ISRCTN83091970 https://doi.org/10.1186/ISRCTN83091970

Safe and effective iron supplementation in malaria endemic areas

Submission date
10/04/2012

Recruitment status
No longer recruiting

Registration date
16/05/2012

Overall study status
Completed

Last Edited
30/01/2017

Condition category
Haematological Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] 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
m.yazdanbakhsh@lumc.nl

Contact information

Type(s)
Scientific

Contact name
Prof Maria Yazdanbakhsh

Contact details
Department of Parasitology
Leiden University Medical Center
Albinusdreef 2
Leiden
Netherlands
2333 ZA

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?
Results article	results	28/01/2017		Yes	No