Response to pneumococcal polysaccharide vaccination in healthy adults

Published: 18-07-2019
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Primary Objective: • To develop new criteria for the interpretation of the IgG response to pneumococcal polysaccharide vaccination using serotype-specific normal values.Secondary Objectives: • To develop criteria for the interpretation of the IgG1,...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Immunodeficiency syndromes
Study type	Interventional

Summary

ID

NL-OMON55592

Source
ToetsingOnline

Brief title
Pneumococcal vaccination in healthy adults

Condition

- Immunodeficiency syndromes

Synonym
specific antibody deficiency; immunodeficiency

Research involving
Human

Sponsors and support

Primary sponsor: Sint Antonius Ziekenhuis
Source(s) of monetary or material Support: St. Antonius Onderzoeksfonds

Intervention

Keyword: antibody deficiency, pneumococcal vaccination, vaccination response

Outcome measures

Primary outcome

Distribution of serotype-specific IgG antibody titers to 13 pneumococcal serotypes four weeks after vaccination.

Secondary outcome

Distribution of serotype-specific IgG antibody titers to 13 pneumococcal serotypes eight weeks after vaccination.

Distribution of serotype-specific IgG1, IgG2, IgM and IgA antibody titers to 13 pneumococcal serotypes four and eight weeks after vaccination.

Distribution of serotype-specific percent change in IgG, IgG1, IgG2, IgM and IgA antibody titers to 13 pneumococcal serotypes four and eight weeks after vaccination in comparison to pre-vaccination.

Study description

Background summary

Polysaccharide vaccination can be used to assess the functioning of the humoral immune system. An impaired response to vaccination supports the diagnosis of an antibody deficiency, and can be an indication for starten immunoglobulin substitution therapy.

However, the current classification of the response to pneumococcal polysaccharide vaccination is not optimal. According to the current diagnostic criteria over 40% of healthy individuals, will be classified as an impaired responder. Because there is significant inter-serotype variation in post-vaccination antibody levels, it should be endeavoured to develop serotype-specific normal values, and study these in cohorts of healthy

individuals, as well as in patients with suspected or proven immunodeficiency.

Study objective

Primary Objective:
• To develop new criteria for the interpretation of the IgG response to pneumococcal polysaccharide vaccination using serotype-specific normal values.

Secondary Objectives:
• To develop criteria for the interpretation of the IgG1, IgG2, IgM and IgA response to pneumococcal polysaccharide vaccination using serotype-specific normal values.
• To study the effect of age and gender on the response to pneumococcal polysaccharide vaccination in healthy adults

Study design

Single-arm intervention study.

Intervention

One-time administration of the 23-valent pneumococcal polysaccharide vaccine.

Study burden and risks

These study procedures have negligible risk for adverse effects on patients* health and/or well-being. The blood draws might cause some minor inconvenience, but carry a negligible risk for any serious damage. Administration of the vaccine might cause minor local side effects, and is associated with a very small probability of more severe side effect. Importantly, the vaccine is currently registered for use in all adults, to prevent pneumococcal infections. Furthermore, nation-wide vaccination recommendations already include the pneumococcal polysaccharide vaccine for healthy elderly because the risk of serious harm was deemed to be very small. Potentially, participants will be protected against invasive pneumococcal infections. 10 Otherwise, there are no direct benefits that derive from participating in the study. We deem the potential inconvenience caused by study procedures to be outweighed by the potential benefits of the study results for future patients.

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

• Age >=18 years and <=80 years
• Fits within pre-specified age and gender stratification blocks
• Informed consent

Exclusion criteria

• Previous vaccination with pneumococcal polysaccharide or conjugate vaccination
• Chronic disease that requires the use of immunosuppressive agents
• Known or highly suspected primary or secondary immunodeficiency
• Pregnancy
• Fever or active infection
• History of allergic reaction to one of the vaccine components

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-01-2020
Enrollment:	210
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	pneumovax 23

Ethics review

Approved WMO Date:	18-07-2019
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	22-08-2019
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	24-06-2021
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United

	(Nieuwegein)
Approved WMO Date:	01-07-2021
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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
EudraCT	EUCTR2019-001118-40-NL
CCMO	NL69183.100.19