A pilot study to characterize T cell responses in young children after influenza infection

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Characterization of T cell responses in young children after influenza infection

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

Summary

ID

NL-OMON33577

Source
ToetsingOnline

Brief title
T cell responses in children after influenza infection

Condition

- Viral infectious disorders

Synonym
influenza

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: min. VWS

Intervention

Keyword: cellular immunity, children, influenza

Outcome measures

Primary outcome

Height of the cellular immune response after stimulation of the white blood cells with influenza virus in vitro. The response will be characterized based on; influenza-specific cytokine induction, number of influenza-specific T cells, T cell activation and functional status.

Secondary outcome

Humoral immune response

Study description

Background summary

Morbidity and mortality caused by influenza infection is higher in young children compared to adults. This may be due to induction of an inadequate immune response in young children. In the USA it is advised to vaccinate children in the age of 6 months to 59 months. The efficacy of vaccines is determined by serological assays like the hemagglutination inhibition assay (HAI). However, the current vaccines are not 100% protective in young children. Therefore, better insight in the mechanisms of the immune system (cellular immunity) is required to develop improved vaccines against influenza in this group.

Study objective

Characterization of T cell responses in young children after influenza infection

Study design

During the influenza season of 2007/2008, 2008/2009 and 2009/2010 children infected with influenza will be recruited via hospitalisation. At entry of the hospital, a serum sample (1 ml) will only be taken in combination with a

regular venapunction for diagnostic purposes. 4-6 weeks after hospitalisation, a second blood draw will take place for isolation PBMC and serum. 5 ml blood will be drawn from children 0-4 years and 10 ml blood from children 5-9 years old.
Control populations will consist of children and adults, recruited before onset of the 2009/2010 influenza season. Procedure of recruitment and blood sampling in the control group of children will be similar as described for the children infected with influenza. Adults will be recruited via RIVM/NVI and blood will be drawn (15 ml) for isolation of PBMC and serum.

Blood will be prepared on day of blood draw. The isolated PBMC will be tested directly in in vitro experiments to determine T cell responses. Serum of both time points will be tested in HI assay.

Study burden and risks

Potential minor bruise, limited pain with blood sampling. Participation to this study likely enables future development of improved vaccines in children.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Children (2-11 years)
Elderly (65 years and older)

Inclusion criteria

Index population: children hospitalized at Wilhelmina Children*s Hospital, Spaarneziekenhuis, St. Antonius Ziekenhuis, and Diakonessenhuis with influenza infection.
Control Group: children hospitalized at Wilhelmina Children*s Hospital without influenza infection.
Adults: adults employed at RIVM/NVI without influenza infection.

Exclusion criteria

Index population: prematurity (gestational age < 37 weeks), chronic lung disease, severe congenital diseases, known immunological dysfunction, current infectious disease other than influenza, hematologic disorder, usage of anticoagulants, influenza vaccination;Control group: prematurity (gestational age < 37 weeks), chronic lung disease, severe congenital diseases, known immunological dysfunction, current infectious disease, hematologic disorder, usage of anticoagulants, influenza vaccination;Adults: known immunological dysfunction, current infectious disease, hematologic disorder, usage of anticoagulants, influenza vaccination

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-05-2008
Enrollment:	125
Type:	Actual

Ethics review

Approved WMO Date:	01-04-2008
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	22-09-2009
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	NL18924.041.07