Effects of intestinal helminth infections in early childhood on immune response, inflammation, anaemia and malnutrition

Submission date	Recruitment status	Prospectively registered
22/07/2005	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
22/07/2005	Completed	Results
Last Edited	Condition category	Individual participant data
13/12/2007	Haematological Disorders	Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number 063122

Study information

Scientific Title

Study objectives

To test whether anthelminthic treatment of children six to 36 months of age decreases severe anaemia, decreases wasting malnutrition, and decreases anorexia.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Anaemia, protein-energy malnutrition, anorexia

Interventions

Double blind Randomised Controlled Trial (RCT) of mebendazole versus an identical-looking but inert placebo.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Mebendazole

Primary outcome(s)

- 1. Haemoglobin less than 70 g/l
- 2. Mid upper arm circumference less than -2 Z scores of international reference
- 3. Maternal report of anorexia

Key secondary outcome(s))

- 1. Weight-for-height less than -1 Z scores of international reference
- 2. Height-for-age less than -2 Z scores on international reference
- 3. Inflammation

Completion date

31/03/2006

Eligibility

Key inclusion criteria

- 1. Six to 24 months of age
- 2. Informed consent
- 3. Residing in selected communities based on geographic catchment area

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Child

Lower age limit

6 months

Upper age limit

24 months

Sex

All

Key exclusion criteria

- 1. Haemoglobin less than 70 g/l
- 2. Refusal of informed consent

Date of first enrolment

01/01/2004

Date of final enrolment

31/03/2006

Locations

Countries of recruitment

Tanzania

United States of America

Study participating centre Cornell University

Ithaca NY United States of America 14853

Sponsor information

Organisation

Cornell University (USA)

ROR

https://ror.org/05bnh6r87

Funder(s)

Funder type

Charity

Funder Name

The Wellcome Trust (UK) (grant ref: 063122)

Funder Name

Burroughs Wellcome Initiative (USA)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration