

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

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| Submission date 22/07/2005 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered |
| Registration date 22/07/2005 | Overall study status Completed | <input type="checkbox"/> Protocol |
| Last Edited 13/12/2007 | Condition category Haematological Disorders | <input type="checkbox"/> Statistical analysis plan |
| | | <input type="checkbox"/> Results |
| | | <input type="checkbox"/> Individual participant data |
| | | <input type="checkbox"/> 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Study information

Scientific Title

Study objectives

To test whether anthelmintic 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

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

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 measure

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

Secondary outcome measures

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

Overall study start date

01/01/2004

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

Age group

Child

Lower age limit

6 Months

Upper age limit

24 Months

Sex

Both

Target number of participants

2500

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)

Sponsor details

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Sponsor type

University/education

Website

<http://www.cornell.edu/>

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

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