P099

FEASIBILITY AND SATISFACTION OF INTERVENTIONS MEASURES (FIM and HIVTSQ) OF IMPLEMENTATION OF LONG-ACTING CAB + RPV ADMINISTRATION OUT OF HIV UNITS: The IMADART study

Alfonso Cabello[1], Irene Carrillo[1], Aws Al-Hayani[1], Marta López[1], Cristina Algar[2], Inmaculada Burillo[2], Beatriz Álvarez[1], Laura Prieto[1], Ignacio Mahíllo-Fernández[2], Macarena Bonilla[2], Laura García[3], José Manuel Caraballo[4], Mónica Esparis[4], Beatriz Gallego[5], Javier Bécares[3], Miguel Górgolas[1]

1Infectious Diseases Division. Fundación Jiménez Díaz University Hospital. FJD - Health Research Institute. Autónoma University of Madrid (UAM). 2 Fundación Jiménez Díaz Health Research Institute (IIS-FJD) 3 Pharmacy Department. Fundación Jiménez Díaz University Hospital. IIS-FJD. 4 Specialist-Care centres. 4 Polyvalent Day Hospital

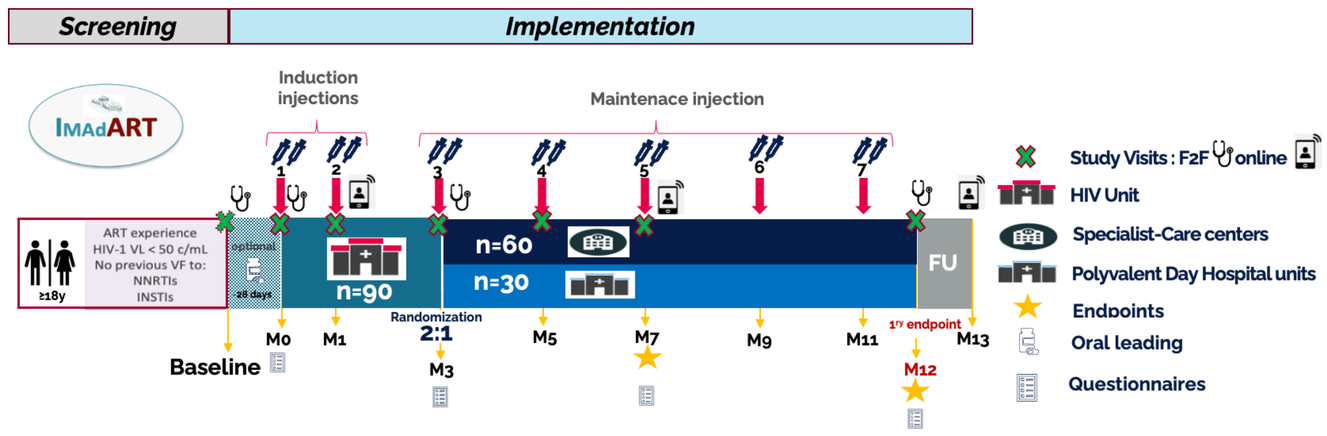
BACKGROUND

Long-acting (LA) CAB LA and RPV LA has shown to be acceptable and feasible for the maintenance of HIV suppression for PWH. The real-world implementation in different health settings outside the hospital HIV Units and closer to patient's neighborhoods still have some challenges and lack of knowledge. Our aim is to evaluate the feasibility of CAB LA + RPV LA administration, as perceived by patients focus upon Polyvalent Day Hospital units vs Specialist-Care centers (out of HIV units). We present the results of the 3-month follow-up.

MATERIALS & METHODS

Phase IV, open-label, randomized, double-arm, implementation-effectiveness multicentre clinical trial, assessing the Feasibility of Intervention Measure of (FIM) and satisfaction of CAB LA + RPV LA administering in different healthcare settings (1:2): Polyvalent Day Hospital (PDH) units and Specialist-Care centres (SCC). Participants completed questions to explore psycological challenges relating to HIV treatment (baseline), and FIM (baseline – month 3), HIVTSQ (baseline – month 3) and Preferred oral vs LA (baseline) questionnaires. The scores were summarized by mean and standard deviation or by median and interquartile range. Changes were summarized by mean or median and the 95% confidence interval. Statistical comparisons were performed using, Mann-Whitney U test to compare centers, and Wilcoxon signed-rank test to compare baseline and 3 months values.

