ISRCTN87099939 https://doi.org/10.1186/ISRCTN87099939

The Côte d'Ivoire dual burden of disease (CoDuBu) study

Submission date	Recruitment status	[_] Prospectively registered
26/07/2017	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
27/07/2017	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
30/10/2017	Other	

Plain English summary of protocol

Background and study aims
The co-occurrence of infectious diseases and non-communicable diseases (not caused by infection) is poorly studied, despite the fact that this dual burden has become a reality for many low- and middle-income countries (LMICs). Even very little is known about how common infectious diseases (e.g. worms and malaria) and non-communicable diseases (e.g. high blood pressure and diabetes) influence each other. Repeated and chronic (long-term) infections that are common in LMICs may alter people's susceptibility to diabetes and heart disease. Worm infections may shift the immune system into a direction protecting against inflammatory diseases, whereas repeated infections such as malaria may increase the risk of inflammatory diseases. Adults surviving often lethal infections in LMICs may have a genetically different susceptibility to age-related diseases (e.g. high blood pressue). As a result, people in LMICs may develop these diseases at different rates and at different ages than Western populations. If confirmed, this calls for changes in the provision of health services. The aim of this study is to carry out a survey of adults from rural and urban parts of the Taabo district in south-central Côte d'Ivoire to study the co-occurrence of worm infections and malaria with metabolic syndrome, high blood pressure and diabetes.

Who can participate?
Adults (aged at least 18) from three selected villages

What does the study involve?
The survey consists of health examinations to assess the incidence of high blood pressure, diabetes, worm and malaria infections, lifestyle and risks of infectious and non-communicable diseases. Confirmatory tests are provided as well as a free first month of treatment and enrolment into subsidized national care programmes. A biobank of collected biospecimens (e.g. stool and urine samples) is set up for future research.

What are the possible benefits and risks of participating?
All participants benefit from health examinations, laboratory tests, physician consultation and treatment, all free of charge. Participants receive health advice from the physician regardless of disease status. Participating health centres are equipped with diagnostic tools, and participating health workers are trained in non-communicable disease diagnosis and management. The

biobank will improve local research. There are no specific risks associated with this study, although providing stool and urine samples might be perceived as shameful. Furthermore, common drugs used for the treatment of worms, malaria, diabetes and high blood pressure might result in some side effects, but these are usually few, short-lived and the benefits outweigh the risk of not being treated.

Where is the study run from?
The study is conducted in three rural communities located in the Taabo district in south-central Côte d'Ivoire

When is the study starting and how long is it expected to run for?
April 2017 to December 2017

Who is funding the study?
Novartis Foundation (Switzerland)

Who is the main contact?
Prof. Nicole Probst-Hensch

Contact information

Type(s)
Scientific

Contact name
Prof Nicole Probst-Hensch

Contact details
Socinstrasse 57
Basel
Switzerland
4051

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Co-occurrence of common chronic infections (soil-transmitted helminths and Plasmodium) and common non-communicable diseases (diabetes and hypertension) in rural and urban Côte d’ Ivoire

Acronym
CoDuBu

Study objectives
Repeated and chronic infections that are common in low- and middle-income countries (LMICs) may alter the susceptibility to diabetes and cardiovascular diseases as well as their related phenotypes, albeit in an infection-specific manner. Adults surviving often lethal infections in the context of LMICs may have a genetically different susceptibility to diabetes and hypertension.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Ethikkommission beider Basel (EKBB, Switzerland), 25/07/2011, ref: 2016-00143
2. Comité National d'Ethique et de la Recherche (CNER, Côte d'Ivoire), 24/03/2017, ref: 032 /IMSHP/CNER-kp

Study design
Observational cross-sectional survey

Primary study design
Observational

Secondary study design
Cross sectional study

Study setting(s)
Community

Study type(s)
Prevention

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
Non-communicable diseases, infectious diseases

Interventions
The study involves a baseline cross-sectional survey which will be carried out in three selected villages in the Taabo HDSS, followed by the establishment of a biobank. The cross-sectional survey consists of health examination to determine anthropometric indices, metabolic syndrome, as well as helminthic and malaria infections. It will also include questionnaire survey with regard to lifestyle and risks of IDs and NCDs. Identified cases of ID and NCD will be managed accordingly. Confirmatory tests will be provided for NCD cases as well as free first month of treatment and enrolment into subsidized national care programmes. A biobank consisting of collected biospecimens will be set-up for future research into mechanisms incolved in ID-NCD interactions.

Intervention Type

Primary outcome measure
All outcomes measured at baseline:
1. Hypertension, assessed using blood pressure monitor and questionnaire
2. Diabetes, assessed using blood glucose and glycosylated hemoglobin tests and questionnaire
3. Helminth infection, assessed using Kato-Katz stool test, Baermann stool test, medical test
4. Malaria, assessed using rapid diagnostic blood test and microscopy

Secondary outcome measures
No secondary outcome measures

Overall study start date
23/04/2017

Completion date
31/12/2017

Eligibility

Key inclusion criteria
1. Age >= 18 years
2. Residence in the selected communities
3. Written informed consent to participate

Participant type(s)
All

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
1000

Key exclusion criteria
1. Residence in the selected communities
2. No written informed consent to participate

Date of first enrolment
23/04/2017

Date of final enrolment
31/05/2017

Locations

Countries of recruitment
Côte d'Ivoire

Switzerland

Study participating centre
Swiss Tropical and Public Health Institute
Socinstrasse 57
Basel
Switzerland
4051

Study participating centre
Centre Suisse de Recherches Scientifiques en Côte d'Ivoire
01
Abidjan
Côte d'Ivoire
01 BP 1303

Study participating centre
Université Félix Houphouët-Boigny
22
Abidjan
BP1106

Study participating centre
Institut National de Sante Publique
Abidjan
Côte d'Ivoire
BP V 47

Study participating centre
Ligue Ivoirienne contre l'Hypertension artérielle et les Maladies Cardiovasculaires
01
Abidjan
Côte d'Ivoire
BP 2858

Study participating centre
Institut Pasteur de Côte d'Ivoire
01
Abidjan
Côte d'Ivoire
BP 490

Sponsor information

Organisation
Swiss Tropical and Public Health Institute

Sponsor details
Socinstrasse 57
Basel
Switzerland
4051

Sponsor type
Research organisation

Website
http://www.swisstph.ch

ROR
https://ror.org/03adhka07

Funder(s)

Funder type
Other

Funder Name
Novartis Foundation

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
International organizations

Location
Switzerland

Results and Publications

Publication and dissemination plan
Planned publication of study protocol and the study results in the peer-reviewed (whenever possible open-access) literature before the end of 2019.

Intention to publish date
31/12/2019

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	27/10/2017		Yes	No