Induction and waning of specific immune mechanisms against Bordetella Pertussis after infection.

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I. Evaluation of the nature and maintenance of specific cellular immune mechanisms after infection with Bordetella pertussis in different age groups, to identify critical parameters for pertussis re-emergenceII. To relate individual patient*s...

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

Summary

ID

NL-OMON36878

Source
ToetsingOnline

Brief title
pertussis specific immunity

Condition

- Bacterial infectious disorders

Synonym
pertussis, whooping cough

Research involving
Human

Sponsors and support

Primary sponsor: RIVM
Source(s) of monetary or material Support: min. VWS

Intervention

Keyword: Bordetella pertussis, Correlates of Protection, Immunity, Whooping cough

Outcome measures

Primary outcome

Main immunological study parameters: trends per age group or time interval

after infection in: i) frequencies, functionality and (fine)specificity of

pertussis-reactive T cells; ii) titers and functionality of pertussis specific

antibody titers; and iii) frequencies, functionality and specificity of

pertussis-reactive memory B cells and plasma cells

Secondary outcome

Secundary microbiological study parameters:

strain variation of patients* pertussis isolates in relation to global trends

and in relation to patients* immune responses.

(per age group): estimation of pertussis incidence and underreporting in the

general population, especially the elderly (by comparing the frequency of cases

in source populations with national notification data); strain prevalence

Study description

Background summary

Bordetella pertussis, the causative agent of whooping cough, has remained endemic despite intensive vaccination. The clinical course of pertussis infection varies widely, from most typical and severe with complications, often in unprotected infants, to mild or asymptomatic in older age groups. In 13-20%

of adults with prolonged cough, pertussis is the cause. Waning immunity on the one hand, and strain adaptation and changing transmission patterns on the other hand, have been proposed to underlie insufficient protection and the current re-emergence of the disease. Since serum antibody titers alone do not fully correlate with protection, and Bordetella pertussis evades humoral effector mechanisms, cell mediated immune mechanisms involving specific T and B lymphocyte populations play a role as well. Waning pertussis immunity postulates that in previously immune (exposed) individuals these correlates of protection dysfunction or disappear with time. How this translates into magnitude, function and fine-specificity of lymphocytes has not been studied. In this study we want to compare the induction, nature and maintenance of specific cellular immune mechanisms after pertussis infection in different age groups, in relation to currently circulating strains. This evaluation is important to define cellular correlates of protection, needed to develop improved pertussis vaccines and vaccination schedules

Study objective

I. Evaluation of the nature and maintenance of specific cellular immune mechanisms after infection with Bordetella pertussis in different age groups, to identify critical parameters for pertussis re-emergence

II. To relate individual patient*s specific cellular immune parameters to genetic characteristics of the patient*s isolate (if available), such as lineage and strain adaptation.

Study design

The study is an observational study in three parts:
I. prospective, with venous blood sample and a questionnaire
II. prospective, with venous blood sample, a questionnaire and a nasopharyngeal and mouth swab.
III. retrospective, with venous blood sample and a questionnaire

Study burden and risks

Burden is minimal, the study consists only of one venous blood sample and for participants in part II also a nasopharyngeal and mouth swab

Contacts

Public
RIVM

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Scientific
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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Children (2-11 years)
Elderly (65 years and older)

Inclusion criteria

I: Patients being within a 4 weeks period after a laboratory-confirmed diagnosis of pertussis
II: Household contact of I
III: Subjects being recovered or recovering from a laboratory-confirmed pertussis infection which was diagnosed > 4 weeks earlier

Exclusion criteria

A: Immunosuppressive medical treatment, like cytostatics and prednisolons that might interfere with the results of the study, within the previous 3 months.
B: Any known primary or secondary immunodeficiency
C: Bleeding disorder

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	03-01-2008
Enrollment:	480
Type:	Actual

Ethics review

Approved WMO Date:	26-06-2007
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	13-10-2008
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	20-05-2011
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	NL16334.040.07