

BIOMARKERS FOR DETECTING ACTIVE SCHISTOSOMIASIS

Background

Schistosomiasis infects 200 million individuals worldwide and if untreated can result in severe morbidity and mortality. Most individuals who are exposed to the parasite causing Schistosomiasis experience hepatic and gut pathology and urinary tract lesions. Coexistence of Hepatitis C virus (HCV) in the same population results in faster progression of fibrosis, cirrhosis and liver failure and cancer in co-infected individuals. Despite subsidized therapy, high reinfection rates make the complete elimination of infection impossible. HCV-antiviral therapy with interferon and ribavirin, is expensive and only about half of those who meet the criteria for treatment will respond to therapy.

The most reliable method for detecting active infection is direct visualization of viable ova microscopically in the stools or urine of those with the infection. However, ova shedding is intermittent and decreases with age, requiring concentration of samples and repeated testing. Serological tests to detect antibodies have become more reliable and species-specific, but cannot separate present from active infection; are not sufficiently reliable and often remain positive for weeks after active infection, especially among patients co-infected with HCV. The absence of a reliable serum based test to screen for active disease makes it difficult to study true prevalence and incidence in areas of high or low exposure, and hampers the ability to assess effectiveness and duration of disease-free state after treatment.

Proteomics and Biomarker Discovery

Proteomics as applied to human health research is the direct measurement of the proteome in biological fluids, i.e., serum, urine, tissue culture supernatant, in different disease states. Proteomic studies of Schistosomiasis may permit detection of proteins produced directly by viable parasites or host proteins or peptides uniquely processed or cleaved in the presence of living worms: collectively referred to as biomarkers.

Data Collection

Individuals living in rural farming communities and presenting to outpatient clinics with symptoms suggestive of active infection, will be requested to participate in the study. They will be interviewed, examined clinically and blood, urine and stool samples will be collected. The questionnaire will inquire about a) history of exposure, diagnosis and treatment for Schistosomiasis, b) previous/current symptoms consistent with infection, e.g., blood in urine, mucus and blood in stool and c) diagnosis of jaundice, hepatitis, HCV, other liver disease or complication (e.g., hematemesis) of liver disease. A physician will examine the patients and blood, stool and urine samples will be collected for testing. It is anticipated that 40 individuals with active infections will be enrolled.

Laboratory Testing:

1. Stool and urine samples will be taken on the 1st visit and 3 microscopic slides will be made for review and microscopically examined for ova.
2. Sera will be tested for antibodies to the parasite causing Schistosomiasis.
3. Sera will be tested for biomarkers to identify active Schistosomiasis.

Consent form to Participate in Research

Title: Biomarkers for Detecting Active Schistosomiasis

Principal Investigator: Dr. Ahmed Sayed Upper Egypt University
Prof. Mohamed Saba Mohandesin University

Name of Research Participant: -----

Background:

Despite the effectiveness of serological tests to detect antibodies against Schistosomiasis, it is still not possible to differentiate between active infections and past infections.

Purpose of the study:

To identify proteomic biomarkers for active cases of colonic Schistosomiasis

Study Methods:

You are invited to participate in this study at no cost to you. You have been selected because you have evidence of Schistosomiasis infection. If you agree to participate, we will ask you to provide samples from your blood, urine and stools. An examination of your colon will be performed using fiberoptic colonoscopy, and a sample of your rectal mucosa will be taken to examine it for Schistosomiasis infection. If you are found to be infected, then you will be treated for free (with Choro heximide tablets).

Costs:

You will not be charged for the cost of laboratory testing or for any treatment that may be provided to you.

Confidentiality:

All information gathered about you will remain undisclosed and you will not be identified when the results of this study are reported.

Rights of the participant:

Your signature on this form indicates that you have read or listened to the information related to this study and agree to participate. You will be given a copy of this consent form for your records. The principal investigator for this study, Dr. Ahmed Sayed, or his designee, will attempt to answer any of your questions. You can call the Upper Egypt University at the following number: XXXXXXXXXX.

If you agree to participate in this study, please sign this form:

Name of subject	Signature	Date
-----	-----	-----

Name of Principal Investigator or his designee	Signature	Date
-----	-----	-----