings will be taken of the sampling locations. This is not a burden for the patiënts as they will be sedated according to standard procedures

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

a) indication to a pathological confirmation of the clinical and radiological (CT)
suspect of sarcoidosis;
b) age > 18 years;
c) ASA score 1-3.

Exclusion criteria

a) inability to consent;
b) steroid therapy (at least 1 week) in the 2 months preceding bronchoscopy;
c) pregnancy;
d) uncontrolled coagulopathy;
e) contraindication to temporary interruption of anticoagulants or antiplatelet drugs, except aspirin;

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):	07-07-2021
Enrollment:	40

Type:	Actual

Medical products/devices used

Generic name:	Video Bronchoscope (EB15-J10 & EB19J10)
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	05-07-2021
Application type:	First submission
Review commission:	METC Amsterdam UMC

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
ClinicalTrials.gov	NCT04743596
CCMO	NL77709.018.21