ISRCTN74312863 https://doi.org/10.1186/ISRCTN74312863

Evaluation of direct-to-inject point-of-care HIV testing to facilitate rapid initiation of long-acting Cabotegravir for pre-exposure prophylaxis

Submission date
17/10/2025

Recruitment status
Recruiting

Registration date
23/10/2025

Overall study status
Ongoing

Last Edited
23/10/2025

Condition category
Other

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
This study will describe and evaluate the implementation of conducting all HIV testing at a patient's first injection appointment to facilitate rapid initiation of long-acting Cabotegravir (CAB-LA) for HIV pre-exposure prophylaxis (PrEP). Rapid initiation of PrEP helps protect patients from HIV during high-risk periods. Programs offering CAB-LA need to address delays and patient loss during the initiation process. Conducting all necessary HIV testing at the first injection appointment, rather than beforehand, could shorten the time from referral to first injection and reduce patient drop-off during this critical period.

Who can participate?
Adult participants from our PrEP Clinic at Grady Memorial Hospital, USA.

What does the study involve?
All patients referred for CAB-LA during the study period will be included in this prospective analysis. The PrEP clinic does not target specific groups for CAB-LA initiation. The team anticipate receiving 250 referrals and starting 200 patients on CAB-LA during this timeframe. A prospective chart review will be conducted for all patients referred to the GHS PrEP program from April 1, 2025, through March 31, 2026, from referral to up to 12 months after CAB-LA initiation (Aims 1 and 2). Interviews will be run for 30 patients after their first injection, and for 10 staff delivering first injections (Aim 3). There are no medical interventions, and all clinical protocols evaluated are standard of care for the clinic.

Patients recruited to participate in the qualitative portion of this study will complete 1 hour 1-hour-long interview. Total enrollment will be 40 participants, including 30 patients and 10 staff participants. The study does not bank any specimens. Chart review data will be banked. Any requests to use this data will require IRB approval. A waiver of informed consent will be requested for the chart review portion of the protocol. Participants recruited for interviews will be asked to consent verbally immediately before the interview. A HIPAA waiver will be

requested as all audio recordings will be de-identified before analysis, and will not be linked to any clinical data obtained through chart review.

What are the possible benefits and risks of participating?
Possible benefits:
Participants will not receive direct benefits from taking part in this study. However, their involvement will help improve how HIV prevention programs deliver injectable PrEP in the future by identifying ways to make the process faster, more efficient, and more patient-centered. Staff input will also support improvements in training and workflow for PrEP delivery.

Possible risks:
The study poses no to minimal risk to participants as all medical procedures are the current standard of care in our clinic, and there is no medical intervention. Individuals participating in patient and staff interviews may experience minor emotional discomfort when discussing personal experiences during interviews. There are no physical or medical risks involved, and participation is entirely voluntary.

Where is the study run from?
Emory University School of Medicine, USA.

When is the study starting and how long is it expected to run for?
March 2025 to September 2026

Who is funding the study?
ViiV Healthcare (UK)

Who is the main contact?
Dr Dylan Baker, dylan.mathieu-henri.baker@emory.edu

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Dr Dylan Baker

Contact details
Emory University School of Medicine
1599 Clifton Rd N E
Atlanta, Georgia
United States of America
30322
-
dylan.mathieu-henri.baker@emory.edu

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil Known

Protocol serial number
Nil Known

Study information

Scientific Title
Evaluation of direct-to-inject point-of-care HIV testing to facilitate rapid initiation of long-acting Cabotegravir for PrEP

Study objectives
Describe and evaluate the implementation of a direct-to-inject HIV testing approach to facilitate rapid initiation of long-acting Cabotegravir for PrEP. By evaluating outcomes of this testing strategy, this research may inform other clinical sites of the impact of implementing this testing strategy for rapid initiation of CAB-LA, as well as future injectable PrEP options.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 05/03/2025, Emory University Institutional Review Board (IRB) (1599 Clifton Rd N E, Atlanta, GA 30322, United States of America; +1 404-712-0720; IRB@emory.edu), ref: STUDY00009264

Study design
Mixed-methods prospective cohort study

Primary study design
Observational

Study type(s)
Other

Health condition(s) or problem(s) studied
Describe and evaluate the implementation of a direct-to-inject HIV testing approach to facilitate rapid initiation of long-acting Cabotegravir for PrEP

