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

Submission date	<b>Recruitment status</b> No longer recruiting	<ul><li>Prospectively registered</li></ul>		
08/12/2008		Protocol		
Registration date	Overall study status Completed	Statistical analysis plan		
27/02/2009		[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

#### Contact name

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#### Contact details

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# Additional identifiers

# Protocol serial number

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

## Study type(s)

Prevention

#### 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(s)

- 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

# Key secondary outcome(s))

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).

#### 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** 

## Healthy volunteers allowed

No

#### Age group

Other

#### Sex

All

#### 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)

#### **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**

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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes