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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 [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 21/12/2005	**Overall study status** Completed	
Last Edited 21/03/2013	**Condition category** Infections and Infestations	

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
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

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
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 measure
Atopy (measured by allergen skin test reactivity)

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

Overall study start date
15/06/2002

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

Age group
Child

Lower age limit
8 Years

Upper age limit
14 Years

Sex
Both

Target number of participants
68 schools; ~2,730 children

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
-

Sponsor information

Organisation
St George's Hospital Medical School (UK)

Sponsor details
Cranmer Terrace
London
United Kingdom
SW17 ORE

Sponsor type
Hospital/treatment centre

Website
http://www.sgul.ac.uk

ROR
https://ror.org/040f08y74

Funder(s)

Funder type
Charity

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

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	Results	13/05/2006		Yes	No