De antistof respons na pneumokokkenvaccinatie bij IBD-patiënten die behandeld worden met immunosuppressiva – de PNEUMOREACT studie

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON29135

Source
Nationaal Trial Register

Brief title
PNEUMOREACT

Health condition

inflammatory bowel disease (inflammatoire darmziekte)
immunosuppressive agents (immunosuppressiva)
pneumococcal vaccination (pneumokokkenvaccinatie)
vaccine immunogenicity (vaccin immunogeniciteit)

Sponsors and support

Primary sponsor: Academic Medical Center
Source(s) of monetary or material Support: initiator = sponsor

Intervention

Outcome measures

Primary outcome

The ratio of the anti-pneumococcal antibodies measured before and four to six weeks after pneumococcal vaccination (T=week0 – PCV13 and T1= 8weeks – PPV23). An adequate response is considered as a 2-fold increase in anti-pneumococcal antibodies.

Secondary outcome

The difference in response rates to pneumococcal vaccination between the control and intervention groups.

Study description

Background summary

This study aims to study the immunogenicity of pneumococcal vaccination with prevenar-13 and two months later, pneumovax-23 in IBD patients on immunosuppressive treatment. To evaluate immunogenicity antibody titers are measured at inclusion and 4-8 weeks after administration of pneumovax-23. Patiets are divided in different groups of immunosuppressive treatment to assess how different immunosuppressives affect immunogenicity of pneumococcal vaccination. Furhtermore, patients will be included who start anti-TNF treatment in the period before, between or after the 2 pneumococcal vaccines, in order to assess whether the starting time of immunosuppressives related to the vaccination schedule further affects immunogenicity. We plan to include 188 participants.

Study objective

1. IBD patients treated with immunosuppressive agents have a diminished anti-pneumococcal antibody response to pneumococcal vaccination.

2. (A) Use of a TNF-alpha inhibitor is associated with a lower antibody response after pneumococcal vaccination than after use of DMARDs and/or corticosteroids. Use of either high-dose monotherapy with a TNF-alpha inhibitor; and (B) use of standard dose TNF-alpha inhibitor plus additional immunosuppressive drugs are associated with an even lower antibody response after pneumococcal vaccination.

3. A longer time-interval between pneumococcal vaccination and treatment initiation with TNF-alpha inhibitors is associated with an enhanced antibody response.

Study design

Not applicable

Intervention

Pneumococcal vaccination with Prevenar-13 and Pneumovax-23, which is recommended for patients with auto-immune disease.

Contacts

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Eligibility criteria

Inclusion criteria

Age > 18 years old

On treatment with an immunosuppressive agent or planned treatment start with a TNF-alpha inhibitor within 3 months after recruitment

Indication for pneumococcal vaccination (PCV13 plus PPV23)

Able and willing to consent

Control group: IBD patients not treated with immunosuppressives

Exclusion criteria

Diagnosis of a primary immune deficiency disorder

Age < 18 years

Control group: treatment with immunosuppressive drugs

Not being able to or not willing to consent

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other

Control: N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	06-12-2016
Enrollment:	188
Type:	Anticipated

Ethics review

Positive opinion

Date:	04-04-2017
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 45696
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL6168
NTR-old	NTR6315
CCMO	NL58768.018.16
OMON	NL-OMON45696

Study results