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

Submission date	Recruitment status	[X] Prospectively registered
18/11/2006	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
21/11/2006	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
25/08/2011	Haematological Disorders	

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-helmintic 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 (biscuitis 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/Land 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

640

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