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

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Helminthic disorders
Study type	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
Leids Universitair Medisch Centrum

Albinusdreef 2
Leiden 2333ZA
NL
Scientific
Leids Universitair Medisch Centrum

Albinusdreef 2
Leiden 2333ZA
NL

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)
Approved WMO Date:	24-11-2015
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
Approved WMO Date:	27-01-2016
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
Approved WMO Date:	01-12-2017
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (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	ID
ClinicalTrials.gov	NCT02194712
CCMO	NL48780.058.14

Study results

Results posted: 15-06-2020

First publication
01-01-1900