

# Comparison of three diagnostic methods to assess albendazole efficacy

<b>Submission date</b> 21/09/2009	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 01/10/2009	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 06/06/2014	<b>Condition category</b> Infections and Infestations	<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
N/A

# Study information

## Scientific Title

Comparison of three diagnostic methods to assess albendazole efficacy: a cross-sectional parasitological survey

## Acronym

Kato-FLOTAC-McMaster

## Study objectives

A single FLOTAC® test is more sensitive than a single Kato-Katz thick smear or a single McMaster test for the diagnosis of soil-transmitted helminth infections.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Ethikkommission beider Basel (EKBB), 14/09/2009, ref: 278/09

## Study design

Observational cross-sectional parasitological survey

## Primary study design

Observational

## Secondary study design

Cross-section survey

## Study setting(s)

Hospital

## Study type(s)

Screening

## Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

## Health condition(s) or problem(s) studied

Soil-transmitted helminthiasis (ascariasis, hookworm disease, trichuriasis)

## Interventions

Each day, a total of 20 children will be enrolled. They are invited to provide a single stool sample that will be subjected to three different diagnostic methods. After stool collection, each child will be treated with a single 400 mg oral dose of albendazole (regardless of the parasitological findings). The next day, another 20 children will be enrolled, following the same procedures. After 21 days (15 working days, 5 days per week), the first roster of 20 children will be re-examined and a second stool sample will be collected from the same 20 children. The baseline and the follow-up surveys will therefore take each 3 weeks.

The total duration of the trial is 6 weeks. We put down 3 months to have some safety margin. Based on the above, please note that there is only one intervention arm; each child will be administered albendazole (400 mg).

**Intervention Type**

Other

**Phase**

Not Applicable

**Primary outcome measure**

Sensitivity of diagnost test, measured at three weeks post-treatment follow-up

**Secondary outcome measures**

Measured at three weeks post-treatment follow-up:

1. Agreement between diagnostic tests for prevalence and infection intensity estimates
2. Negative predictive value

**Overall study start date**

27/09/2009

**Completion date**

31/12/2009

## Eligibility

**Key inclusion criteria**

1. Child judged healthy by study physician
2. Written informed consent provided by child's parent or guardian
3. Provision of stool sample
4. No recent history of anthelmintic treatment (drugs administered within the past 2 weeks)
5. School-aged children between 5 and 16 years (although in some cases this can go as high as 20 years), either sex

**Participant type(s)**

Patient

**Age group**

Other

**Sex**

Both

**Target number of participants**

300

**Key exclusion criteria**

1. Too sick to attend school or participate in the study (e.g. severe diarrhoea, severe anaemia, high fever, etc.)
2. No parental/guardian's permission to participate (absence of written informed consent)

3. Do not provide a stool sample
4. Recent history of anthelmintic treatment (drugs administered within the past 2 weeks)

**Date of first enrolment**

27/09/2009

**Date of final enrolment**

31/12/2009

## **Locations**

**Countries of recruitment**

Italy

Tanzania

**Study participating centre****Department of Biology**

Torino

Italy

10122

## **Sponsor information**

**Organisation**

Ivo de Carneri Foundation (Italy)

**Sponsor details**

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**Sponsor type**

Research organisation

**Website**

<http://www.fondazionedecarneri.it/en/>

## **Funder(s)**

**Funder type**

Research organisation

**Funder Name**

Ivo de Carneri Foundation (Italy)

**Funder Name**

University of Naples Federico II (Italy) - Department of Pathology and Animal Health, Faculty of Veterinary Medicine

## Results and Publications

**Publication and dissemination plan**

Not provided at time of registration

**Intention to publish date****Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/08/2013		Yes	No