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Does the eradication of endoparasites promote allergic disease?

Submission date	Recruitment status	[_] Prospectively registered
31/10/2005	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
15/11/2005	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
16/10/2008	Skin and Connective Tissue Diseases	[_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Carsten Flohr

Contact details
Oxford University Clinical Research Unit
Hospital for Tropical Diseases
Ho Chi Minh City
Viet Nam
flohr@dng.vnn.vn

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Acronym
DB Study

Study objectives
Allergic disease is becoming increasingly frequent in urban centres of developing nations, such as Viet Nam. In this context, the role of endoparasite exposure has been debated for years. Some but not all cross-sectional studies suggest that the relatively high prevalence of allergic disease and atopy in urban areas of developing countries may be partly explained by a reduction in exposure to endoparasites, especially hookworm and Ascaris lumbricoides. It is likely that some of the effects demonstrated in cross-sectional population-based studies are due to confounding or even reverse causality, such that atopics have an immune system that reduces worm burden. Only an intervention study will be able to clarify this matter.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Nottingham Research Ethics Committee 2, Ref. REC/Q2010305, 3rd Dec 2004

Study design
Double blind 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
Allergic disease, soil-transmitted helminths

Interventions
The original study protocol used three-monthly single dose Mebendazole 500 mg over one year. After the first treatment round, investigators noticed low efficacy of this regime. Therefore, a treatment comparison study was conducted to select the best treatment, and Albendazole 400 mg for three consecutive days was chosen.

The amended protocol compares three-monthly Albendazole versus placebo over 9 months.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Albendazole

Primary outcome measure
Change in percent fall in peak expiratory flow after exercise challenge post gut worm treatment

Secondary outcome measures
Change in skin prick test hypersensitivity, host cytokine profiles, and allergic disease prevalence (skin examination for eczema and questionnaire-based for wheeze and rhinitis) post gut worm treatment

Overall study start date
01/04/2005

Completion date
30/06/2006

Eligibility

Key inclusion criteria
All primary and secondary school children (age 6-15) in four communes in Khanh Hoa province, central Viet Nam

Participant type(s)
Patient

Age group
Child

Sex
Both

Target number of participants
1600

Key exclusion criteria
Known allergy to Albendazole

Date of first enrolment
01/04/2005

Date of final enrolment
30/06/2006

Locations

Countries of recruitment
Viet Nam

Study participating centre
Oxford University Clinical Research Unit
Ho Chi Minh City
Viet Nam

Sponsor information

Organisation
University of Nottingham (UK)

Sponsor details
Centre for Population Sciences and Centre for Respiratory Research
Institute of Clinical Research
University of Nottingham
Nottingham
England
United Kingdom
NG7 2RD
j.britton@virgin.net

Sponsor type
University/education

Website
http://www.nottingham.ac.uk/icr/

ROR
https://ror.org/01ee9ar58

Funder(s)

Funder type
Charity

Funder Name
Asthma UK (UK)

Alternative Name(s)
Asthma UK, Asthma + Lung UK

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

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