The Genetic variability in the host response to community-acquired pneumonia

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To determine the genetic risk of susceptibility to, or severity of community-acquired pneumonia by comparing the interpersonal genetic variation of the host immune response of patients with community-acquired pneumonia to healthy controls and by...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bacterial infectious disorders
Study type	Observational invasive

Summary

ID

NL-OMON35629

Source
ToetsingOnline

Brief title
Genetic risk of pneumonia

Condition

- Bacterial infectious disorders
- Respiratory tract infections

Synonym
lower respiratory tract infection, pneumonia

Research involving
Human

Sponsors and support

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

Intervention

Keyword: coagulation, community-acquired pneumonia, genetic risk of infection, host response to infection, Streptococcus pneumonia

Outcome measures

Primary outcome

1.To identify genetics variations associated with the genetic risk of

susceptibility to community-acquired pneumonia.

Secondary outcome

1.To identify genetic variations associated with a severe community-acquired

pneumonia on admission. Pneumonia severity will be determined by (a) mortality

of community-acquired pneumonia within 24 hours; (b) Pneumonia severity scores:

Pneumonia Severity Index and CURB-65 score (appendix 4) and (c) Location of

treatment after first survey in ER (ward versus ICU).

2.To indentify genetic variations associated with poor response to treatment:

determined by (a) development of complications during hospitalization (b)

mortality after first day and within 30 days of admission. (c) admission to ICU

during hospitalization.

Study description

Background summary

Community-acquired Pneumonia is still the most important causes of hospital admission and mortality due to infectious diseases in western countries. Insight into the genetic variability in the host response to community-acquired pneumonia seems promising and will lead to a better understanding of the biological role of different genes and their products in the pathogenesis of

pneumonia. Moreover, a better insight into the influence of host genetic variation on the pathophysiological derangements and severity of pulmonary infections seems vital in order to develop new therapeutic approaches and more individualized treatment for community-acquired pneumonia.

Study objective

To determine the genetic risk of susceptibility to, or severity of community-acquired pneumonia by comparing the interpersonal genetic variation of the host immune response of patients with community-acquired pneumonia to healthy controls and by comparing interpersonal genetic variation of the host response in patients with variable degree of pneumonia severity.

Study design

The study is designed as prospective multicenter case-control study; a genome-wide association study. We intent to collect blood samples from 2000 patients with community-acquired pneumonia admitted to one of the participating hospitals.
Genotyping will be used to identify subtle genetic variations, which may be associated with and increased risk of susceptibility to/or severity of community-acquired pneumonia. To identify these genetic variations genotype results of 2000 patients with community-acquired pneumonia be related to 2000 population controls.

Study burden and risks

none

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

1.Age of 18 years of older
2.Admission to the hospital
3.Community-acquired pneumonia defined as:
a.New or progressive infiltrate on a chest X-ray and
b.2 of the following criteria:
-Cough
-sputum production
-dyspnea
-rectal temperature > 38oC or < 36.1oC
-ausculatory findings consistent with pneumonia
-leucocytosis (>10.000/mm3, or >15% bands)
-C-reactive protein > 3 times the upper limit of normal
4. A least three grandparents form Dutch origin

Exclusion criteria

1.Hospitalization for more than >=48h in the 2 weeks prior to enrollment in the study
2.Infections other than pneumonia that need immediate treatment
3.Life expectancy < 2 months

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	09-12-2009
Enrollment:	2000
Type:	Actual

Ethics review

Approved WMO Date:	12-05-2009
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	16-04-2010
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL25409.041.08