

# Identification of novel agents for HIV cure or remission

<b>Submission date</b> 08/09/2021	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 14/09/2021	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 28/05/2025	<b>Condition category</b> Infections and Infestations	<input type="checkbox"/> 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 not 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

## Contact information

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Scientific

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Public

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**Additional identifiers****Clinical Trials Information System (CTIS)**

Nil known

**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

**Study design**

Multicenter longitudinal cohort study

**Primary study design**

Observational

**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)

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, The European & Developing Countries Clinical Trials Partnership (EDCTP), The European & Developing Countries Clinical Trials Partnership, European and Developing Countries Clinical Trials, 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?
<a href="#">Results article</a>		01/01/2021	28/05/2025	Yes	No
<a href="#">Results article</a>		31/05/2023	28/05/2025	Yes	No
<a href="#">Results article</a>		19/03/2025	28/05/2025	Yes	No
<a href="#">Other publications</a>	Healthcare provider interview study		11/06/2024	Yes	No

<a href="#">Other publications</a>	Patient questionnaire study	01/01/2021	11/06/2024	Yes	No
<a href="#">Protocol file</a>			13/09/2021	No	No
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes