ISRCTN86951400 https://doi.org/10.1186/ISRCTN86951400

Persistent digestive disorders and their association with bacterial, parasitic and viral pathogens in Dabou, south Côte dIvoire

Submission date
29/08/2013

Recruitment status
No longer recruiting

Registration date
02/10/2013

Overall study status
Completed

Last Edited
28/03/2019

Condition category
Infections and Infestations

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

Plain English summary of protocol

Background and study aims
Diarrhoea continues to be a major public health problem, particularly in tropical and subtropical countries. While acute diarrhoea has been extensively studied, few studies have focused on the diagnosis and treatment of long-lasting diarrhoeal episodes (14 days and longer). Many pathogens could possibly be involved, including more than 30 bacterial, parasitic and viral infectious agents. However, the most relevant pathogens in tropical settings still need to be identified. The main aim of this study is to find out whether a study setting in Dabou, south Côte dIvoire might be suitable to serve as study site in a multi-country investigation to assess persistent diarrhoea in Africa and Asia. To do this, we will look at the prevalence of a wide range of pathogens and selected bacteria in people with and without symptoms of diarrhoea.

Who can participate?
Individuals aged over 12 months who live in the city of Dabou or one of 11 surrounding villages.

What does the study involve?
Symptomatic patients presenting with persistent diarrhoea (14 days or more, as assessed by trained medical staff) will be assigned to the symptomatic group, while asymptomatic patients without any gastrointestinal complaints at time of enrolment and in the four preceding weeks will be assigned to the control group. All participants will be examined with standardised, quality-controlled tests. A small amount of stool will be stored and a subset of samples will be tested for several different types of bacteria, parasites and viruses. Finally, a questionnaire survey will be conducted.

What are the possible benefits and risks of participating?
A detailed laboratory diagnostic assessment of stool samples for various pathogens will be offered to all study participants. If a helminth or a symptomatic intestinal protozoon infection is diagnosed, free treatment will be offered to the infected individual, according to national guidelines. All personnel who will perform medical examinations and treatment will be 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. The treatment with the medication in case of parasitic infection will be done following national guidelines. These treatments might result in side effects (e.g., headache), but these are usually mild and disappear after a short while.

Where is the study run from?
The study will be conducted in the Hôpital Méthodiste de Dabou, located in south Côte dIvoire (about 40 km west of Abidjan, the economic capital of Côte dIvoire).

When is the study starting and how long is it expected to run for?
The study will start in October 2012 and will run for about 4 weeks. Detailed laboratory follow-up work might take up to 1 year.

Who is funding the study?
The study is funded by the NIDIAG network supported by the European Commission.

Who is the main contact?
Prof. Dr. Jürg Utzinger
juerg.utzinger@unibas.ch

Contact information

Type(s)
Scientific

Contact name
Dr Juerg Utzinger

Contact details
Socinstrasse 57
Basel
Switzerland
4002
+41 61 284 81 29
juerg.utzinger@unibas.ch

Additional identifiers

ClinicalTrials.gov (NCT)
NCT02105714

Protocol serial number
N/A

Study information

Scientific Title
Persistent digestive disorders and their association with bacterial, parasitic and viral pathogens in Dabou, south Côte dIvoire: an exploratory case-control study

Study objectives
Persistent diarrhoea (lasting 14 days or longer) is associated with a broad range of infectious pathogens of the gastrointestinal tract, including bacteria, parasites and viruses (for further details of our study hypothesis, see Becker et al., 2013, Persistent digestive disorders in the tropics: causative infectious pathogens and reference diagnostic tests. BMC Infect Dis 13: 37).

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Institutional Research Commission of the Swiss Tropical and Public Health Institute (Basel, Switzerland) and the Swiss Center for Scientific Research in Côte d'Ivoire (Centre Suisse de Recherches Scientifiques en Côte dIvoire) (CSRS; Abidjan, Côte dIvoire)
2. Directorate General of the Methodist Hospital Dabou (Direction Générale de lHôpital Méthodiste de Dabou). Dabou, Côte dIvoire, 01 October 2013

Study design
Case-control study

Primary study design
Observational

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Persistent diarrhoea, gastrointestinal infection, bacteria, helminths, intestinal protozoa, viruses

Interventions
All non-pregnant participants who are diagnosed with soil-transmitted helminths and symptomatic participants who are diagnosed with intestinal protozoa will be offered free treatment:
1. Soil-transmitted helminths (Ascaris lumbricoides, Trichuris trichiura, hookworm): Albendazole 400 mg (single dose)
2. Strongyloides stercoralis: Ivermectin 200 µg/kg (single dose)
3. Schistosoma mansoni: Praziquantel 40 mg/kg (single dose)
4. Entamoeba histolytica: Metronidazole 500-750 mg (thrice a day for 7 days)
5. Giardia intestinalis: Metronidazole 250-400 mg (thrice a day for 5 days; pediatric dose: 5 mg /kg)

No follow-up examinations were performed in our study, meaning that all examinations were carried out at baseline.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)

Infection status in relation to gastrointestinal complaints measured using a clinical questionnaire and battery of diagnostic tests employed on human stool samples.

Key secondary outcome(s))
Clinical symptomatology and related variables (specific symptoms, treatment prior to enrolment, age and sex), comparison of different diagnostic techniques measured using a clinical questionnaire and battery of diagnostic tests employed on human stool samples.

Completion date
31/10/2013

Eligibility

Key inclusion criteria
1. Individuals aged above 12 months presenting with persistent diarrhoea (≥3 stools per days for ≥14 days; symptomatic group) or without any gastrointestinal complaints in the 4 preceding weeks (asymptomatic control group) will be eligible to participate.
2. Participants from the City of Dabou and 11 surrounding villages will be invited to participate.
3. Written informed consent of all participating individuals will be obtained. If the individual is aged below 16 years, the written informed consent will be signed by the childs parents or legal guardians; additionally, these young participants will assent orally.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Other

Sex
All

Key exclusion criteria
1. Individuals in need of immediate intensive care.
2. Individuals who are unable or unwilling to give written informed consent.
3. Individuals who do not meet the inclusion criteria for either study group, e.g. people with acute diarrhoea.

Date of first enrolment
01/10/2012

Date of final enrolment
31/10/2013

Locations

Countries of recruitment

Côte d'Ivoire

Switzerland

Study participating centre
Socinstrasse 57
Basel
Switzerland
4002

Sponsor information

Organisation
Institute of Tropical Medicine (Belgium)

ROR
https://ror.org/03xq4x896

Funder(s)

Funder type
Government

Funder Name
NIDIAG network (collaborative project; http://www.nidiag.org) supported by the European Commission under the Health Cooperation Work Programme of the 7th Framework Programme (grant agreement no. 260260)

Results and Publications

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 protocol	01/10/2018		Yes	No

Protocol article		18/08/2015		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes