

Iron fortification and parasite control to reduce anaemia among schoolchildren in Cote d'Ivoire

Submission date 18/11/2006	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 21/11/2006	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 25/08/2011	Condition category Haematological Disorders	<input type="checkbox"/> 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
PPOOB--102883

Study information

Scientific Title

Acronym

IronSPAlbenPrazi

Study objectives

Iron fortification, intermittent preventive treatment for malaria, and regular anti-helminthic treatment - alone and in combination - reduce anaemia in schoolchildren.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approval received from the local Ethics Committee (Ethikkommission Beider Basel [EKBB]) on the 4th September 2006, and the 28th September 2006 (Protocol Number: 224/06).

Study design

Randomised, double-blind, clinical trial (2 x 2 x 2 factorial design)

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Prevention

Participant information sheet

Health condition(s) or problem(s) studied

Mild to moderate anaemia

Interventions

1. Iron fortification (biscuits with two x 10 mg Fe/day/child; four per week)
2. Intermittent preventative treatment (sulfadoxine (500 mg) and pyrimethamine (25 mg); three times, interval: three-month)
3. Albendazole (400 mg) and praziquantel (40 mg/kg); three times, interval: three-month

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Iron fortification, sulfadoxine, pyrimethamine, albendazole and praziquantel

Primary outcome measure

1. Reduction in anaemia
2. Change in cognitive performance

Secondary outcome measures

Number of clinical malaria episodes during trial period

Overall study start date

27/11/2006

Completion date

31/08/2007

Eligibility**Key inclusion criteria**

1. Child, aged six to 14 years, both sexes, attending the local primary school of five selected villages
2. For girls, not pregnant (as assessed by medical doctor)
3. Absence of major systemic illnesses (as assessed by medical doctor upon initial full clinical assessment)
4. Anticipated residence in the study area for at least one year
5. Mild to moderate anaemia defined as Haemoglobin (Hb) more than 80 g/L and less than 115 g/L in children aged between six and 12 years, and Hb more than 80 g/L and less than 120 g/L in children more than or equal to 12 years
6. No known or reported hypersensitivity to albendazole, praziquantel or sulfadoxine-pyrimethamine
7. No known or reported history of significant chronic illness
8. No known history of anthelmintic treatment in the four weeks prior to study enrolment
9. Written informed consent of parents or legal guardian

Participant type(s)

Patient

Age group

Child

Lower age limit

6 Years

Upper age limit

14 Years

Sex

Both

Target number of participants

Key exclusion criteria

1. Hb less than 80g/L
2. Attending any other clinical trials during the study period
3. Presence of any abnormal medical condition, judged by the investigator medical team

Date of first enrolment

27/11/2006

Date of final enrolment

31/08/2007

Locations**Countries of recruitment**

Côte d'Ivoire

Switzerland

Study participating centre

ETH Food Science and Nutrition

Zurich

Switzerland

8092

Sponsor information**Organisation**

ETH Food Science and Nutrition (Switzerland)

Sponsor details

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Sponsor type

Government

Website

<http://www.ethz.ch/>

ROR

<https://ror.org/05a28rw58>

Funder(s)

Funder type

Industry

Funder Name

The Medicor Foundation (Liechtenstein)

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	01/01/2008		Yes	No
Results article	results	01/03/2010		Yes	No
Results article	results	01/12/2010		Yes	No