Assessment of infection activity in travelers and migrants diagnosed with chronic schistosomiasis: a multicentric prospective cohort study

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To determine the proportion of travelers and migrants diagnosed with chronic schistosomiasis as per each centre*s routine assessment, who have active infection at presentation (as assessed and classified by composite reference standards integrating...

Ethical review	Approved WMO
Status	Pending
Health condition type	Helminthic disorders
Study type	Observational invasive

Summary

ID

NL-OMON57449

Source
ToetsingOnline

Brief title
SchistACT (Schistosomiasis ACTive & ACTion)

Condition

- Helminthic disorders

Synonym
Bilharzia, schistosomiasis

Research involving
Human

Sponsors and support

Primary sponsor: IRCCS Sacro Cuore Don Calabria

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

Intervention

Keyword: CAA antigen test, diagnosis, Schistosomiasis

Outcome measures

Primary outcome

Primary objective

To determine the proportion of travelers and migrants diagnosed with chronic schistosomiasis according to site-specific diagnostic practice, who have active infection at presentation (as assessed and classified by composite reference standards integrating clinical, laboratory and diagnostic features, such as microscopy, PCR (where available), POC-CCA (where available), and serum CAA results).

Endpoint: proportion of enrolled participants fulfilling the composite reference standards for active infection

Secondary outcome

To explore the accuracy and added value of serum CAA determination as test of cure 6 weeks after the WHO standard treatment regimen (40 mg/kg single dose praziquantel), compared to conventional (microscopy) and novel methods (PCR, POC-CCA) in sites where the latter would be available.

Endpoint: number of participants with initial active infection who will be CAA negative at week 6 post-treatment compared to number of participants fulfilling the composite definition of clinical and parasitological cure, and to number of negative results by each other separate diagnostic method.

Study description

Background summary

Conventional methods to diagnose chronic schistosomiasis in the nonendemic setting usually cannot differentiate between past and active infection, likely leading to frequent unnecessary treatment. Novel methods, such as the detection of CAA circulating antigen, have been developed for clinical use in non-endemic settings. We hypothesize that:
1. The determination of CAA in serum can help identify the subset of travelers and migrants diagnosed with chronic schistosomiasis who have an ACTIVE infection
2. The determination of CAA in serum can help assess cure within a short timeframe after treatment in this population

Study objective

To determine the proportion of travelers and migrants diagnosed with chronic schistosomiasis as per each centre*s routine assessment, who have active infection at presentation (as assessed and classified by composite reference standards integrating clinical and laboratory features, including microscopy, PCR (where available), POC-CCA (where available), and serum CAA results).

Study design

Clinical multicentric prospective cohort study with IVD (not for CE marking), of travelers and migrants diagnosed with chronic schistosomiasis, according to site-specific diagnostic practice (that may include microscopy, locally used serology, in house PCR or POC-CCA)

Study burden and risks

All eligible participants identified as having chronic schistosomiasis according to site-specific diagnostic practice will have a standardized baseline clinical and laboratory assessment at enrollment that will include blood sampling for hematology, Schistosoma serology available at each site, and PCR for Schistosoma where available; urine sampling for microscopy, determination of hematuria as indirect markers of schistosomiasis morbidity, and Schistosoma PCR (where available) and POC-CCA urine strip assay (where available); and stool sampling for microscopy and PCR where available, and fecal occult blood as indirect markers of schistosomiasis morbidity.

Composite reference standards will be used to assess and classify infection activity. Organ-specific ultrasound and other examinations will be left to the physician*s decision, but results will also be captured. Serum (at least 1 mL

leftover from routine diagnostics) will be sent to LUMC, Netherlands, where CAA will be determined with the UCP-LF CAA assay (dry format) designed for routine use. Participants will be asked to sign an additional consent form, optional and not precluding the enrollment in the study, to permit the storage of the leftover serum at LUMC for 15 years, to allow secondary research. All patients diagnosed with chronic schistosomiasis according to site-specific diagnostic practice will be treated with the standard WHO regimen (40 mg/kg single-dose praziquantel) at inclusion, without waiting for the CAA result. All participants will be seen again after 6 weeks (+/- 1 week) for clinical and laboratory reevaluation, following the current standard of care, and CAA will be determined again on leftover serum.

Participation of the patient to the study will terminate at this point. Administration of additional courses of praziquantel and further follow-up will be left at the physician*s discretion after the 6 weeks follow-up visit, based on usual local practice, clinical assessment, and serial results of used diagnostics.

For this study a single additional blood tube (5 ml) will be withdrawn at the second hospital visit.

Contacts

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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) diagnosis of chronic schistosomiasis (>3 months after last potential exposure) according to site-specific diagnostic practice
(2) signed informed consent (and assent for minors).

Exclusion criteria

1. age below 16 years;
2. exposure to praziquantel after the last potential exposure to schistosomes
3. acute infection, i.e. likely infection <3 months before presentation

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-05-2025
Enrollment:	15
Type:	Anticipated

Ethics review

Approved WMO Date:	06-05-2025
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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
CCMO	NL87549.078.24