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

No registrations found.

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

Summary

ID

NL-OMON24856

Source
Nationaal Trial Register

Brief title
VIPPP

Health condition

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

Sponsors and support

Primary sponsor: Amsterdam UMC (locatie AMC)
Source(s) of monetary or material Support: ZON MW grant

Intervention

Outcome measures

Primary outcome

- 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.

Secondary outcome

1. Geometric mean concentrations (GMCs) of hepatitis A antibodies measured before and at different time points after vaccination in ICPs and controls.

2. GMCs of hepatitis A antibodies in previously fully vaccinated ICPs and controls at related to the time interval between vaccination and titer assessment.

3. Seroconversion rate in previously partially and fully vaccinated ICPs and controls defined as the proportion of vaccinated patients with a post-immunization antibody GMC ≥10 mIU/ml.

4. Differences in seroconversion rates and GMCs between ICPs and controls at the different time points.

- Pneumococcal arm

1. GMCs of serotype specific pneumococcal antibodies against individual vaccine serotypes present in PCV13 and PPSV23 in ICPs and controls and fold changes compared to baseline antibody concentrations

2. Changes in seroconversion rate and GMCs over time
3. B and T-cell responses measured at different time points.

4. Differences in seroconversion rates, GMCs, and cellular immune response between ICPs and controls at the different time points.

- Associations:

1. The influence of three different categories of immunosuppressive drugs and the degree of immunosuppression based on dose and number of immunosuppressive drugs on primary and secondary endpoints.

2. The influence of CD4+ count and use of cART in HIV patients on the primary and secondary endpoints.

3. The influence of age, sex, and intoxications (smoking/alcohol) on the primary and secondary endpoints.

Study description

Background summary

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.

Study objective

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.

Study design

- 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.

Intervention

- 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)

Contacts

Public
Meibergdreef 9
M.P. Grobusch
Amsterdam 1100 DD
The Netherlands
+31 (0)20 5664380
Scientific
Meibergdreef 9
M.P. Grobusch
Amsterdam 1100 DD
The Netherlands
+31 (0)20 5664380

Eligibility criteria

Inclusion criteria

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

Exclusion criteria

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

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial

Control: N/A , unknown

Recruitment

NL

Recruitment status:	Other
Start date (anticipated):	27-07-2018
Enrollment:	570
Type:	Unknown

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	25-07-2018
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 56421
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

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

Study results