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

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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...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON29135

Bron
Nationaal Trial Register

Verkorte titel
PNEUMOREACT

Aandoening

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

Ondersteuning

Primaire sponsor: Academic Medical Center
Overige ondersteuning: initiator = sponsor

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

Not applicable

Onderzoeksproduct en/of interventie

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

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen

(Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders

Controle: N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	06-12-2016
Aantal proefpersonen:	188
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	04-04-2017
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 45696
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten