Abnormal immune system in Down syndrome: allergic sensitization and hepatitis B vaccination status 2 - blood sample

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Determine whether the prevalence of allergic sensitilization, defined as at least one allergen specific IgE with a concentration of >= 0,35 kU/l, is lower in people with than without DS. Analyse whether this prevalene is depending on age, how…

Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON40983

Source
ToetsingOnline

Brief title
All-HBV-DS2 - blood sample

Condition

- Other condition
- Immune disorders NEC

Synonym
Down syndrome, trisomy 21

Health condition

downsyndroom

Research involving
Human

Sponsors and support

Primary sponsor: Jeroen Bosch Ziekenhuis
Source(s) of monetary or material Support: Co-assistentenonderzoekspotje Jeroen Bosch Ziekenhuis; Stichting Peribosch.

Intervention

Keyword: allergic sensitization, Down syndrome, hepatitis B vaccination response, immune system

Outcome measures

Primary outcome

Percentage of people with at least one allergen specific IgE with a

concentration of >= 0,35 kU/l; the percentage of people with a protective titer

against HBV (anti-HBs-titer >=10 IE/l).

Secondary outcome

The concentration of total IgE, the concentration of specific IgE*s in the

inhalation antigen and food antigen mix, the relation between age and

sensitization and between sensitization, allergy related symptoms and the

performance of diagnostic tests and/or treatments and the percentage of people

with elevated total IgE. The level of the HBV titer (anti-HbS).

Study description

Background summary

Several studies have shown that Down syndrome (DS) is associated with an aberrant immune system. On the one hand there are data showing that children with DS have fewer allergies, on the other hand DS frequently leads to recurrent wheezing and airway infections resulting in tests and treatment for

allergy, especially at a young age. There are no large studies showing the prevalence of allergic sensitization in people with DS. This study aims to fill this knowledge gap. Besides, some studies describe a decreased response to vaccinations, among others to hepatitis B (HBV) vaccination. It is important to have data to decide whether it is clinically relevant to routinely determine the titer after HBV vaccination in DS and to offer booster vaccinations . The long term course of the anti-HBs-titer is not yet sufficiently clarified.

Study objective

Determine whether the prevalence of allergic sensitilization, defined as at least one allergen specific IgE with a concentration of >= 0,35 kU/l, is lower in people with than without DS. Analyse whether this prevalene is depending on age, how many patients with DS and allergic sensitization have symptoms and how often diagnostics and/or treatment for asthma and/or other allergies is performed in DS. Also, the concentration of total IgE is determined. Besides, it is determined whether a protective titer against HBV, defined as an anti-HBs-titer >=10 IE/l, is less often found in persons with than without DS, and what is the titer of anti-HBs in the long term.

Study design

Multicenter, cross-sectioneel study. The will be compared with people without DS from the literature.
An extra 4 ml (2-16 years) or 7 ml (>=16 years) of blood will be sampled for study purposes, but only during an already planned venepuncture. The presence of sensitization will be determined using total IgE, inhalation antigen mix and food antigen mix, with determination of specific IgE*s in case of a positive mix test result. Besides, the titer of anti-HBs will be determined. Informed consent will be asked from the parents and - if possible - the patient >=12 years. With retrospective chart review and a short questionnaire for the parents at inclusion, the presence of allergy related symptoms, the use of diagnostics and/or treatment, as well as the HBV vaccination status will be analyzed.

Study burden and risks

Participation in the All-HBV-DS2 - blood sample study does not offer the patient direct benefit, but there are no real risks either. The only extra effort that is asked of parents and patient, is the completion of a short questionnaire. The risk of taking an extra 4 ml (<16 years) or 7 ml (>=16 years) of blood during an already planned venepuncture is negligible. More data on the prevalence of allergic sensitization and the response to HBV vaccination is useful for clinical decision making. Especially at a young age, other problems can cause symptoms like wheezing, for instance anatomical abnormalities. Besides, this study can produce more data to decide whether it is clinically

relevant to routinely measure the titer after HBV vaccination in DS. This study could lead to new insights regarding the national vaccination program specifically for DS.

Contacts

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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

Down syndrome; 2 years of age or older; planned venepuncture.

Exclusion criteria

No informed consent; participation in the All-HBV-DS1-leftover serum study (study on the same subject, but leftover serum is used for the tests). In each participant the tests will only be performed once.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-03-2014
Enrollment:	580
Type:	Anticipated

Ethics review

Approved WMO

Date:	07-04-2014
Application type:	First submission
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	NL48287.028.14