

# Immunomodulatory treatment and travel-related health risks

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To establish efficacy of pre-travel vaccinations by determination of protective serum antibody titres against hepatitis A, DTP and polysaccharide Vi of Salmonella typhi. To quantify health risks related to preventive actions and consequences of...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Diabetic complications
<b>Study type</b>	Observational invasive

## Summary

### ID

NL-OMON33688

### Source

ToetsingOnline

### Brief title

Immunomodulatory treatment and travel-related health risks

### Condition

- Diabetic complications
- Autoimmune disorders
- Hepatobiliary neoplasms malignant and unspecified

### Synonym

immunocompromised due to treatment

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Leids Universitair Medisch Centrum

**Source(s) of monetary or material Support:** Ministerie van OC&W,ZonMW,Gemeente Den Haag

## Intervention

**Keyword:** Attitudes and practices in travellers, Health knowledge, Immunocompromised traveller Vaccination

## Outcome measures

### Primary outcome

To quantify travel-related infectious diseases

To measure the consequences of illness with regard to frequency and direct costs of seeking medical care, the type of medical care, and the absence from work.

To establish efficacy of pre-travel vaccinations by determination of protective serum antibody titres against hepatitis A, DTP and polysaccharide Vi of *Salmonella typhi*.

### Secondary outcome

To develop evidence-based guidelines for the prevention of health problems in the immunocompromised individuals treated with MTX and / or immunosuppressive biologicals because of RA (or other medical conditions).

To quantify costs of travel advice and direct costs of seeking medical care and number of day\*s absence from work.

## Study description

### Background summary

International travel is undertaken by an ever-increasing number of people for professional and recreational purposes, and more people travel greater distances. Travellers are exposed to a variety of health risks in exotic environments. Many of these risks are related to infectious diseases. In particular, the individual immunocompromised by underlying medical condition or

treatment with immunomodulatory therapy (MTX, biologicals) is at risk for acquiring an infection, and is more prone to suffer its adverse consequences. Literature indicates that in the healthy population many of such health risks can be minimised by suitable precautions taken before, during and after travel, through health education, preventive vaccinations and prophylaxis. However, in this respect there is a lack of information on individuals immunocompromised due to MTX or biologicals. Moreover, the efficacy of preventive measures and standard vaccinations in these individuals immunocompromised by underlying medical condition or immunomodulatory drugs is largely unknown. Literature provides no guidance on these issues, and \*expert\* opinions prevail.

## **Study objective**

To establish efficacy of pre-travel vaccinations by determination of protective serum antibody titres against hepatitis A, DTP and polysaccharide Vi of *Salmonella typhi*.

To quantify health risks related to preventive actions and consequences of illness related to travel in non-western immigrant and autochthonous immunocompromised rheumatoid arthritis (RA) patients treated with MTX and/or anti-TNF- $\alpha$  monoclonals or rituximab.

## **Study design**

This is an observational cohort study.

## **Study burden and risks**

Subjects fill in 3 questionnaires, 3 diaries, and send 2 faecal samples by mail, travel time and blood samples. All these materials are collected during a period of 12 months. Not all subjects are sampled an identical blood volume. This depends on the exposition to health risks during travel.

## **Contacts**

### **Public**

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### **Scientific**

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

- a rheumatic condition; the subject is treated OR have been treated for at least 3 months with one or more of the following medication: methotrexate (Emthexate®, Ledertrexate®), leflunomide (Arava®) infliximab (Remicade®), etanercept (Enbrel®), adalimumab (Humira®), Abatacept (Orencia®), rituximab (Mabthera®).
- travelling to a (sub)tropical destination during therapy, OR returning from a (sub)tropical destination within a 3 months period after ending therapy.

### Exclusion criteria

- individuals less than 18 years old;
- mentally incapacitated persons

## 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:	Recruitment stopped
Start date (anticipated):	20-04-2009
Enrollment:	2000
Type:	Actual

## Ethics review

Approved WMO	
Date:	16-03-2009
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO	
Date:	03-09-2009
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO	
Date:	08-11-2012
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

## 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

CCMO

### ID

NL25634.058.08