

# Detection of schistosoma CAA in travellers after high-risk water contact

Published: 09-12-2014

Last updated: 21-04-2024

Primary objective: to assess the UCP-LF CAA test in travellers with high-risk water contact as compared to routine diagnostics

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

## Summary

### ID

NL-OMON45019

### Source

ToetsingOnline

### Brief title

CAA in travellers

## Condition

- Helminthic disorders

### Synonym

Bilharzia, Schistosomiasis

### Research involving

Human

## Sponsors and support

**Primary sponsor:** Leids Universitair Medisch Centrum

**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** schistosomiasis, travellers

## Outcome measures

### Primary outcome

Primary endpoint:

The sensitivity and specificity of urine UCP-CAA in travellers with reported high-risk water contact, as compared with routine diagnostics.

### Secondary outcome

Secondary endpoint:

The percentage of travellers with persisting positive urine UCP-LF CAA six weeks after conventional praziquantel treatment

## Study description

### Background summary

Schistosomiasis is increasingly encountered among travellers returning from the tropics and is known for its focal endemicity, associated with the presence of the snail intermediate host in fresh water. Because schistosomiasis in travellers is often atypical or asymptomatic due to the low intensity of infection, many infections likely go undiagnosed and will develop into chronic schistosomiasis. Conventional treatment of schistosomiasis in travellers with praziquantel 40mg/kg daily dose is known for its modest success rate. Diagnosis of schistosomiasis relies on egg detection, which has a poor sensitivity in low burden infections, or serology, which is inadequate to monitor cure. The department of parasitology of the LUMC has developed a novel diagnostic test to detect circulating anodic antigen (CAA) with the up-converting phosphor lateral flow (UCP-LF) technique, that can be performed on serum and urine to detect low intensity schistosomiasis infections and confirm cure after praziquantel treatment. This study will assess the performance of the UCP-LF CAA assay in urine of travellers with high-risk water contact.

### Study objective

Primary objective: to assess the UCP-LF CAA test in travellers with high-risk water contact as compared to routine diagnostics

## Study design

Open label, prospective, observational study

## Study burden and risks

Travellers with reported high-risk water contact are requested to participate in the study. The attending physician records data on their health and travel history and ask their consent to donate blood, urine and faeces in addition to routine diagnostic procedures (max 3 occasions). No more than 60 mL blood will be drawn in total. Risks associated with participating in the study are related to a maximum of three venapunctures in addition to routine diagnostics. Participants do not benefit directly from their participation, as there is no interventions; study participation will be altruistic. However, a summary of study results will be sent out to all study participants if requested on recruitment.

## 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

1. Any self-reported high risk water contact, including wading, showering, surfing, walking along wet shore bare-footed or washing with water from a high-risk source, within 2 years prior to reporting to the outpatient department
2. Agreement to perform routine diagnostic procedures to diagnose schistosomiasis infection
3. Willing to provide a maximum of three additional blood samples in addition to routine diagnostic procedures
4. Able to provide informed consent

## Exclusion criteria

1. Previous treatment for schistosomiasis
2. Known positive schistosomiasis serology before last high risk water contact
3. The use of immunosuppressive or immunomodulatory drugs at presentation that compromise the interpretation of schistosomiasis serology

## Study design

### Design

**Study type:** Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Diagnostic

### Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 01-01-2015

Enrollment: 155

Type: Actual

## Ethics review

Approved WMO

Date: 09-12-2014

Application type: First submission

Review commission: METC Leiden-Den Haag-Delft (Leiden)  
metc-ldd@lumc.nl

Approved WMO

Date: 24-11-2015

Application type: Amendment

Review commission: METC Leiden-Den Haag-Delft (Leiden)  
metc-ldd@lumc.nl

Approved WMO

Date: 27-01-2016

Application type: Amendment

Review commission: METC Leiden-Den Haag-Delft (Leiden)  
metc-ldd@lumc.nl

Approved WMO

Date: 01-12-2017

Application type: Amendment

Review commission: METC Leiden-Den Haag-Delft (Leiden)  
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## 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

ClinicalTrials.gov  
CCMO

### ID

NCT02194712  
NL48780.058.14

## Study results

Results posted: 15-06-2020

### First publication

01-01-1900