Serum antibody response to influenza A in children with Down syndrome

Published: 20-05-2010
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Measuring specific antibody titers against influenza A (subtype H1N1 and / or seasonal vaccine) in DS children. DS anti-influenza antibody titers will be compared with controls available from the same laboratory.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Immunodeficiency syndromes
Study type	Observational non invasive

Summary

ID

NL-OMON34503

Source
ToetsingOnline

Brief title
DS-influenza

Condition

- Immunodeficiency syndromes
- Viral infectious disorders

Synonym
Down syndrome, trisomy 21

Research involving
Human

Sponsors and support

Primary sponsor: Jeroen Bosch Ziekenhuis
Source(s) of monetary or material Support: Stichting Peribosch

Intervention

Keyword: antibody, Down syndrome, influenza, vaccine

Outcome measures

Primary outcome

Specific anti-influenza A (subtype H1N1 and / or seasonal) antibody titers will

be measured.

Secondary outcome

not applicable.

Study description

Background summary

Children with Down syndrome show an increased incidence of infections and auto-immune diseases. Past publications have already increased the general knowledge on the DS immune system. Assaying specific antibody production against influenza A (subtype H1N1 and seasonal) can be used as a model to assess T-cell dependent (anti-protein) antibody responses can be used to further increase this knowledge. Over the course of the last quarter of 2009 influenza A vaccinations have been given to risk groups on a global scale, including several Dutch DS children.

Study objective

Measuring specific antibody titers against influenza A (subtype H1N1 and / or seasonal vaccine) in DS children. DS anti-influenza antibody titers will be compared with controls available from the same laboratory.

Study design

This is an observational study. At the time of a medically indicated regular venepuncture, 5 ml of extra blood will be drawn for study purposes.

Study burden and risks

Patients will not directly benefit from participating in this study. The burden

involved is limited due to the fact that patients will not need to undergo an extra venepuncture. The expected increase of knowledge about the DS immune system outweighs the limited burden imposed on patients participating in this study.

Contacts

Public
Jeroen Bosch Ziekenhuis

Nieuwstraat 34
5211 NL 's-Hertogenbosch
NL
Scientific
Jeroen Bosch Ziekenhuis

Nieuwstraat 34
5211 NL 's-Hertogenbosch
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

Inclusion criteria

down syndrome
vaccination with Influenza A

Exclusion criteria

immunodeficiency other than down syndrome
recent infections prior to blood sample collection
treatment with immunosuppressive drugs in last year prior to blood collection
history of oncological disease

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-04-2010
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO Date:	20-05-2010
Application type:	First submission
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	06-09-2010
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	30-11-2010

Application type:	Amendment
Review commission:	METC Brabant (Tilburg)

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	NL32172.028.10