Protection after yellow fever vaccination in patients using medication suppressing the immune system.

No registrations found.

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

Summary

ID

NL-OMON20476

Source
NTR

Brief title
YETI study

Health condition

yellow fever vaccination

Sponsors and support

Primary sponsor: Academic Medical Center, Amsterdam, the Netherlands
Source(s) of monetary or material Support: Academic Medical Center, Amsterdam, the Netherlands

Intervention

Outcome measures

Primary outcome

Proportion of those with CD8 positive T cells in the group using immunosuppressive medication versus healthy controls.

Secondary outcome

Proportion of those with Virus Neutralising antibody present in the group using immunosuppressive medication versus healthy controls.

Proportion of those with local adverse events n the group using immunosuppressive medication versus healthy controls.

Study description

Background summary

Rationale:

The immune response following yellow fever vaccinations may be suboptimal in those using immunosuppressive medication. Possibly, this population has a less durable and lower immunologic memory response compared to healthy controls, and more frequent revaccination might be required in this group.

Objective:

Our main objective is to compare duration and height of immune memory in vaccinees who were using immunosuppressive medication at the time of vaccination to health vaccinees. Our secondary outcome measures are antibodies present and adverse events in both groups.

Study design:

Retrospective observational study.

Study population:

Patients using immunosuppressive medication vaccinated with the yellow fever vaccine maximum 20 years ago, aged > 18 years shall be included. Healthy controls matched by age, sex and time after vaccination shall be included as well.

Main study parameters/endpoints:

The main endpoint is the proportion of those with immunologic memory in the patient group compared to the control group.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:

Participants shall be asked to fill in one questionnaire on adverse events and a venapunction shall be performed at one clinical visit. Risks are bruising and pain of the arm (both expected to be mild and transient). Benefits for participants are increased insight in their immunologic response and the awareness of protection against the yellow fever virus.

Study objective

Yellow fever specific T cells are present in 70% of patients using immunosuppressive medication versus 99% of healthy volunteers.

Study design

N/A

Intervention

1. Administration of a questionnaire about adverse events following vaccination;

2. Venapunction (54 mL) on 1 day.

Contacts

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Eligibility criteria

Inclusion criteria

1. Age > 18 years;

2. YF 17D vaccination administered.

Exclusion criteria

1. Age < 18 years;

2. Vaccination administered > 20 years ago.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	14-08-2012
Enrollment:	60
Type:	Anticipated

Ethics review

Positive opinion

Date:	16-08-2012
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 37037
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL3430
NTR-old	NTR3581
CCMO	NL40560.018.12
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON37037

Study results

Summary results
N/A