A cluster-randomised study of the effect of albendazole treatment on the prevalence of childhood atopy among children with geohelminth infections

Submission date	Recruitment status No longer recruiting	Prospectively registered	
17/12/2005		☐ Protocol	
Registration date	Overall study status	Statistical analysis plan	
21/12/2005	Completed	[X] Results	
Last Edited 21/03/2013	Condition category Infections and Infestations	Individual participant data	

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

Protocol serial number 060120

Study information

Scientific Title

Study objectives

Geohelminth infections suppress atopy in children and this suppression is reversible by anthelmintic treatment.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approval received from:

- 1. St George's Hospital London (UK) 2002
- 2. Hospital Pedro Vicente Maldonado (Ecuador) 2002

Study design

Cluster-randomised trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Geohelminth infections

Interventions

Bimonthly albendazole (400 mg) for 12 months (total of seven treatments) versus no intervention.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Albendazole

Primary outcome(s)

Atopy (measured by allergen skin test reactivity)

Key secondary outcome(s))

- 1. Allergic symptoms
- 2. Exercise-induced bronchospasm
- 3. Flexural dermatitis

Completion date

01/09/2004

Eligibility

Key inclusion criteria

Schools:

- 1. Access during rainy season
- 2. Total size less than 150 children
- 3. Preliminary meetings attended by a majority of parents

Individuals:

- 1. Healthy children in second to seventh year of primary education (i.e. aged eight to 14 years)
- 2. Informed written consent by a parent

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Child

Lower age limit

8 years

Upper age limit

14 years

Sex

All

Key exclusion criteria

Schools:

- 1. Limited access during rainy season
- 2. Total size more than 150 children
- 3. Preliminary meetings attended by minority of parents

Individuals:

- 1. Children not in second to seventh year of primary education
- 2. No informed written consent by a parent

Date of first enrolment

15/06/2002

Date of final enrolment

01/09/2004

Locations

Countries of recruitment

Ecuador

Study participating centre
Hospital Pedro Vicente Maldonado
Quito
Ecuador

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Sponsor information

Organisation

St George's Hospital Medical School (UK)

ROR

https://ror.org/040f08y74

Funder(s)

Funder type

Charity

Funder Name

The Wellcome Trust (UK) (grant ref: 060120)

Results and Publications

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	13/05/2006		Yes	No