

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

NTR

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

Public

Koekoekslaan 1
G. Wagenvoort
Nieuwegein 3435 CM
The Netherlands
0883203000

Scientific

Koekoekslaan 1
G. Wagenvoort
Nieuwegein 3435 CM
The Netherlands
0883203000

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