ISRCTN83830814 https://doi.org/10.1186/ISRCTN83830814

Effect of repeated three-monthly albendazole treatments on malaria and allergic disease

Submission date	Recruitment status	[_] Prospectively registered
08/12/2008	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
27/02/2009	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
02/12/2019	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
05-PP-35

Study information

Scientific Title
Parasitic infections and Inflammatory Diseases: The web of immune responses, host genetics and environmental exposure

Study objectives
Intestinal helminth infections suppress atopy and incidence of malaria and this suppression is reversible by antihelminthic treatment

Ethics approval required
Old ethics approval format

Ethics approval(s)
University of Indonesia, approved on 11/09/2006 (ref: 194/ PT02.FK/Etik/2006)

Study design
Randomised double-blind placebo-controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Helminth and malaria parasitic diseases

Interventions
400 mg albendazole (oral) or matching placebo every three months for 2 years.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Prevalence of malaria parasite, assessed throughout the study for 3 years
2. Infection with intestinal helminth before treatment and within 1, 2 and 3 years after start of

treatment
3. Skin reactivity to allergens assessed before treatment and within 1, 2 and 3 years after start of treatment

Secondary outcome measures
Immune response to malaria and helminth antigens, assessed before albendazole treatment and within 1, 2 and 3 years after the start of treatment (with the last treatment given at least 2 months before immunological determination).

Overall study start date
01/11/2008

Completion date
01/11/2011

Eligibility

Key inclusion criteria
1. Both males and females
2. Age >=2 years. No upper age limit.
3. Those who have given informed consent

Participant type(s)
Patient

Age group
Other

Sex
Both

Target number of participants
4,000

Total final enrolment
4004

Key exclusion criteria
1. History of chronic liver, heart or central nervous system (CNS) disease
2. Allergy to albendazole

Date of first enrolment
01/11/2008

Date of final enrolment
01/11/2011

Locations

Countries of recruitment

Indonesia

Netherlands

Study participating centre
Department of Parasitology
Leiden
Netherlands
2333 ZA

Sponsor information

Organisation
Royal Netherlands Academy of Arts and Sciences (Netherlands)

Sponsor details
Kloveniersburgwal 29
Amsterdam
Netherlands
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knaw@bureau.knaw.nl

Sponsor type
University/education

Website
http://www.knaw.nl

ROR
https://ror.org/043c0p156

Funder(s)

Funder type
University/education

Funder Name
Royal Netherlands Academy of Arts and Sciences (Netherlands) (ref: 05-PP-35)

Alternative Name(s)
Royal Netherlands Academy of Arts and Sciences, KNAW

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
Netherlands

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	01/07/2013		Yes	No
Results article	results	09/08/2018		Yes	No
Results article	gut microbiome results	06/11/2019	02/12/2019	Yes	No