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Parasites and risk factors for heart attack and stroke in rural and urban areas of Gabon

Submission date 21/10/2021	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 26/10/2021	**Overall study status** Completed	
Last Edited 26/10/2021	**Condition category** Circulatory System	

Plain English summary of protocol

Background and study aims
Non communicable diseases (NCDs) and Infectious diseases (IDs), such as malaria and intestinal parasites are highly prevalent in sub-Saharan Africa. Their dual burden, associated risk factors and impact are poorly studied in Central Africa.
The ParCaM study will estimate and compare the frequency of cardio-metabolic diseases risk factors (CMDRF), including metabolic syndrome, hypertension, and inflammatory biomarkers in individuals with or without intestinal parasite infection (IPIs). Differences between specific age groups, type of parasitism (protozoa, helminths) and geographical (urban versus rural) areas will be emphasized. In addition, risk groups will be identified.

Who can participate?
Volunteers
Age between 18-60 years
Residency in the city where the study will be conducted (for at least two years)
Consent form signed by the participant and the medical investigator at inclusion

What does the study involve?
A standardized World Health Organization STEPwise NCDs surveillance questionnaire will be used to obtain demographic characteristics, lifestyle, and risk factors. Blood pressure, height, weight, BMI, and waist circumference will be measured. A parasitological analysis will identify intestinal protozoa, soil-transmitted helminths including urinary and intestinal schistosomiasis. Clinical chemistry and immunological tests will allow us to identify metabolic syndrome (which involves glucose, insulin, lipids levels) and the chronic inflammation biomarkers (IL-6, TNF-, sCD14, hsCRP). The Framingham score will determine the 10-year cardiovascular risk at the beginning and the end of the follow-up. In Phase 2, selected participants will be included in an 18-month prospective cohort study to estimate the frequency of occurrence of any CMD event or risk factor.

What are the possible benefits and risks of participating?
Benefits: Cardiovascular and metabolic health status will be assessed for free, free health check up each year during three years, free treatment of parasitic diseases, cardiovascular tests done_
Risks: small pain at the venous sampling injection site, 7 ML of blood drawn 3 times in 27 months

Where is the study run from?
Universite des Sciences de la Sante (Gabon)

When is the study starting and how long is it expected to run for?
October 2019 to June 2023

Who is funding the study?
European & Developing Countries Clinical Trials Partnership

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
TMA2017-1956

Study information

Scientific Title
Contribution of intestinal parasite infections in the risk of developing cardio-metabolic diseases in rural and urban areas of Gabon: a pilot study.

Acronym
ParCam

Study objectives
Inflammatory response and dysbiosis due to intestinal parasite infection (IPI) lead to dyslipidemia, type 2 diabetes and their cardiovascular (CVD) consequences. This will be translated into higher frequency of these CMD risk factors (CMDRF) in participants chronically or repeatedly infected when compared to uninfected participants. As exposition to IPI and type of parasitism are different between urban and rural areas, biomarkers of CMDRF will show different patterns according to the urbanisation. Precisely, we hypothesise that there will be more metabolic syndrome, more inflammation (as measured by IL-6, TNF-α, hsCRP) and more monocyte activation (as measured by sCD14) in chronically or repeatedly parasite-infected than in uninfected participants with difference according to urbanisation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 10/02/2021, Comite National d'ethique pour la Recherche (Bp 2217 Libreville - Gabon; +241 66815320; no email provided), ref: PROT N'002/2020/PR/SG/CNE

Study design
Obervational cohort study

Primary study design
Observational

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Risk of cardiometabolic diseases in patients with chronic parasitism

Interventions
During Phase I, the population and the chief from the districts of Libreville and Koulamoutou from two provinces in Gabon, will be informed about the aim, the importance and the benefit of the study. In addition, the study team will be trained on biological sample collection, testing and storage and the questionnaire related to this study will be tested. Phase I will be carried out over a period of 12 months. Data management standard operating procedures (SOPs) and methodology will be set up.

The second phase will be the cross-sectional survey, which corresponds to the screening for physical and biological risk factors over a 12-15 month period. After eligibility criteria verification and informed consent, interview, clinical examination and blood collection for biochemical tests and further biomarkers measurements will be performed at day 0. On day 1, urine and stools samples will be collected for parasitological tests and for aliquots of consenting participants for further sub-studies and will be stored in a -80°C freezer as well as dried blood spots.
The third phase will be the 27month prospective cohort study comparing the frequency of the occurrence of CMDRF or events including hypertension among the parasite-infected and uninfected participants of urban and rural areas. This phase will include three control visits: visit

1 (12-15 months after inclusion), visit 2 (24-27 months after inclusion), and visit 3 (36-39 months after inclusion). For all these visits, a delay of ± 1 month will be allowed. During each visit, a record of medical history and treatment, a complete clinical examination with blood pressure, determination of blood glucose, HbA1c, and lipids parameters as well as a sample for biomarker measurement and the Framingham score risk will be determined. The parasitological stool analysis will be performed during visits 2 and 3. At the last visit, the complete procedure as performed in phase 2, as well as the complete biomarkers measurement to determine the occurrence of CMD including hypertension or the modification of CMDRF will be realised.

Intervention Type
Other

Primary outcome(s)
Frequency or incidence of CMD risk factors (defined as the presence of any of the following conditions: metabolic syndrome, high level of inflammatory and monocyte activation markers, High Framingham score) in parasitic-infected and non-infected individuals in urban versus rural areas (from patient records at months 36-39)

Key secondary outcome(s))
Measured using patient records:
1. Incidence of IPIs in urban and rural areas (months 24 – 27, and months 36-39)
2. Prevalence of new CMDRF in urban and rural areas at the end of the cohort study (months 36-39)
3. Evolution of Framingham score globally and according to the type of parasitism and study area (months 12-15; months 24-27, and months 36-39)
4. Evolution of the levels of inflammatory biomarkers in participants from urban and rural areas (months 12-15; months 24-27, and months 36-39)
5. Incidence of CMDRF, including metabolic syndrome, chronic inflammation, and high blood pressure in the general population and between groups. (months 36-39)

Completion date
30/06/2023

Eligibility

Key inclusion criteria
1. Age between 18-60 years
2. Residency in the city where the study will be conducted (since at least two years)
3. Consent form signed by the participant and the medical investigator at inclusion

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit

18 years

Upper age limit
60 years

Sex
All

Key exclusion criteria
1. Patients <18 years and >60years
2. Severe clinical event under investigation, that is life-threatening, uncontrolled
3. Refusal to participate in the study
4. Patient who should travel a long distance to the study site
5. History of coronary disease or stroke
6. Active/chronic viral hepatitis
7. HIV infection
8. Tuberculosis known patients
9. Fever or antimalarial drug intake within the last 2 months
10. Other antiparasitic treatment within the 6 months preceding the recruitment

Date of first enrolment
23/09/2020

Date of final enrolment
31/01/2023

Locations

Countries of recruitment
Gabon

Study participating centre
Universite Des Sciences De La Sante- Centre De Recherche Biomedicale en Pathogenes Infectieux Et Pathologies Associees
Faculte De Medecine
Libreville
Gabon
4009

Sponsor information

Organisation
European & Developing Countries Clinical Trials Partnership

ROR

https://ror.org/031jv9v19

Funder(s)

Funder type
Government

Funder Name
European & Developing Countries Clinical Trials Partnership

Results and Publications

Individual participant data (IPD) sharing plan
Statement will be made available later

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?
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