Study outline



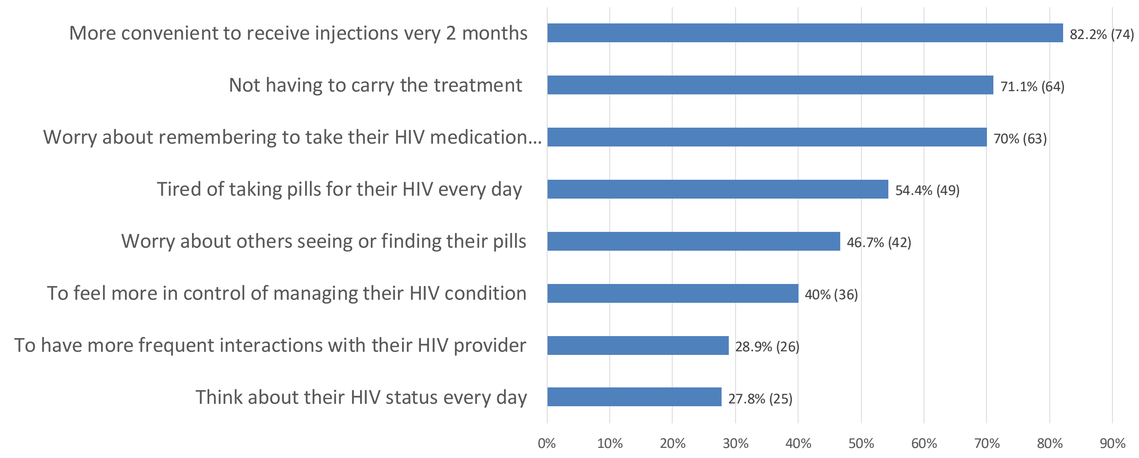
RESULTS

Table 1. Participant's baseline characteristics*[1]

Age (years) (median – IQR)		44 (36-51)
Gender at birth	Male / Female	85 (94.4%) / 5 (5.6%)
HIV transmission	MSM / MSW / IDU/ unknown	81 (91.0%) / 4 (4.5%) / 3 (3.4%) / 1 (1.1%)
Race	Caucasian / Latinamerican / others	72 (80.0%) / 17 (18.9%) / 1 (1.1%)
Chemsex use	Yes	28 (31.1%)
Hepatitis B co-infection	HBsAg / Anti-HBc / Anti-HBs +	0% / 16 (18.0%) / 56 (62.2%)
CD4 cells/mm^3 (mean – SD)	Baseline CD4+	843 ± 325
Median time with HIV (years)		9.3 (IQR: 6.1-14.1)
Median time with ART (years)		8.6 (IQR: 5.9-12.7)
Previous drug resistance testing not available		47 (52.2%)

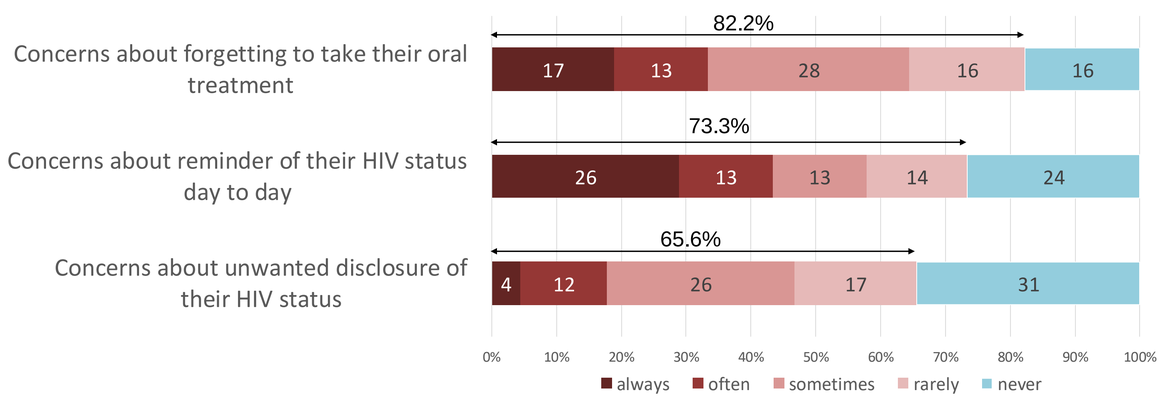
*[1] Five (5.6%) participants had Anti-HBc+ and Anti-HBs-

Figure 1. Reasons to prefer switch to long-acting treatment*[2]



