Vaccinations in persons with a condition affecting the immune system: paramount and paradox.

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Immunocompromised patients (ICPs) are at increased risk of infections, some of which are preventable by vaccination. However, ICPs are also less likely to mount effective post-vaccination immune responses, leading to a clinical paradox: precisely…

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

Samenvatting

ID

NL-OMON24856

Bron
Nationaal Trial Register

Verkorte titel
VIPPP

Aandoening

Immunocompromised; HIV; Immunosuppressive medication; Stem cell transplantation; Organ transplantation; rheumatic diseases; inflammatory bowel disease; Vaccine; Vaccination; Hepatitis A vaccine; Pneumococcal vaccine; Immunogenicity

Ondersteuning

Primaire sponsor: Amsterdam UMC (locatie AMC)
Overige ondersteuning: ZON MW grant

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

- Hepatitis A arm: Seroconversion rate, defined as the proportion of vaccinated patients with a post-immunization antibody GMC ≥10 mIU/ml in ICPs and healthy individuals 2 months after each vaccination.

- Pneumococcal arm: Seroconversion rate defined as the proportion of patients with a post-immunization antibody concentration of ≥1.3 µg/ml for 70% of all measured serotypes in ICPs and controls 2 months after the full vaccination schedule.

Toelichting onderzoek

Achtergrond van het onderzoek

Immunocompromised patients (ICPs) are at increased risk of infections some of which are preventable by vaccination. However ICPs are also less likely to mount an effective post-vaccination immune response, leading to a clinical paradox: precisely this patient group that would most benefit vaccination is the least likely to produce an effective immune response. In this prospective cohort study the response to hepatitis A and pneumococcal vaccination will be characterized in adults using immunosuppressive agents, people living with HIV and following hematopoietic stem cell transplantation. Serum and PBMCs will collected at fixed time points. before and after vaccination. Data in this study will be used to improve vaccination guidelines for ICPs.

Doel van het onderzoek

Immunocompromised patients (ICPs) are at increased risk of infections, some of which are preventable by vaccination. However, ICPs are also less likely to mount effective post-vaccination immune responses, leading to a clinical paradox: precisely this patient group that most needs protection is least likely to produce a protective immune response.

Onderzoeksopzet

- Antibody assessment hepatitis A arm: 0, 2, 6, 8, 12, 3 years months after first vaccination

- Antibody assesment pneumococcal arm: 0,2,4,6, 12, 3 years months after vaccination.

- Antibody assesment after revaccination in patients who underwent stem cell transplantation: 0, 4, 8, 10, 12 months, 3 years.

- PBMC isolation: 0,2,4 months after first pneumococcal vaccination.

Onderzoeksproduct en/of interventie

- Vaccination according to the guidelines (2 doses of inactivated hepatitis A vaccine at 0 and 6 months; One dose of prevenar13 at 0 and one dose of pneumovax23 at 2 months; after allogeneic SCT Prevenar13 at 0,1,2 and 8 months and Pneumovax23 at 10 months)

- Blood withdrawal for antibody assessment and PBMC isolation before and at different time points after vaccination

- Long term follow up (beyond the scope of this trial)

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

o Indication for hepatitis A and/or or pneumococcal vaccination

o Age 18-70 years old

o At least one of the following criteria:

1. Diagnosed with HIV; and/or

2. Treated with one or more immunosuppressive agent(s); if only treated with corticosteroids, daily dose should be (the equivalent of) > 10 mg prednisolone

3. Haematopoietic stem cell transplant (HSCT) recipients months after allogeneic HSCT.

o Being able and willing to consent

- Control group:

o Immunocompetent individuals aged 18-65 years

o Indication for hepatitis A and/or or pneumococcal vaccination

o Able and willing to consent

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

o Diagnosis of one of the following

1. Primary immune deficiency disorder

2. Active malignancy

3. Hemophilic disorder precluding intramuscular vaccination

4. Asplenia or haemoglobinopathy

o Receiving chemotherapy

o Autologous HSCT recipient

o Allergy to any of the components of the hepatitis A or pneumococcal vaccines

o Naturally acquired hepatitis A immunity (either assessed in the medical history or at first antibody concentration measurement)

o Previous vaccination with any pneumococcal conjugate vaccine

o Previous vaccination with pneumococcal polysaccharide vaccine (Pneumovax®) <5 years before enrollment

o Donor lymphocyte infusion < 28 days

o Pregnancy

o Not being able or willing to consent

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	Niet-gerandomiseerd

Controle: N.v.t. / onbekend

Deelname

Nederland

Status:	Anders
(Verwachte) startdatum:	27-07-2018
Aantal proefpersonen:	570
Type:	Onbekend

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	25-07-2018
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 56421
Bron: ToetsingOnline

Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7193
NTR-old	NTR7385
CCMO	NL65687.018.18
OMON	NL-OMON56421

Resultaten