Vaccinations in the Immunocompromised population: paramount and paradox.

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Immune disorders NEC
Study type	Observational invasive

Summary

ID

NL-OMON56421

Source
ToetsingOnline

Brief title
VIPPP-study

Condition

- Immune disorders NEC
- Infections - pathogen unspecified

Synonym
Immunocompromising conditions, impaired immune system

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Zon Mw (2018),Beurs van International Society of Travel Medicine (2020)

Intervention

Keyword: hepatitis A, immunocompromised, pneumococcal infection, rabies vaccination, vaccination

Outcome measures

Primary outcome

The proportion of ICPs and controls with protective antibody titers

(seroconversion rate) after rabiës/hepatitis A/pneumococcal vaccination.

Secondary outcome

- Strength of the humoral immune response measured in geometric mean

concentrations (GMCs) of antibodies in ICPs and controls before and at

different time points (7 days, 1,2,4, 6, 8, 10,12 months, 3 years) after

rabiës, hepatitis A and pneumococcal vaccination.

- In vitro post-vaccination cellular immune response measured after

pneumococcal vaccination.

- The differences in immune response after hepatitis A and pneumococcal

vaccination between ICPs and non-ICP controls.

- The long term immune response after vaccination.

- The immune response after hepatitis A booster vaccination in participants

with low antibodies 1-5 years after primary vaccination

- Boostability three years after PCV13 + PPSV23 (T36), defined as the

proportion of ICPs who had seroreverted at T36 and , who seroconvert again 7

days after booster vaccination with PCV20.

- The influence of age, gender, time between vaccination and antibody

measurment, intoxications, group and dose of immunosuppressive medication and

CD4+ count (in HIV patients) on the seroconversion rate and GMCc of antibodies

after rabiës, hepatitis A and pneumococcal vaccination.

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 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. Although guidelines advice vaccination of this patient group, data on immunogenicity of current rabiës, hepatitis A an pneumococcal vaccination schedules are scare and heterogeneous.

Study objective

The objective of this study is to determine the immune response after hepatitis A and pneumococcal vaccination in different groups of ICPs. The overarching aim of the study is to improve vaccine regimens and to optimize guideline recommendations specifically targeted to ICPs. In addition a well-defined cohort of ICPs and controls will be established to allow long term follow up of the immune respons after vaccination

Study design

Prospective cohort study

Study burden and risks

Since rabiës, hepatitis A and pneumococcal vaccines will only be administered to people with an indication for vaccination according to national and local guidelines, no additional risk or benefit related to the vaccine is posed by study participation. Apart from the visits to the clinic to receive vaccination, participating subjects have to make a maximum of 6 extra shorts visits to the vaccination clinic for blood sampling for the purpose of antibody measurement. Antibody measurements in ICPs after hepatitis A and pneumococcal vaccination are indicated by local guidelines, but not as often as proposed in this study. However, venous blood sample collection is a low risk intervention. The benefit of participation in this study is closer monitoring of vaccination status against common potentially life-threatening infections.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Patient group:
- Indication for rabies/hepatitis A and/or or pneumococcal vaccination
- Age 18-70 years old;
- At least of the following criteria
1. Diagnosed with HIV; and/or
2. Treated with one or more immunosuppressive agents for underlying disease/organ transplant; and/or
3. Hematopoietic stem cell transplant (HSCT) recipients 3-24 months after HSCT.
- Able and willing to consent
Control group:
- Immunocompetent individuals aged 18-70 years.
- Indication for hepatitis A and/or or pneumococcal vaccination

- Able and willing to consent.

Exclusion criteria

Diagnosis of one of the following
1. Primary immune deficiency disorder
2. Active malignancy
3. Hemophilic disorder precluding intramuscular vaccination.
4. Functional asplenia
- Receiving chemotherapy
- An allergy to any of the components of the hepatitis A or pneumococcal vaccines.
- Naturally acquired hepatitis A immunity (either assessed in the medical history or at first antibody concentration measurement)
- Previous vaccination with any pneumococcal conjugate vaccine
- Previous vaccination with Pneumovax 23 <5 years before enrollment.
- Age <18 years or >70 years
- Donor lymfocyte infusion < 28 days
- Pregnancy
- No indication for hepatitis A/pneumococcal vaccination
- In ICPs only: Steroids < 10 mg prednisolone or its equivalent as only immunosuppressant (low dose corticosteroids).
- Not being able or willing to consent
- Previous vaccination against rabies

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL
Recruitment status: Recruiting

Start date (anticipated):	06-08-2018
Enrollment:	980
Type:	Actual

Ethics review

Approved WMO Date:	25-06-2018
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	24-07-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	15-02-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	05-04-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	29-04-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	24-09-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	25-03-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	18-09-2023

Application type:	Amendment
Review commission:	MEC Academisch Medisch Centrum (Amsterdam) Kamer G4-214 Postbus 22660 1100 DD Amsterdam 020 566 7389 mecamc@amsterdamumc.nl
Approved WMO Date:	28-09-2023
Application type:	Amendment
Review commission:	MEC Academisch Medisch Centrum (Amsterdam) Kamer G4-214 Postbus 22660 1100 DD Amsterdam 020 566 7389 mecamc@amsterdamumc.nl
Approved WMO Date:	20-08-2024
Application type:	Amendment
Review commission:	MEC Academisch Medisch Centrum (Amsterdam) Kamer G4-214 Postbus 22660 1100 DD Amsterdam 020 566 7389 mecamc@amsterdamumc.nl

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 24856
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
Other	7385 (NTR)
CCMO	NL65687.018.18
OMON	NL-OMON24856