Interventions
In this mixed-methods observational study, we will evaluate the implementation of a direct-to-inject HIV testing strategy for the rapid initiation of long-acting injectable cabotegravir (CAB-LA) for HIV PrEP within the Grady Health System (GHS) PrEP Program. The population will include all patients referred to the GHS PrEP Program between October 1, 2025, and September 30, 2026, who are eligible for CAB-LA initiation, as well as clinical staff administering first injections. The intervention is the implementation of a “direct-to-inject” strategy in which same-day initiation of CAB-LA is offered using integrated HIV testing (rapid POC 4th-generation Ag/Ab, serum Ag/Ab, and HIV RNA testing) without requiring a prior testing visit or oral lead-in. There is no formal comparison group, as we will study the implementation of our current standard clinical practice, and there are no changes to clinical protocols associated with this study. The outcomes will

include quantitative measures of implementation timeliness (e.g., time from referral to initiation), retention and persistence on CAB-LA, safety and appropriateness (including HIV testing results and seroconversions), and sociodemographic predictors of progression along the CAB-LA care continuum.

We will use the RE-AIM implementation science framework to provide a structure for our evaluation. Our primary outcome aims to evaluate reach and effectiveness. We will describe the protocol's reach in starting high-risk individuals on CAB-LA. The effectiveness of this method will be evaluated by describing concordance of pre-initiation and serum testing results, the time taken from medication approval to first injection, and the proportion of patients approved for CAB-LA who were started on the medication.

Qualitative outcomes will include patient and staff perceptions of acceptability, feasibility, satisfaction, and implementation barriers and facilitators related to the direct-to-inject strategy. The study period will include a prospective chart review for up to 12 months following initiation (Aims 1–2) and semi-structured interviews with approximately 30 patients and 10 staff (Aim 3).

Intervention Type
Mixed

Primary outcome(s)
The time between CAB-LA PrEP referral and first CAB-LA injection using the direct-to-inject HIV testing strategy for CAB-LA initiation, measured using EMR abstraction of referral and injection dates to calculate the interval between events for all patients referred from October 1st, 2025, and September 30th, 2026

Key secondary outcome(s))
1. The GHS PrEP CAB-LA Continuum of Care using a direct-to-injection approach measured using EMR abstraction of referral, education, medication authorization, and injection dates to assess completion of each step in the continuum between October 1st, 2025, and September 30th, 2026
2. The appropriateness of using a direct-to-inject HIV testing strategy for CAB-LA initiation, measured using congruence between point-of-care (POC) HIV test results and corresponding serum HIV laboratory results abstracted from the electronic medical record (EMR) at the time of first CAB-LA injection between October 01, 2025 and September 30, 2026
3. Staff and patient perspectives regarding the adoption of same-day POC HIV testing for CAB-LA initiation measured using semi-structured interviews analyzed through thematic analysis within 30 days of CAB-LA initiation for patients and within 12 months of study start for staff

Completion date
30/09/2026

Eligibility

Key inclusion criteria
1. All patients aged 18 and older referred to our clinical CAB-LA program from April 1st 2025, to March 31st 2026, will be eligible for manual chart abstraction of data.
2. All people who initiate CAB-LA with the GHS PrEP program between October 2025 and September 30th 2026, will be eligible to participate in the patient interview.
3. Any healthcare staff who participates in the care of patients on CAB-LA will be eligible to participate in the interview if they:
3.1. Are a licensed CMA, LPN, or APP at GHS

3.2. Have administered at least 5 CAB-LA injections prior to interview
3.3. Have completed at least 5 POC HIV tests prior to interview
3.4. Have completed prior training on CAB-LA administration
3.5. Have completed prior training on POC HIV testing

Participant type(s)
Patient, Health professional

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
Minors, prisoners, cognitive impairment or impaired decision making capacity

Date of first enrolment
01/10/2025

Date of final enrolment
30/09/2026

Locations

Countries of recruitment
United States of America

Study participating centre
Grady Memorial Hospital
80 Jesse Hill Jr Dr SE
Atlanta, Georgia
United States of America
30303

Study participating centre
Grady Ponce De Leon Center
341 Ponce De Leon Ave. NE
Atlanta, Georgia
United States of America
30308

Sponsor information

Organisation
ViiV Healthcare (United Kingdom)

ROR
https://ror.org/01cc9yk21

Funder(s)

Funder type
Industry

Funder Name
ViiV Healthcare

Alternative Name(s)
ViiV Healthcare Limited

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analyzed during the current study are not publicly available to protect participant privacy.

IPD sharing plan summary
Not expected to be made available

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