Efficacy of hepatitis A vaccination in immunocompromised travelers.

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26720

Source
NTR

Brief title
HEPAVIT

Health condition

hepatits A
vaccination
immunosuppression

Hepatitis A
vaccinatie
immuunsuppressie

Sponsors and support

Primary sponsor: no sponsor
fund=initiator=sponsor
Source(s) of monetary or material Support: investigator initiated
fund=initiator=sponsor

Intervention

Outcome measures

Primary outcome

- Antibody titres after booster vaccination.

Secondary outcome

- Antibody titres after first hepatitis A vaccination

- Antibody production after the booster vaccination for hepatitis A

- Determination of disease or medication related and demographic parameters that are predictive for decreased antibody production to hepatitis A vaccination.

Study description

Background summary

Travelers who take immunosuppressive medication have a substantially increased risk of infection compared to the normal population and are thus candidates for preventive measures such as vaccination.
However, immunosuppression often alters the efficacy of vaccination. The antibody titres may be insufficient and even when sufficient may drop more quickly. When no protective antibodies are present after vaccination, the immunocompromised patient may become infected leading to spread of the disease among the population. Therefore, in case of insufficient antibody production the traveller needs passive immunisation with immunoglobulins, which is, however, expensive, has a limited protective duration and has the risk of transmission of blood borne diseases. In this study we propose to compare standard vaccination of hepatitis A with a vaccination regime that includes a booster vaccination in travellers taking immunosuppressive medication.

Study objective

An extra booster vaccination will improve efficacy of hepatitis A vaccination in travellers using immunosuppressive medication.

Study design

preparation 3 months

inclusion 18 months

follow-up 24 months

Intervention

Boostervaccination of hepatitis A 2 weeks after first vacciantion.

Contacts

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Eligibility criteria

Inclusion criteria

1. All consecutive patients > 18 years of age using immunosuppressive medication who come to the travel clinics and need vaccination with hepatitis A according to LCR guidelines.

- Immunosuppressive medication is defined as use of cyclosporine A, azathioprine, cyclophosphamide, methotrexate, TNF-á blockers, prednisone use eqal to 10 mg/day or a cumulative dose of > 700 mg., tacrolimus, mycophenolate mofetil.

The study group will be compared with travelers > 18 years old that are immunocompetent.

Exclusion criteria

1. Allergy to the advised vaccine or its components.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-03-2009
Enrollment:	600
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

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
NTR-new	NL677
NTR-old	NTR1522
Other	:
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A