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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

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