Bronchoalveolar lavage in healthy volunteers.

Published: 10-08-2006
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Primary Objective: To perform BAL in healthy volunteers, who can serve as control subjects in (future) studies.

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

Summary

ID

NL-OMON31475

Source
ToetsingOnline

Brief title
BAL in healthy volunteers

Condition

- Respiratory disorders NEC

Synonym
Besnier Boeck Disease, Interstitial Lungdisease, Sarcoidosis

Research involving
Human

Sponsors and support

Primary sponsor: Sint Antonius Ziekenhuis
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Biological Markers, Bronchoalveolar Lavage, Immunophenotyping, reference

values

Outcome measures

Primary outcome

Relative frequencies of different monocyte and lymphocyte subtypes.

Protein analyses

Secondary outcome

not applicable

Study description

Background summary

Bronchoalveolar Lavage (BAL is part of the standard diagnostic procedure for patients suspected of interstitial lung diseases (ILDs).1
Fluid obtained by lavage can be analyzed cytologically (cellular component) and chemically (non cellular component). Analyses of the cellular component include the relative quantity of different cell types (lymphocytes, neutrophils, eosinophils) and cell-subtypes. In addition to the cellular component, proteins present in the fluid and in cells themselves can be analyzed by mass spectrometry.
Regarding Interstitial Lung Diseases, the most prominent value of BAL is its role in the diagnostic procedure, for in some conditions levels of a specific cell-(sub)type or protein can be either elevated or reduced. This knowledge is not only useful for diagnostic purposes, as elevation or reduction of a specific cell-type or protein can also provide information about the underlying pathologic processes. Furthermore, BAL can also be used in the assessment of disease severity, and in extension, for evaluation of treatment.
In the St. Antonius Hospital, many patients with an ILD are treated and scientific research on the etiology of these diseases is conducted, some in which results of BAL are used. To facilitate these studies, we are planning to conduct a series of Bronchoalveolar Lavages in healthy volunteers. The results of the current study will be used as *control* values in the different studies involving BAL that are and will be conducted at the department of pulmonary diseases. These are predominantly studies trying to dissolve the etiology of sarcoidosis and other ILDs.

Study objective

Primary Objective: To perform BAL in healthy volunteers, who can serve as control subjects in (future) studies.

Study design

This study is of an observational design, and involves invasive measurements. Bronchoalveolar Lavage and venipuncture are once performed in healthy volunteers.

Study burden and risks

Single venipuncture for atopy screening, if negative then continuation with study:
Single roentgenologic examination of the thorax and simple spirometry (to exclude pulmonary diseases)
Single Bronchoalveolar Lavage and venipuncture (100 ml). Risks and side effects during lavage: Dyspnea. Side effects after Lavage: Pharyngeal Irritation, coughing, fever, pain when breathing. The risks of drawing blood from a vein are minimal.

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

-age between 18 and 65 years
-capability of giving informed consent

Exclusion criteria

- pulmonary disease
- diseases related to the immune system
- active infection
- immunosuppressive medication
- employees of the departments of pulmonary medicine and Medical Microbiology and Immunology are excluded from participation
- exclusion criteria for undergoing bronchoalveolar lavage
- if atopy screening is positive i.e. IgE > 100 and/or phadia-top >1

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	11-01-2007
Enrollment:	55
Type:	Actual

Ethics review

Approved WMO Date:	10-08-2006
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	26-03-2008
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	22-12-2008
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	NL12191.100.06