

# Safe and effective iron supplementation in malaria endemic areas

<b>Submission date</b> 10/04/2012	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 16/05/2012	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 30/01/2017	<b>Condition category</b> Haematological Disorders	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Iron supplementation is an important public health intervention. However, in areas where malaria is common, iron supplementation may not be without risk because iron can stimulate the growth of malaria parasites. The aim of this study is to compare the incidence of malaria between children given iron supplementation and children not given iron supplementation.

### Who can participate?

School age children (6-18 years old) tested as not infected with malaria.

### What does the study involve?

The children will be randomly allocated to receive Albendazole (a drug to treat infections caused by worms) for three consecutive days in combination with either iron supplementation or a matching placebo (dummy drug) for 6 days per week for a total of 8 weeks.

### What are the possible benefits and risks of participating?

Participants will receive anti-worm treatment for worm infections and iron treatment for their anemia. The iron tablet is given in individual doses based on body weight and under supervision of a medical doctor, so there is little or no risk of dangers from the side effects.

### Where is the study run from?

Nangapanda Region, District of Ende, Flores Island, Indonesia

### When is the study starting and how long is it expected to run for?

July 2011 to January 2012

### Who is funding the study?

Nutricia Research Foundation (Netherlands)

### Who is the main contact?

Prof. Maria Yazdanabkshsh  
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# Contact information

## Type(s)

Scientific

## Contact name

Prof Maria Yazdanbakhsh

## Contact details

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# Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

2010-26

# Study information

## Scientific Title

Towards safe and effective iron supplementation in malaria endemic areas: randomized double-blind placebo controlled trial

## Study objectives

Iron supplementation in anemic subjects with submicroscopic malaria increases hemoglobin levels but does not increase parasitaemia.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Ethical Committee of Faculty of Medicine, University of Indonesia, 08/03/2010, ref: 96/PT02.FK/ETIK/2010, addendum ref: 459/PT02.FK/43/N/2011

## Study design

Randomized placebo-controlled clinical 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**

Anemia, malaria and geohelminths

**Interventions**

400 mg albendazole per day orally for three consecutive days in combination with iron supplementation or matching placebo 6 mg/kg body weight for 6 days/week for total duration 8 weeks.

**Intervention Type**

Supplement

**Phase**

Not Applicable

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

Albendazole, iron supplements

**Primary outcome measure**

Microscopic and submicroscopic incidence of malaria

**Secondary outcome measures**

1. Changes in hemoglobin levels
2. Iron parameters (ferritin, sTFR)
3. Endothelial cells markers (ICAM-1 and Vwf)
4. C-reactive protein (CRP)

**Overall study start date**

28/07/2011

**Completion date**

31/01/2012

**Eligibility****Key inclusion criteria**

1. Those who have given informed consent
2. Both males and females

3. Aged between 6-18 years old
4. Malarial parasitemia negative by microscopy
5. Hemoglobin (Hb) > 8 g/dl
6. Hb < 11.5 g/dL for children aged <7 years
7. Hb <12 g/dL for girls aged >= 7 years
8. Hb <13 g/dL for boys aged >=7 years

**Participant type(s)**

Patient

**Age group**

Child

**Lower age limit**

6 Years

**Upper age limit**

18 Years

**Sex**

Both

**Target number of participants**

350

**Key exclusion criteria**

Clinical symptoms indicating malaria or any severe underlying condition

**Date of first enrolment**

28/07/2011

**Date of final enrolment**

31/01/2012

**Locations****Countries of recruitment**

Indonesia

Netherlands

**Study participating centre**

Leiden University Medical Center

Leiden

Netherlands

2333 ZA

# Sponsor information

## Organisation

Nutricia Research Foundation (Netherlands)

## Sponsor details

Danone Place Schiphol

P.O. Box 75538

Schiphol-Airport

Amsterdam

Netherlands

1118 ZN

## Sponsor type

Research organisation

## Website

<http://www.nutricia-research-foundation.org>

## ROR

<https://ror.org/00vt3ry76>

# Funder(s)

## Funder type

Research organisation

## Funder Name

Nutricia Research Foundation (Netherlands)

## Alternative Name(s)

## Funding Body Type

Private sector organisation

## Funding Body Subtype

Trusts, charities, foundations (both public and private)

## 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?
<a href="#">Results article</a>	results	28/01/2017		Yes	No