Individual sensititivy for the development of interstitial lung diseases (ILD)

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

Summary

ID

NL-OMON33852

Source
ToetsingOnline

Brief title
Individual sensitivity for interstitial lung diseases

Condition

- Respiratory disorders NEC

Synonym
chronic inflammatory lung diseases, lung fibrosis, sarcoidosis

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W,een onderzoekssubsidie van de sarcoidose belangenvereniging

Intervention

Keyword: individual sensitivity, inflammation, interstitial lung diseases, oxidative stress

Outcome measures

Primary outcome

differences in the production of and the protection against ROS

differences in the occurring inflammatory reaction

Secondary outcome

differences in the presence of so-called volatile organic compounds (VOCs) in

the exhaled air

Study description

Background summary

Interstitial lung diseases (ILD) is a collective noun for various chronic lung diseases, including sarcoidosis and idiopathic lung fibrosis (IPF). Sarcoidosis is a multi-systemic disease that includes damage to the lungs in 90% of the patients. It*s difficult to give a concise definition of sarcoidosis, due to the fact that its exact cause is still unknown, but generally the diseases can be described as a systemic, granulomatous and antigen-driven disorder. IPF is a disease of the lungs only, in which an unknown cause induces a strong inflammation reaction leading to acute lung damage that ultimately results in the formation of scar tissue and stiffness of the lungs.

Unfortunately, the exact cause of ILD is still unknown. It is suggested that environmental and work-related exposure to various triggers can exert an effect on the course of the diseases. Examples of such triggers include viruses, bacteria, organic agents such as pollen and cotton dust and inorganic agents like metals and talc. Since the exact cause of ILD is still unknown, it is difficult to treat these diseases. Consequently, the current guideline is no medication or anti-inflammatory agents in severe cases. Unfortunately, this therapy is not completely effective.

Triggers that are suggested to cause ILD can exert their effects via various mechanisms. On the one hand, they can induce an inflammatory reaction as we recently demonstrated for various triggers including instillation

material and sicila (Boots et al, unpublished data). During such an inflammatory reaction, cytokines are released that can induce oxidative stress, i.e. an imbalance between the formation of and the protection against reactive oxygen species (ROS), in various cells and tissues. On the other hand, ILD-inducing triggers may directly cause an increased ROS production that subsequently can evoke an inflammatory reaction. In other words, triggers that are suggested to cause ILD may exert their effect by inducing an increased ROS production as well as an enhanced inflammatory reaction.

Study objective

The objective of the current study is to investigate the individual sensitivity for the development of ILD after exposure to various triggers. Main focus will be the differences in the formation of and the protection against ROS as well as the occurring inflammatory reaction after exposure to such triggers.
Furthermore, a simple blood test will be developed to study and eventually even predict the individual reaction of subjects to various triggers. Finally, to fully characterize the development of ILD after exposure to various triggers, the exhaled air of patients will be studied in order to identify specific markers of oxidative stress and damage.

Study design

This study is designed to investigate the individual sensitivity for the development of ILD after exposure to various triggers. Furthermore, this study will be used to develop a simple blood test in order to investigate or even predict the individual reaction of subjects to various exposures. To this extent, ILD patients will be asked to fill in 2 questionnaires regarding either their possible exposures or their health and quality of life. Moreover, the patients will be asked to donate 5L exhaled air and 20 ml blood.
Based on the questionnaires, the ten most frequently occurring triggers will be selected. The individual sensitivity for the development of ILD will be tested by ex vivo adding these triggers to the blood of each participant, after which various markers of oxidative stress and inflammation will be measured. To study the effects of triggers on individual level, all participants will also be tested for their one specific exposure.
This study will be performed with 100 ILD patients in total, 50 sarcoidosis and 50 IPF patients. Patients will be recruited by their own physician, after which the researcher will provide oral and written information in case patients are interested.

Study burden and risks

The burden for the participants is minimal since they are only asked to donate 20 ml blood and 5 L exhaled air. Furthermore, they have to fill in 2

questionnaires, one regarding their possible exposures and one regarding their health and quality of life.

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

ILD diagnosis confirmed by lung biopsy, X ray or BALF analysis

Exclusion criteria

smoking
pregnancy or lactation

use of vitamins or nutritional supplements

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-09-2008
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO

Date:	20-08-2008
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Approved WMO

Date:	08-06-2009
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL22962.068.08