

Safe and effective iron supplementation in malaria endemic areas

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

Protocol serial number

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

Study type(s)

Prevention

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(s)

Microscopic and submicroscopic incidence of malaria

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Child

Lower age limit

6 years

Upper age limit

18 years

Sex

All

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)

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

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	28/01/2017		Yes	No