High Acceptability and Safety of Out-of-Hospital Cabotegravir and Rilpivirine Administration (HOLA Study)

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BACKGROUND

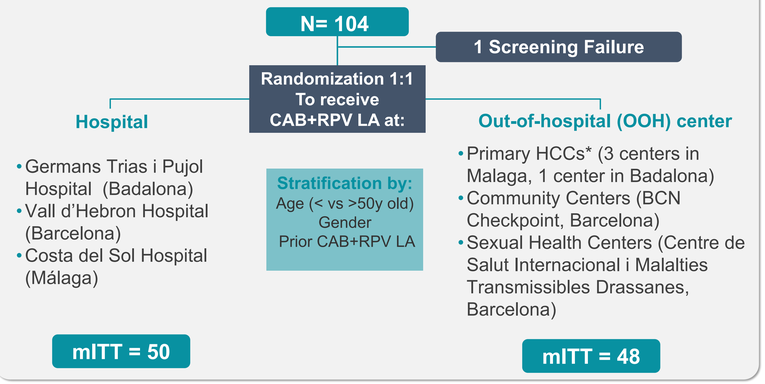
- Long-acting (LA) injectable antiretroviral therapy (ART) with cabotegravir and rilpivirine (CAB+RPV) may improve **convenience, adherence and quality of life for people with HIV** (PWH).
- While its efficacy and safety have been demonstrated in clinical trials and real-world studies, **administration is often limited to hospital settings**, which may pose logistical barriers.

The HOLA study evaluates the **acceptability and safety of CAB+RPV LA administration in alternative settings in Spain**—particularly in primary care and community-based centers.

Trial registration no.: **NCT06185452**/EUCT: **2023-503963-41-00**

METHODS

HOLA Study[1]: A 12-month, prospective, hybrid (implementation-effectiveness), phase IV, open-label study in PWH, who are undetectable (VL<50c/mL) and are starting or being treated with CAB+RPV LA



Primary outcomes:

- Acceptability at month 12 (Acceptability of Intervention [AIM]) from the point of view (PoW) of PWH.
- Safety (drug-related AEs and drug-related discontinuations).

Main secondary outcomes:

- Feasibility (Feasibility of Intervention [FIM]) and appropriateness (Intervention Appropriateness [IAM]) at month 12, from the PoW of PWH.
- Satisfaction with treatment (HIVTSQc) at month 12.
- Patient Reported Outcome Measures by HIV Clinic Screening Tool (PROMS-CST-HIV) at month 12.

The AIM, IAM and FIM are four-item measures of implementation outcomes, whose scale values range from 1 to 5. Reported statistics employed the use of the Wilcoxon rank sum test and 2-sample test for equality of proportions with continuity correction.

*HCC: healthcare centre; BL: baseline

[1]Negredo E, et al. BMJ Open 2025;15:e088514. doi:10.1136/bmjopen-2024-088514

Findings from the HOLA study provide additional evidence on the acceptability and safety of delivering CAB+RPV LA outside hospital settings and provide data to inform scalable, person-centered models of care for PWH.

Table 1. Baseline characteristics of the study participants.

	Hospital Group N = 50	OOH Group N = 48
Age, mean (SD)	38.6 (8.99)	39.5 (9.78)
Gender identity, n (%)		
Cis men	48 (96%)	44 (92.2%)
Cis women	1 (2%)	4 (7.8%)
Trans women	1 (2%)	0 (0%)
Ethnicity, n (%)		
Caucasian	35 (70%)	36 (75%)
Latin	13 (26%)	9 (18.75%)
Other	2 (4%)	3 (6.25%)
Mode of transmission, n (%)		
Men who have sex with men	41 (82%)	36 (75%)
Heterosexual contact	3 (6%)	8 (16.7%)
Other	6 (12%)	4 (8.3%)
Years since diagnosis, mean (SD)	8.48 (5.63)	8.27 (7.16)
CAB+RPV LA at BL*, n (%)	44 (88%)	42 (87.5%)
Viral load <50 c/mL, n (%)	50 (100%)	48 (100%)

Table 2. Adverse events (in ITT population).

	Hospital Group	OOH Group
Adverse events, n (%)	38 (73%)	38 (73%)
Grade 1	16 (42%)	24 (63%)
Grade 2	21 (55.3%)	14 (37%)
Grade 3-4	0 (0%)	0 (0%)
SAEs	1 (2.7%)	0 (0%)
Drug-related AEs	13 (34%)	18 (47%)
Drug-related discontinuations	1	0

ADDITIONAL INFORMATION

This work has been carried out within the framework of the Doctoral Program in Medicine of the Autonomous University of Barcelona. The study has received funding from ViiV Healthcare (award number #219546). Author Contact Information: enegredo@lluita.org

RESULTS

Primary endpoints:

- 98 PWH have completed all visits and questionnaires (**Table 1**).
- **Safety data was comparable** across groups **(Table 2)**:
  - No virological failures.
  - **1 discontinuation in the Hospital Group** due to a drug-related AE (injection site pain).
  - **3 discontinuations in the OOH Group** due to withdrawal of ICF.
- At month 12, **acceptability** was high across both groups (p= 0.182) (**Table 3**).

Secondary endpoints:

- Differences across groups at month 12 were significant in terms of **appropriateness** (AIM) (Δ= 0.30, p=0.042) and **feasibility** (FIM)(Δ= 0.24, p=0.029), in favor of OOH Group (**Table 3**).
- **Satisfaction with treatment** (HIVTSQ) was overall good in both groups at month 12 (Δ= 0.66, p=0.59).
- Potential psychosocial benefits of OOH administration (PROMS-CST-HIV) from baseline to month 12 were seen in the emotional distress (Δ=-0.42 in OOH Group, Δ=-0.08 in the Hospital Group, p=0.28), and social support (Δ=0.23 in OOH Group, Δ=-0.02 in the Hospital Group, p=0.31) domains. However, differences were not statistically significant.

Table 3. Acceptability, appropriateness and feasibility measures at 12 months, proportion of participants with scores >4 (of a maximum score of 5); and satisfaction with treatment (HIVTSQc).

	Hospital Group	OOH Group	p-value
Acceptability of Intervention (AIM), mean (SD)	4.28(1.05)	4.43 (1.06)	0.182
AIM > 4, n (%)	39 (78%)	40 (83.3%)	0.680
Intervention Appropriateness (IAM), mean (SD)	4.06 (1.11)	4.36 (1.16)	**0.042**
IAM > 4, n (%)	34 (68%)	39 (81.2%)	0.203
Feasibility Intervention (FIM), mean (SD)	4.17 (1.08)	4.41 (1.13)	**0.029**
FIM **>** 4, n (%)	36 (72%)	40 (83.3%)	0.270
Satisfaction (HIVTSQc), mean (SD)	26.40 (6.07)	27.06 (5.30)	0.591

CONCLUSIONS

- Implementation of CAB+RPV LA in out-of-hospital facilities is equally **acceptable,** but more feasible and appropriate from the point of view of PWH, **without compromising safety**, nor satisfaction with treatment.
- A **collaborative approach** with primary care and community centers is beneficial, but voices of PWH need to be considered during implementation.
- **Psychosocial benefits** may be derived in terms of emotional distress and social support.

PLAIN LANGUAGE SUMMARY

CAB+RPV LA injections given outside the hospital are safe, well-liked, and acceptable for people with HIV.