Onderzoek naar infectieziekten (en de gevolgen) bij reizigers die reizen met afweeronderdrukkende medicijnen of met suikerziekte.

No registrations found.

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

Summary

ID

NL-OMON24814

Source
Nationaal Trial Register

Brief title
Op reis

Health condition

immunocompromised traveller
imuungecompromiteerde reiziger
diabetic travelel
reiziger met diabetes mellitus
MTX
biological

Sponsors and support

Source(s) of monetary or material Support: ZonMW
Leids Universitair Medisch Centrum
Municipal Health Service The Hague

Intervention

Outcome measures

Primary outcome

The incidence, morbidity, mortality and association between variables will be calculated. These endpoints will be compared in several subpopulations.

In the immunocompromised patients, we will assess the association between subject-related variables (personal characteristics, including immigrant status, disease activity, cumulative use of immunosuppression, ...) on the one hand and travel-related disease variables (febrile illness, febrile respiratory illness, diarrhoea) on the other hand, after correcting for the independent travel-related variables (destination, duration, accommodation, purpose). Subjects reporting a travel-related disease will be compared to those reporting no travel-related disease.

Secondary outcome

1. Serum antibody levels at several time points before and after active immunisation against DTP, hepatitis A, hepatitis B, meningococci (A/C/Y/W-135) and Vi polysaccharide in relation to age, gender, medical condition, and type of immunosuppression;

2. Conversion rate in quantiferon testing and Interferon Gamma Release Assay (IGRA);

3. Distribution of regulatory T-cell subset markers in (high and low) responders to vaccinations;

4. Incidence of faecal carriage of potentially pathogenic micro-organisms after travel in the subgroup rheumatic travellers and travel companion (basic sample);

5. Incidence of carriage of MRSA, antibiotic-resistant Gram-negatives, and Clostridium in those hospitalized abroad;

6. Incidence of household transmission of the following indicator micro-organisms: methicillin-resistant Staphylococcus aureus (MRSA), Salmonella, extended spectrum betalactamase-producing or gentamycine-resistant Gram-negatives. Clostridium species in faeces, or penicillin-resistant pneumococci in throat.

Study description

Background summary

The number of individuals who are immunocompromised and travel abroad for professional or recreational purposes is increasing rapidly. This study will quantify the health risks, morbidity and consumption of professional medical care abroad and on return at home. In addition, the study will establish whether the standard vaccinations (DTP, hepatitis A, and Salmonella typhi polysaccharide Vi) will lead to protective serum antibody levels in this group of immunocompromised individuals.

Study objective

To quantify health risks in relation to preventive actions and consequences of illness related to
travel in immigrant and non-immigrant immunocompromised travellers treated
with MTX and/or anti-TNF-alpha monoclonals, imuran or rituximab.

Study design

N/A

Intervention

No intervention (Observational cohort study).

Contacts

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Eligibility criteria

Inclusion criteria

Inclusion immunocompromised traveller:

1. The subject is treated OR have been treated for at least 3 months with one or more of the following medication: methotrexaat (Emthexate®, Ledertrexate®), Imuran® / Puri-Nethol®, leflunomide (Arava®) infliximab (Remicade®), etanercept (Enbrel®), adalimumab (Humira®), Abatacept (Orencia®), rituximab (Mabthera®), anakinra (Kineret®), tocilizumab (RoActemra®), Simponi® or Cimzia®;

2. Travelling to a (sub)tropical destination during therapy, OR returning from a (sub)tropical destination within a 3 months period after ending therapy;

3. A subject may be included without travel companion;

4. Is autochthon or non-western immigrant.

The group diabetic traveller:

1. Independent of type of diabetes mellitus (I or II);

2. Diabetic medication: Insulin and/or oral;

3. Independent of complications due to diabetes mellitus;

4. A diabetic subject may be included without travel companion;

5. Autochthon or non-western immigrant.

Exclusion criteria

The following persons cannot take part in this study:

1. Individuals less than 18 years;

2. Persons speaking another language than Dutch, Moroccan, Turkish or English;

3. Mentally incapacitated persons;

4. Western immigrant.

Study design

Design

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

Control: N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-04-2009
Enrollment:	2000
Type:	Actual

Ethics review

Positive opinion

Date:	10-09-2012
Application type:	First submission

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	NL3453
NTR-old	NTR3604
Other	METC Leiden University : p08.199
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A