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Comparison of three diagnostic methods to assess albendazole efficacy

Submission date	Recruitment status	[_] Prospectively registered
21/09/2009	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
01/10/2009	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
06/06/2014	Infections and Infestations	

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 anthelminthic 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 anthelminthic 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
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Sponsor information

Organisation
Ivo de Carneri Foundation (Italy)

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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?
Results article	results	01/08/2013		Yes	No