The Vaccination Cohort Study on: 1. Immunologic Protection after Vaccination of Immune-compromised Patients 2. Assessment of the Infection Rate after International Travel

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This study has two goals:1. Investigate the cellular and humoral immune response of immune compromised travellers compared to the healthy traveller.2. Investigate the epidemiology of travel related infectious diseases in a population of dutch...

Ethical review	Not approved
Status	Will not start
Health condition type	Hepatobiliary neoplasms malignant and unspecified
Study type	Observational invasive

Summary

ID

NL-OMON38641

Source
ToetsingOnline

Brief title
The Vaccination Cohort Study

Condition

- Hepatobiliary neoplasms malignant and unspecified

Synonym
Travellers vaccination

Research involving

Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Immunecompromised, Infections, Travellers, Vaccination

Outcome measures

Primary outcome

The antibody titer after vaccination of immune compromised patients compared to

immunocompetent patients and the incidence of infectious diseases during travel

Secondary outcome

1a The capability of naïve memory B cells to generate an

antibody response after live, conjugated and polysaccharide vaccine dose

increase in case of non-responders

1b Dendritic cell function and antigen presentation properties

1c CD8+ cytotoxic properties

1d Waning effects of vaccines by the presence of a prolonged (i.e. after 6

months) qualitative antibody response by detecting high affinitive IgG

antibodies in serum as well as B-cell reactivation properties

Study description

Background summary

Individuals with immune deficiencies are at increased risk for infectious diseases compared to general population. In addition, the responsiveness after immunization can be diminished due to impaired function of monocytes, B cells

and/or T cells as well as other co-morbidity and the use of certain immunosuppressive drugs . Exposure to infectious pathogens sharply increases during travel, especially if people travel to tropical destinations. The aim of this study is to investigate the cellular and humoral immune response after vaccination of the immunecompromised host and to investigate travel related infections in general.

Study objective

This study has two goals:
1. Investigate the cellular and humoral immune response of immune compromised travellers compared to the healthy traveller.
2. Investigate the epidemiology of travel related infectious diseases in a population of dutch travellers

Study design

This will be a longitudinal observational cohort study. Potential candidates will receive a letter at least one week prior to their visit to the travel clinic containing information about the study and a patient information document. Questions about the study can be asked during the first visit. Inclusion to the study will only take place after signing the informed consent document. Thereafter, the participant is asked to donate two peripheral blood samples of 5 ml at three of four time points in this study as well as one urinal and one fecal sample at two time points if patients travel to a destination outside Europe or the United States/Canada (moments can overlap). In addition, persons are asked to keep a diary during their travel, noting only possible infectious events (fever, illness, contact with ill persons). Participation in the study is terminated when all samples are collected or when the patient decides to opt out. In practice, participation will not exceed the duration of 12 months.

Blood samples:
1 Before vaccination (null serum).
2 Four weeks after vaccination (optimal time interval to measure immune response) or after return from travel (to measure seroconversion to certain infections, depending on the travel history).
4 After 9-12 months (to assess waning of the immune response).

Urine and fecal samples:
1 Prior to travel.
2 After returning from travel.

Study burden and risks

Study participants will donate 10 ml of blood at three visits to the travel

clinic. In case of a trip outside Western Europe, participants will be asked to a collect a faecal and urinal sample before and after their journey. In addition, study participants will be asked to keep a diary during their trip to assess the rate of possible exposure to infectious pathogens.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Children (2-11 years)
Elderly (65 years and older)

Inclusion criteria

All individuals, irrespective of age, sex and underlying illness visiting the Erasmus MC *vaccination and travel clinic* requiring travel related, medically indicated or voluntary vaccination(s)

Exclusion criteria

No informed consent

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:	Will not start
Enrollment:	200
Type:	Anticipated

Ethics review

Not approved

Date:	10-02-2014
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
CCMO	NL44830.078.13