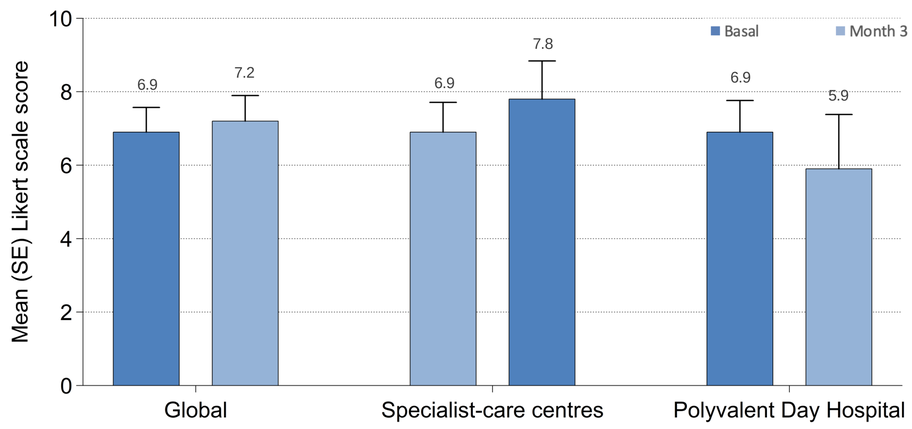
***[2] Preferred oral vs LA: 85 (94.4%) preferred LA; 5 (5.6%) reported no preference (baseline)**

Figure 2. Concerns reported by patients about the last 6 months*[3]



***[3] Questions to explore psycological challenges relating to HIV treatment (baseline)**

Figure 3. Feasibility Implementation Measure (FIM)*[4]



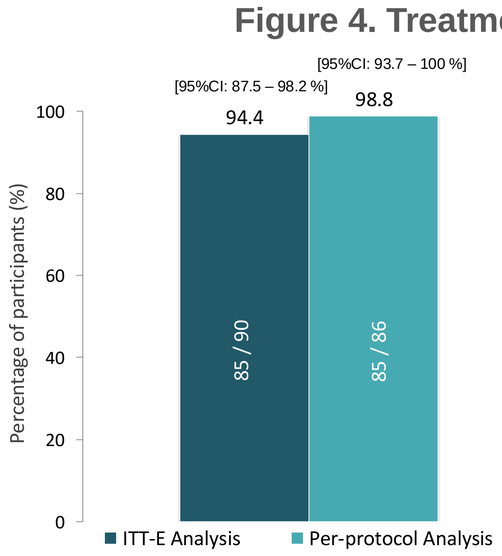
***[4] Five-point Likert-type scale: strongly disagree (-2 points), disagree (-1), neither agree nor disagree agree (0), agree (+1), strongly agree (+2); Maximum score = +10; mínimum score = -10. SE: standard error**
[#]Baseline visit was conducted in HIV Unit

Table 2: Treatment satisfaction (HIVTSQs score)*[5]

	Baseline	Month 3	
Total Score [median (IQR)]	55 (49 – 63)	64 (56 – 66)	
Median (95% CI) change from baseline to Month 3			
Global	**+ 5.5** (1.5 – 9)		*p = 0.011*
Specialist-Care-Centres	+ 3.5 (-4 – 9)		
Polyvalent Day Hospital	**+ 8.5** (4 – 13)		*p = 0.005*

***[5]** Due to the skewness of the data distribution, HIVTSQs were summarized using medians instead of means. No differences between PDH and SCC was observed.

Figure 4. Treatment persistence at month 3 *[6]



Discontinuations	5 (5.6%)
Injection site reaction (ISR)	1 (1.1%)
Withdrawal of consent (change of city address or patient decisión)	3 (3.3%)
Researcher discretion (lack of adherence to visit schedules)	1 (1.1%)

***[6] HIV-1 RNA viral load was not measured per protocol at Month 3. At Month 1, 90/90 participants had an HIV-1 RNA viral load < 50 c/mL. None discontinuation due to adverse events (excluding ISRs)**

CONCLUSIONS

Treatment with CAB LA + RPV LA administered in different healthcare settings, outside of HIV units, is feasible after 3 months of switching from oral-ART and show high treatment satisfaction by participants. High viral suppresion levels were maintained by PWH without protocol defined virologic failure, and nor discontinuations by AEs - excluding ISRs.
This is a short 3 months of following-up and longer follow-up will be needed to reassure these conclusions.

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