

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

Submission date
17/12/2005

Recruitment status
No longer recruiting

☐ Prospectively registered
☐ Protocol

Registration date
21/12/2005

Overall study status
Completed

☐ Statistical analysis plan
☒ 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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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

Primary study design

Interventional

Study design

Cluster-randomised trial

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