

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

Submission date
08/12/2008

Recruitment status
No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date
27/02/2009

Overall study status
Completed

☐ Statistical analysis plan

☒ Results

Last Edited
02/12/2019

Condition category
Infections and Infestations

☐ Individual participant data

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
1011 JV

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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