Community Acquired Pneumonia: Outcome, Quality of Life and Immune Status

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The aim of this study is to investigate immune response to pneumococcal vaccination in patients after community acquired pneumonia with S. pneumoniae compared to pneumonia patients with another pathogen.

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

Summary

ID

NL-OMON40285

Source
ToetsingOnline

Brief title
CAPolista

Condition

- Immunodeficiency syndromes
- Bacterial infectious disorders

Synonym
host defense, Immune response

Research involving
Human

Sponsors and support

Primary sponsor: Sint Antonius Ziekenhuis
Source(s) of monetary or material Support: Subsidie wordt t.z.t. aangevraagd bij

producent vaccins (Pfizer)

Intervention

Keyword: Immune respons, Pneumonia, Streptococcus pneumoniae, Vaccination

Outcome measures

Primary outcome

Immune response to pneumococcal vaccination in patients who were diagnosed with CAP due to S. pneumoniae in comparison with patients with another causative pathogen. Main parameters are antibody titres against the different pneumococcal serotypes before and after vaccination and avidity maturation of these antibodies.

Secondary outcome

* To investigate antibody response after pneumococcal vaccination in patients with community acquired pneumococcal pneumonia in the past who failed to elicit a specific antibody response previously.

* To investigate the cellular immune responses after pneumococcal vaccination in patients with community acquired pneumococcal pneumonia in the past compared to pneumonia patients with another pathogen..

* To investigate quality of life by the RAND-36 score in patients with a community acquired pneumonia in the past.

* To investigate the long-term mortality after community acquired pneumococcal pneumonia.

Study description

Background summary

Community acquired pneumonia (CAP) is an important health problem with significant morbidity, mortality and cost. The most identified pathogen in CAP is Streptococcus pneumoniae. This was also the causative agent most frequently found in the Ovidius and Triple-P study, two consecutive clinical trials initiated by the St. Antonius Hospital Nieuwegein. Diagnosis of pneumococcal pneumonia can be based on positive blood cultures, sputum cultures, urine antigen testing or a serotype specific antibody response. When pneumococcal pneumonia is diagnosed by a positive culture, a matching serotype specific antibody response is expected. However not all patients in the Ovidius and Triple-P study with a culture proven pneumococcal pneumonia showed an antibody response against the infecting pneumococcal serotype.

Patients who survived pneumococcal pneumonia are considered as a high-risk population for pneumococcal disease in the future. Possibly these patients have an impaired immune response against S. pneumoniae. In this study, pneumococcal vaccination of patients with S. pneumoniae CAP in the past enables investigating their immune response after vaccination. Furthermore this study provides information to determine if there is a difference in vaccination response between pneumococcal pneumonia patients who had a culture matching serotype specific antibody response and between pneumococcal pneumonia patients who failed to elicit this response previously. Possibly these latter patients had a temporarily low titre due to the infection but another explanation is that there might be a structurally impaired immune response against S. pneumoniae or certain serotypes.

Study objective

The aim of this study is to investigate immune response to pneumococcal vaccination in patients after community acquired pneumonia with S. pneumoniae compared to pneumonia patients with another pathogen.

Study design

The design is a prospective cohort study with patients who were included in the Ovidius or the Triple-P study and diagnosed with CAP due to S. pneumoniae. The control group will consist of patients who were included in the same studies but who were diagnosed with pneumonia with another pathogen.

Study burden and risks

Patients will be vaccinated with a pneumococcal vaccine Prevnar 13. Blood samples will be drawn before the vaccination and three * four weeks after vaccination; so two blood samples will be drawn. The study can only be done using these patient groups because we want to investigate immune response to

pneumococcal vaccination in patients after community acquired pneumonia with S. pneumoniae and compare these with immune responses at time of the CAP. The vaccine will be used in the authorised form; therefore no additional risks are to be expected. Only in very rare cases severe adverse events occur. Benefit is possible protection against the encapsulated bacterium S. pneumoniae that is known to cause serious infections.

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

1. Patients who participated in the Ovidius or Triple-P study (2004-2009).
2. Diagnosis in these studies with pneumococcal pneumonia or pneumonia due another identified organism.
3. Age * 18 years.

4. Signing of informed consent.

Exclusion criteria

1. Diagnosis of pneumonia without an identified causative organism.
2. Fever at time of vaccination.
3. Previous/known allergic reaction to any of the components of the vaccine given.
4. Mentally incompetent.
5. Previous pneumococcal vaccination.
6. Clinical pneumonia within 1 month prior to inclusion.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	30-04-2014
Enrollment:	140
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Prevnar 13

Ethics review

Approved WMO Date:	09-09-2013
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	19-12-2013
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	19-03-2014
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Not approved Date:	06-08-2014
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	18-08-2014
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

ID: 21679

Source: NTR
Title:

In other registers

Register	ID
EudraCT	EUCTR2013-002166-39-NL
CCMO	NL44924.100.13
OMON	NL-OMON21679