ISRCTN83988447 https://doi.org/10.1186/ISRCTN83988447

# 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

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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

## Primary study design
Interventional

## Study design
Randomised controlled trial

## 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