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Aetiology of anaemia and public health implications in the Taabo health demographic surveillance system, south-central Côte dIvoire

Submission date
09/11/2012

Recruitment status
No longer recruiting

Registration date
29/11/2012

Overall study status
Completed

Last Edited
21/10/2016

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Anaemia is caused when there aren't enough red blood cells or haemoglobin (the part of the red blood cell that carries oxygen) to meet the body's needs. Anaemia affects more than two billion people worldwide and is a huge public health problem in developing countries. For instance, it is currently estimated that in Africa, about half of the children and women of childbearing age are at risk of anaemia. It is commonly thought that lack of iron is the main cause for anaemia. However, anaemia can result from other diet deficiencies, as well as from parasitic diseases such as malaria and helminthiases (worm infection), or from genetic disorders such as haemoglobinopathies. The aim of this study is to find out which factors (e.g., nutrient deficiencies, parasitic infections) are associated with anaemia in different population groups in a typical rural setting of Côte d'Ivoire, West Africa.

Who can participate?
Infants (aged 6-23 months), young school-aged children (aged 6-8 years) and young women (aged 15-25 years) living in one of the three selected localities

What does the study involve?
Participants are assessed to see how haemoglobin concentration changes over time in response to specific health interventions (e.g., treatments and preventive chemotherapy against soil-transmitted helminthiasis and schistosomiasis, and treatments of clinical malaria and severe anaemia cases). Additionally, the prevalence of haemoglobinopathies (genetic defect that affects haemoglobin) is determined in the study area. The participants undergo tests, namely examination of blood, urine and faeces samples for parasites, and haemoglobin measurements. These tests are conducted at the start of the study and at four further follow-up surveys once every 3-4 months. Moreover, a blood sample is collected at the start of the study, after 6 months and at the end-of-study survey.

What are the possible benefits and risks of participating?
Findings from this study will increase knowledge about anaemia in West Africa, which might lead to suggestions on how to locally better prevent and control anaemia. Participants are examined

regularly over a 14-month period by qualified medical staff. Participants are treated if a clinical malaria episode or a helminth infection is diagnosed, according to national guidelines. These treatments might result in some adverse events, which are usually brief. All personnel who perform the medical examinations and treatment are qualified and well experienced (i.e. medical doctors, nurses and technicians who are well acquainted to do this type of work). All methods applied within the study are routinely used in the field, the laboratories and the hospitals and therefore do not place participants under any specific risk. Particular care is taken when sampling blood, as there are small risks such as bruise, infection and/or inflammation of the vein, and discomfort at the time of taking a blood sample. These risks are minimized by doing the blood collection with all the precautions using sterile material and performed only by experienced staff.

Where is the study run from?
Taabo HDSS (Côte d'Ivoire)

When is the study starting and how long is it expected to run for?
April 2010 to June 2011

Who is funding the study?
Swiss National Science Foundation (Switzerland)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title
Aetiology of anaemia and public health implications in the Taabo health demographic surveillance system, south-central Côte dIvoire

Study objectives
Anaemia is associated with sociodemographic variables, micronutrient deficiencies, parasitic infections and inflammatory parameters and these associations depend on the host age and sex.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Ethikkommission beider Basel (EKBB), Switzerland, 10/10/2010, ref: 252/09 (Amendment - 17 /04/2010)
2. Comité National dÉthique et de la Recherche, Ministère de la Santé et de lHygiène publique, 23/03/2010, ref: 1086 MSHP/CNER

Study design
Prospective longitudinal trials

Primary study design
Observational

Secondary study design
Cross sectional study

Study setting(s)
Other

Study type(s)
Screening

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Anaemia, malaria, helminth infection

Interventions
Non-pregnant participants who were diagnosed with soil-transmitted helminths at the baseline or at one of the four further follow-up surveys:
1. Single-dose albendazole (400 mg for school-aged children and women and 200 mg for infants)
Participants who were diagnosed with Schistosoma mansoni or S. haematobium at the baseline or at one of the four further follow-up surveys:
2. Single-dose praziquantel (40 mg/kg for children >2 years old)

Suspected clinical malaria cases (defined by a positive rapid diagnostic test (RDT) and tympanic temperature >38°C):
3. artesunate-amodiaquine (infants: 25 mg + 67.5 mg/day for 3 days; children: 100 mg + 270 mg /day for 3 days; women: 2 x 100 mg + 270 mg/day for 3 days)
Severely anaemic participants (i.e., haemaglobin level <8 g/dl, according to national guidelines of Côte dIvoire) with a positive RDT for malaria
4. treatment with artesunate-amodiaquine or referral to the nearest health center if their RDT is negative.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Haemoglobin concentration

Secondary outcome measures
1. Iron status indicators
2. Parasitic infection variables

Overall study start date
15/04/2010

Completion date
28/06/2011

Eligibility

Key inclusion criteria
1. Infants, aged 6-23 months (males and females); children aged 6-8 years (males and females); and women aged 15-25 years at the baseline cross-sectional survey
2. Participants will be randomly selected from an existing database kept by the Taabo HDSS
3. Written informed consent (or fingerprint for illiterate people) of school-aged children, women and a parent/guardian of infants and school-aged children at baseline or at one of the four further cross-sectional surveys
4. Written approval of the study physician

Participant type(s)
Patient

Age group
Mixed

Sex
Both

Target number of participants
Approximately 750

Key exclusion criteria
People who are severely ill, as judged by the study physician.

Date of first enrolment
15/04/2010

Date of final enrolment
28/06/2011

Locations

Countries of recruitment
Côte d'Ivoire

Switzerland

Study participating centre
Swiss Tropical and Public Health Institute
Basel
Switzerland
CH-4002

Sponsor information

Organisation
Swiss National Science Foundation (SNSF) (Switzerland)

Sponsor details
Wildhainweg 3
PO Box 8232
Bern
Switzerland
CH-3001

Sponsor type
Government

Website
http://www.snf.ch/

ROR
https://ror.org/00yjd3n13

Funder(s)

Funder type
Government

Funder Name
Schweizerischer Nationalfonds zur Förderung der Wissenschaftlichen Forschung (ref: IZ70Z0_123900)

Alternative Name(s)
Schweizerischer Nationalfonds, Swiss National Science Foundation, Fonds National Suisse de la Recherche Scientifique, Fondo Nazionale Svizzero per la Ricerca Scientifica, Fonds National Suisse, Fondo Nazionale Svizzero, Schweizerische Nationalfonds, SNF, SNSF, FNS

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Switzerland

Funder Name
Eremitage Fund of the Rudolf Geigy-Foundation (Switzerland)

Funder Name
Fairmed (Switzerland)

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	01/09/2012		Yes	No
Results article	results	01/11/2012		Yes	No
Results article	results	01/06/2013		Yes	No