

Does the eradication of endoparasites promote allergic disease?

Submission date
31/10/2005

Recruitment status
No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date
15/11/2005

Overall study status
Completed

☐ Statistical analysis plan

☐ Results

Last Edited
16/10/2008

Condition category
Skin and Connective Tissue Diseases

☐ Individual participant data

☐ 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
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