Immune response against pneumococcal vaccination in patients after pneumonia

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21679

Source
Nationaal Trial Register

Brief title
CAPolista

Health condition

immune respons
pneumococcal vaccination
pneumococcal conjugate vaccination
PCV13
pneumonia

Sponsors and support

Primary sponsor: Sint Antonius Hospital
Source(s) of monetary or material Support: Pfizer

Intervention

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

NA

Study objective

The immune response to pneumococcal vaccination in patients after community acquired pneumonia with S. pneumoniae is different compared to pneumonia patients with another pathogen.

Study design

1) Week 1, first blood draw, vaccination, RAND36.
2) After 3-4 weeks, second blood draw.

Intervention

13-valent pneumococcal conjugate vaccination, prevenar 13 (PCV13)

Contacts

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Eligibility criteria

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

Changed 2-sep-2014:
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 conjugate vaccination.

6. Pneumococcal polysaccharide vaccination within 6 months prior to inclusion.

7. Clinical pneumonia within 1 month prior to inclusion.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-04-2014
Enrollment:	140
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	07-03-2014
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 40285
Bron: ToetsingOnline

Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL4221
NTR-old	NTR4460
CCMO	NL44924.100.13
OMON	NL-OMON40285

Study results