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ACceptability of long-acting ART in Cognitive ImpAirment (ACACIA)

Submission date
17/01/2024

Recruitment status
Recruiting

Registration date
19/01/2024

Overall study status
Ongoing

Last Edited
07/02/2024

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
This study examines whether people living with HIV (PLWH), who also experience cognitive issues, find taking an injectable long-acting combination antiretroviral therapy (cART) called cabotegravir + rilpivirine (CAB+RPV) once every two months, instead of their normal cART regimen, acceptable and whether it improves health-related quality of life.

Who can participate?
PLWH aged 40 years old and over who have a cognitive impairment and are eligible to switch to long-acting injectable CAB+RPV

What does the study involve?
Participants will be spoken to by their doctor about this research study if they want to switch and are eligible to take long-acting injectable cART. The study will assess their quality of life, cognition, and treatment satisfaction over 11 months.

During this timeframe, they will attend the HIV clinic to receive their cART injections every two months (as is required for this medication) and on the first, second and month-11 visits they will be asked to complete some questionnaires and a computerized cognitive assessment.

Along with this, they may be invited to take part in a one-to-one interview with a researcher to discuss their experiences of taking injectable cART.

What are the possible benefits and risks of participating?
There are no immediate benefits for individuals participating in this study. The questionnaires and interviews conducted in the study aim to furnish NHS clinics with more information about those who derive the most benefit from long-acting injectable cART. Participants will receive a one-time payment of £40 as reimbursement for the time devoted to completing the study procedures.

No significant risks are associated with participating in this study. The study visits coincide with the regular schedule for ART injection appointments. However, engaging in activities such as answering questionnaires, undergoing cognitive assessments, and participating in interviews is

not part of routine care. Participants may experience fatigue during these activities, but they are encouraged to take breaks, and a research nurse will be available for assistance if needed. These methods have proven effective in understanding patient experiences and treatment satisfaction and have been utilized in other trials for many years without posing significant risks. Additionally, participants, especially those involved in one-to-one interviews, may find discussing their experiences with HIV and ART distressing. Participants have the option to discontinue their participation at any time without providing a reason. Moreover, they can discuss any concerns with the research team, someone they trust, such as friends or family, or an independent individual.

Where is the study run from?
The University Hospitals Sussex NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
August 2022 to July 2026

Who is funding the study?
ViiV Healthcare Ltd (UK)

Who is the main study contact?
Dr Kate Alford, K.Alford3@bsms.ac.uk (UK)

Contact information

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Public, Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
322785

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
115VER/322785, IRAS 322785, CPMS 55563

Study information

Scientific Title
An exploratory study of the acceptability, and impact on health-related quality of life of long-acting cabotegravir + rilpivirine in people with HIV and cognitive impairment

Acronym
ACACIA (ACceptability of long-acting ART in Cognitive ImpAirment)

Study objectives
In people living with HIV (PLWH) on effective combination antiretroviral therapy (ART) with cognitive impairment, switching from any standard oral ART-based regimen (PI, NNRTI or INSTI) to long-acting injectable cabotegravir + rilpivirine (CAB+RPV) will be acceptable, tolerable, and associated with improvements in health-related quality of life and cognition

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 16/04/2023, West Midlands - Solihull Research Ethics Committee (UK) (Equinox House, City Link, Nottingham, NG24LA, United Kingdom; +44 (0)207 104 8191; solihull.rec@hra.nhs.uk), ref: 23/WM/0053

Study design
Single-arm single-centre mixed-method study

Primary study design
Observational

Secondary study design
Longitudinal study

Study setting(s)
Hospital, Medical and other records

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
People living with HIV who have a cognitive impairment

Interventions
This study is a 23-month (with a 12-month recruitment period and an 11-month follow-up period per participant), single-arm, single-centre, mixed-methods study examining the acceptability, tolerability and impact of long-acting injectable CAB+RPV on health-related quality of life and cognition in PLWH with cognitive impairment.

