# 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 [ ] Statistical analysis plan Registration date Overall study status 21/11/2006 Completed [X] Results [ ] Individual participant data **Last Edited** Condition category 25/08/2011 Haematological Disorders

#### Plain English summary of protocol

Not provided at time of registration

# **Contact information**

## Type(s)

Scientific

#### Contact name

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## Additional identifiers

Protocol serial number

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

#### Study type(s)

Prevention

#### 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(s)

- 1. Reduction in anaemia
- 2. Change in cognitive performance

## Key secondary outcome(s))

Number of clinical malaria episodes during trial period

# 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

#### Healthy volunteers allowed

No

#### Age group

Child

#### Lower age limit

6 years

#### Upper age limit

14 years

#### Sex

Αll

#### 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

Switzerland

Study participating centre
ETH Food Science and Nutrition
Zurich
Switzerland
8092

# Sponsor information

### Organisation

ETH Food Science and Nutrition (Switzerland)

#### **ROR**

https://ror.org/05a28rw58

# Funder(s)

# Funder type

Industry

#### **Funder Name**

The Medicor Foundation (Liechtenstein)

# **Results and Publications**

Individual participant data (IPD) sharing plan

# IPD sharing plan summary

Not provided at time of registration

#### **Study outputs**

<b>7</b>					
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				

Results article 01/12/2010 Yes No