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Identification of novel agents for HIV cure or remission

Submission date
08/09/2021

Recruitment status
No longer recruiting

Registration date
14/09/2021

Overall study status
Completed

Last Edited
28/05/2025

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
HIV continues to be a major public health problem in Africa. Although taking HIV medications has reduced HIV-associated deaths and improved lifespan, it does cure people of the infection. Patients must take medications daily for the rest of their lives and this comes with side effects, high costs, and the virus becoming resistant to some of the medication.
It is difficult to cure HIV because after infection some of the virus hides in cells that are not dividing and sleeps there until the HIV medicine is discontinued then they come out and make the person sick. One way to try and cure HIV is therefore to find compounds that can wake the virus up from sleep so that the HIV medicine can work to clear them and destroy the cells that contain them. In this study, we propose to screen several compounds for their ability to wake the sleeping virus up, select the most effective and test them in non-dividing cells taken from HIV patients whose viruses are undetectable.

Who can participate?
Adults (18 years and above) living in Ghana who are HIV infected and on HIV medication. These persons must be attending clinic at the three study sites: Korle-Bu Teaching Hospital, Korle-Bu, Accra, University of Ghana Hospital, Legon, Accra and LEKMA Hospital, Teshie, Accra. The persons must willingly decide to be part of the study and must give a written, signed consent.

What does the study involve?
Each eligible person will be asked to answer questions concerning their knowledge about efforts being made to cure HIV. Every three months when they come to clinic, they will be asked about how they are doing, whether they are taking their HIV medications and whether they have any problems with the medications. Then one tube of blood (about 10 mls) will be collected from them to be used to measure how much of the virus is in the blood and their white cell (CD4) counts. On some visits, their urine samples will be collected. The whole process during each visit will take about 20 minutes. We intend to follow them up for two years during this study. We will select those who have undetectable virus to partake in the studies to wake the sleeping virus up. This study will help better understand HIV in order to figure out whether it can be better treated or eventually even be cured.

What are the possible benefits and risks of participating?
Benefits: The CD4 count and viral load will be measured every 3 months. The participant's doctor will be informed if the viral load is going up or not coming down as expected even though the participant is taken their medications. Your doctor may change your medications at that point. This could be a potential benefit from the study
Potential Risks: Participants may experience discomfort, bruising, and/or bleeding at the site of needle insertion. This will be monitored for about 5 minutes after the blood is taken to make sure you the participant is fine before leaving the clinic. Occasionally, some people experience dizziness or feel faint. The investigator is willing to discuss your concerns about any of these risks.

Where is the study run from?
Noguchi Memorial Institute for Medical Research, University of Ghana, Legon, Accra (Ghana)

When is the study starting and how long is it expected to run for?
March 2018 to April 2025

Who is funding the study?
The study is funded by the European and Developing Countries Clinical Trials Partnership. This project is part of the EDCTP2 programme support by the European Union.

Who is the main contact?
Dr. George Boateng Kyei, gkyei@noguchi.ug.edu.gh

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Scientific

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Additional identifiers

Protocol serial number
TMA2017SF-1955

Study information

Scientific Title
Identification of novel HIV reactivation agents: towards building translational HIV Cure Research Infrastructure in Ghana

Acronym
H-CRIS

Study objectives
Epigenetic modifying compounds will be more effective reactivation agents

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 05/09/2018, Noguchi Memorial Institute for Medical Research Institutional Review Board (Accra, Ghana, +233 302916438; nirb@noguchi.ug.edu.gh), ref: CPN 002/18-19; renewed 04/04/2025

Primary study design
Observational

Study design
Multicenter longitudinal cohort study

Study type(s)
Screening

Health condition(s) or problem(s) studied
identification of epigenetic modifying compounds and assessing their effectiveness in reactivating HIV from latency

Interventions
An epigenetic library of compounds will be screened in vitro for their ability to reactivate HIV from latency. The most effective will be selected and evaluated in resting T cells isolated from HIV patients on combination antiretroviral therapy and virally suppressed. The in vitro assessment of compounds will be accomplished in the first phase while the patients are followed up and their viral loads measured every 3 months for 2 years. Then the virally suppressed patients (viral load < 50copies/ml) will be selected and their blood samples collected for the ex-vivo assay for reactivation studies.

Intervention Type
Other

Primary outcome(s)
Reactivation capacity of the compounds in patient resting T cells will be measured using the quantitative RT PCR method at 48 hours of incubation ex-vivo

Key secondary outcome(s)
Virologic suppression will be measured using viral load measurements with real time PCR every 3 months for 2 years

Completion date
30/04/2025

Eligibility

Key inclusion criteria
1. HIV infected
2. Adults 18 years and above
3. On combination antiretroviral therapy
4. Provided informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Total final enrolment
390

Key exclusion criteria
Not providing informed consent

Date of first enrolment
21/08/2019

Date of final enrolment
06/02/2020

Locations

Countries of recruitment
Ghana

Study participating centre
Korle Bu Teaching Hospital
Korle Bu
Accra
Ghana
-

Study participating centre
University of Ghana Hospital
Legon
Accra
Ghana
-

Study participating centre
LEKMA Hospital
LEKMA
Teshie
Accra
Ghana
-

Sponsor information

Organisation
Noguchi Memorial Institute for Medical Research

ROR
https://ror.org/00f1qr933

Funder(s)

Funder type
Government

Funder Name
European and Developing Countries Clinical Trials Partnership

Alternative Name(s)
The European & Developing Countries Clinical Trials Partnership, The European & Developing Countries Clinical Trials Partnership (EDCTP), European and Developing Countries Clinical Trials, Le partenariat Europe-Pays en développement pour les essais cliniques, A Parceria entre a Europa e os Países em Desenvolvimento para a Realização de Ensaios Clínicos, EDCTP

Funding Body Type
Private sector organisation

Funding Body Subtype
International organizations

Location
Netherlands

Results and Publications

Individual participant data (IPD) sharing plan
All data generated or analysed during this study will be included in the subsequent results publication.

IPD sharing plan summary
Available on request, Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/01/2021	28/05/2025	Yes	No
Results article		31/05/2023	28/05/2025	Yes	No
Results article		19/03/2025	28/05/2025	Yes	No
Other publications	Healthcare provider interview study		11/06/2024	Yes	No
Other publications	Patient questionnaire study	01/01/2021	11/06/2024	Yes	No
Protocol file	Study website		13/09/2021	No	No

Study website	11/11/2025	11/11/2025	No	Yes