T-cell mediated immunity against Aspergillus fumigatus

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To study the mechanisms by which T-cells can contribute to the defense against Aspergillus fumigatus.To study the role of the immune system and the role of Aspergillus antigens in the switch from a Th1 to a Th2 profile in patients with ABPA.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Allergic conditions
Study type	Observational invasive

Summary

ID

NL-OMON35724

Source
ToetsingOnline

Brief title
T-Af

Condition

- Allergic conditions
- Fungal infectious disorders

Synonym
Aspergillosis, fungal infection

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: Aspergillus, T cell

Outcome measures

Primary outcome

Frequency and cytokineprofile of Aspergillus-specific T-cells in blood and

broncho-alveolar lavage fluid

Presence and type of Aspergillus-specific antibodies

Secondary outcome

nvt

Study description

Background summary

Invasive aspergillosis is a common and life-threatening infectious complication in patients with hematological diseases, in patients after stem cell transplantation or solid organ transplantation and in patients with the primary immune deficiency Chronic Granulomatous Disease. It is known that patients with granulocytopenia have an increased risk of invasive aspergillosis, but in recent years there is increasing evidence that T-cells also play an essential role in the defense against Aspergillus fumigatus.
Another patient group, patients with Allergic Bronchopulmonary Aspergillosis (ABPA) exhibit an allergic overreaction to Aspergillus fumigatus. The Aspergillus-specific T-cells in these patients have a Th2 profile. It is unknown what the cause is of the switch from a Th1 to a Th2 profile.

Study objective

To study the mechanisms by which T-cells can contribute to the defense against Aspergillus fumigatus.
To study the role of the immune system and the role of Aspergillus antigens in the switch from a Th1 to a Th2 profile in patients with ABPA.

Study design

Observational mechanistic study

Study burden and risks

At one to three time points 50 ml of blood will be drawn, if possible during an existing vena puncture. When a broncho-alveolar lavage is performed BAL-fluid will be collected for this research project.
No benefit for the participants is expected, neither any negative effects.

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

Diagnosis Invasive Aspergillosis or suspected for this diagnosis
Diagnosis allergic reaction to Aspergillus

Partner of patient with allergic reaction to Aspergillus

Exclusion criteria

< 18 year of age
Not able to get informed consent

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	30-08-2012
Enrollment:	150
Type:	Actual

Ethics review

Approved WMO

Date:	23-06-2011
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL35939.058.11

Study results

Date completed: 02-11-2015

Actual enrolment: 9

Summary results
Trial is onging in other countries