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BERNHARD-NOCHT-INSTITUT
FÜR TROPENMEDIZIN

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Protocol for a Multicenter Research Project: Evaluation of PCR testing for Diagnosing Katayama syndrome

Schistosomiasis is confirmed by microscopic detection of eggs in stool, urine, or organ biopsies. The sensitivity of these procedures is variable due to fluctuation of egg shedding. Serological tests on the other hand do not distinguish between active and past disease. In patients with acute disease (Katayama syndrome), both serology and egg detection may produce false negative results. To overcome these obstacles, we developed a novel diagnostic strategy: detection of cell-free parasite DNA for human plasma by PCR [1].

Study goals:

- 1) Confirm the initial findings in a larger cohort.
- 2) Evaluate the potential as a tool for treatment control.

Inclusion criteria:

Patients with

- a recent history of travelling to a region endemic for schistosomiasis AND
- Fever ($>38,4^{\circ}\text{C}$) AND
- Eosinophilia (>700 eosinophiles/ μl absolute count or $>10\%$ relative count).

Protocol:

Patients will be tested by PCR (requiring 7,5ml EDTA blood) and serology (requiring 3ml heparin serum) at the initial presentation and on a follow-up visit six month later.

Tests will be performed free of charge at the Bernhard Nocht Institute for Tropical Medicine, Hamburg, Germany.

Results will be communicated to the centers as soon as possible.

Outcome:

- Comparison of PCR results with serology and egg detection (as done by the centers in the course of disease)

- Comparison of PCR results at month 6 with serology and egg detection (as done by the centers), correlation with treatment modalities in the centers (beginning of praziquantel treatment during or after Katayama syndrome; 1-day vs. 3-day treatment etc)

Reference:

[1] Wichmann D, Panning M, Quack T, Kramme S, Burchard GD, Grevelding C, Drosten C. Diagnosing schistosomiasis by detection of cell-free parasite DNA in human plasma. PLoS Negl Trop Dis. 2009;3(4):e422

Participation in the study:

Centers that want to participate are requested to send 7,5ml EDTA blood and 3ml heparin serum to the following address.

**Bernhard-Nocht-Institut für Tropenmedizin
Zentrale Labordiagnostik
Prof. Dr. Egbert Tannich
Bernhard-Nocht-Str. 74
D-20359 Hamburg
Germany**

Please take care that the blood arrives in Hamburg in the beginning of a new week, not on Fridays or weekends.

Please fill in patient data into form sheet (see attachment) and send this together with the blood sample.

Authorship order: If the study is published, D. Wichmann will be the first author, criteria for other authors will include total of patient contribution and analytic/writing effort (similar to GeoSentinel publication guidelines).

For any questions please contact:

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or

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