This is an observational study which includes some questionnaires and assessments for people living with HIV who have switched to long-acting injectable antiretroviral therapy (ART). This study examines whether people living with HIV, who also experience cognitive issues, find taking an injectable long-acting combination antiretroviral therapy (cART) called Vocabria + Rekambys (generic name: cabotegravir + rilpivirine) once every two months, instead of their normal cART regimen, acceptable and whether it improves health-related quality of life. Participants are required to complete three health-related quality of life questionnaires (WHOQOL-Bref, HIVPROM and DEMQOL), a treatment satisfaction questionnaire (HIVTSQs12) and a brief cognitive assessment (CogniFit) at routine appointments on Day 0 (first switch appointment), week 4 (end of oral ART lead in)(N.B. not CogniFit), and week 48 (study end). A sub-sample of participants, purposively selected to represent the population, will take part in a single in-depth interview with a researcher from week 16 onwards. Additionally, HIV clinical variables will be recorded from routine blood samples taken at each long-acting injectable ART appointment and information on injection schedule completion and any reasons for discontinuation will be captured from patients medical records at the end of the study. All study activities will be held at University Hospitals Sussex NHS Foundation Trust and will be administered and/or supported by a research nurse.

Intervention Type
Behavioural

Primary outcome measure
Health-related quality of life is measured using patient reported outcome measures (DEMQOL, WHOQOL and HIVPROM) at baseline (day 0), week 4 (following oral CAB+RPV lead-in) and at week 48 (study end)

Secondary outcome measures
1. Changes in cognitive function will be measured using the CogniFit at baseline (day 0) and at week 48 (study end)

2. Acceptability of long-acting injectable CAB+RPV will be assessed based on:
2.1. The proportion of participants who complete all scheduled injections over the study period measured using patient medical records at the study end
2.2. The findings from in-depth qualitative interviews conducted with a representative sample of participants and held between 6 and 11 months post-injection commencement
3. Tolerability will be assessed based on:
3.1. The proportion of participants who receive at least 1 injection and who discontinue receiving injections before the full course of injections due to intolerability of injection, frequency of injections or burden of study procedures measured using patient medical records at the study end
3.2. The proportion of participants with serious clinical adverse events measured using patient medical records and medical laboratory abnormalities after 4, 12 and 48 weeks of switching from any ART-based regimen (PI, NNRTI or INSTI) to LA injectable CAB+RPV
3.3. Proportion of participants with plasma HIV RNA<50 copies per mL measured using the Roche assay at weeks 4, 12 and week 48 captured from patient medical records at the study end

Overall study start date
01/08/2022

Completion date
14/07/2026

Eligibility

Key inclusion criteria
1. Eligible for LA injectable ART by the multidisciplinary (MDT) clinical team at University Hospitals Sussex NHS Foundation Trust based on criteria defined by the British HIV Association (BHIVA)
2. HIV-1 positive subjects
3. Age ≥ 40 years old
4. Evidence of clinically significant cognitive impairment, which for this protocol will be defined as participants meeting all of the following criteria:
4.1. Patient-reported symptoms of cognitive impairment (ongoing symptoms)
4.2. Current or past clinical neuropsychological testing reporting cognitive impairment
5. Able to understand the study, sign the consent form, and be willing to undertake all study procedures

Participant type(s)
Patient

Age group
Adult

Lower age limit
40 Years

Sex
Both

Target number of participants

20

Total final enrolment
20

Key exclusion criteria
1. Patient deemed not to be eligible for LA injectable CAB+RPV by the MDT clinical team and based on the criteria defined by BHIVA
2. Existing neurological disease that could affect the ability of patients to participate in the study
3. Current history of major depression or psychosis
4. Recent head injury (past six months)
5. Current alcohol abuse or drug dependence
6. Has completed the CogniFit assessment in the last year for clinical or research purposes

Date of first enrolment
13/11/2023

Date of final enrolment
14/10/2025

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
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Sponsor type
University/education

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ROR
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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

Publication and dissemination plan
The results of the study will be presented in relevant national and international congresses and will be submitted for publication to relevant peer-reviewed international scientific journals. Clinical investigators will adequately and thoroughly inform the participants at each site about the preliminary and final results of the study

Intention to publish date
14/10/2026

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