The Implementation of Every 2 Months Cabotegravir and Rilpivirine Long-Acting Injections From the Perspective of Healthcare Providers in the German CARLOS Cohort, 6-Month Outcomes

Key Takeaways

- The CARLOS study is a prospective, non-interventional, 3-year multicenter cohort study that provides the first insights into healthcare provider (HCP) perspectives on the real-world implementation of cabotegravir + rilpivirine long-acting (CAB + RPV LA) in Germany.
- Most patients could return to their daily activities immediately following treatment, with HCPs identifying multiple techniques to minimize pain during injection and giving advice to reduce soreness after injection.
- Although some concerns surrounding LA therapy remained during the first 6 months, the overall feeling about CAB + RPV LA implementation was positive for the majority of HCPs.

Introduction

- CAB + RPV LA is the first complete LA regimen recommended in treatment guidelines for the maintenance of viral suppression in people living with HIV (PLHIV).
- The prospective CARLOS cohort study is a non-interventional, 3-year multicenter study conducted in PLHIV who switched from suppressive daily oral therapy to CAB + RPV LA administered every 2 months (Q2M), in accordance with the label in routine clinical care in Germany.
- This interim analysis at Month (M) 6 summarizes HCP perspectives on the Implementation of CAB + RPV LA in a real-world setting.

Results

- Between April 2021 and May 2022, 21 of 22 participating HIV clinics and private practices had recruited 347 HCPs, of whom 29 were from the CARLOS study centers (n=14). Figures 3 and 4
- Most patients could return to their daily activities immediately following treatment, with HCPs estimating that 80% of patients (n=12/20) could do so immediately after injection.
- Table 1. HCP Occupation and Clinical Trial Experience

<table>
<thead>
<tr>
<th>Parameter</th>
<th>n (%)</th>
<th>Baseline (n=43)</th>
<th>M6 (n=38)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Investigator/physician</td>
<td>20 (47)</td>
<td>18 (42)</td>
<td></td>
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<tr>
<td>Prior experience with CAB + RPV LA</td>
<td>12/20 (60)</td>
<td>9/16 (56)</td>
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<tr>
<td>Administrators</td>
<td>11/20 (55)</td>
<td>9/16 (56)</td>
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<tr>
<td>Nurse</td>
<td>16 (37)</td>
<td>14 (37)</td>
<td></td>
</tr>
<tr>
<td>Prior experience with CAB + RPV LA</td>
<td>11/16 (69)</td>
<td>6/14 (43)</td>
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</tr>
<tr>
<td>Administrators</td>
<td>13/16 (81)</td>
<td>10/14 (71)</td>
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<tr>
<td>Office staff</td>
<td>7 (16)</td>
<td>8 (21)</td>
<td></td>
</tr>
<tr>
<td>Prior experience with CAB + RPV LA</td>
<td>5/7 (71)</td>
<td>6/8 (75)</td>
<td></td>
</tr>
<tr>
<td>Administrators</td>
<td>0/7</td>
<td>0/8</td>
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</tbody>
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HCP Perception on the Implementation of CAB + RPV LA

- At M6, the overall feeling about implementing CAB + RPV LA was positive in 92% (extremely positive 21%; very positive 42%; somewhat positive 29%) of HCPs (n=36/38) and was similar between those with or without prior trial experience (90% [n=19/21] vs. 94% [n=16/17], respectively).
- Overall, 73% (n=27/37) of HCPs spent ≤120 minutes, 14% (n=5/37) spent 21–40 minutes, and 14% (n=5/37) spent >40 minutes per week to ensure patients’ attendance at the next injection appointment.

Average Time Patients Spent in the Clinic/Practice for Each Injection Visit

- At M6, the average time patients spent in clinic/practice for each injection visit was estimated to be 21–40 minutes by 50% of HCPs (n=19/38), and ≤20 minutes by 37% of HCPs (n=14/38) (Figure 1).
- Overall, 66% of HCPs (n=25/38) considered the time spent in clinic as extremely or very acceptable for patients (≥12/18 somewhat acceptable).

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- Overall, 66% of HCPs (n=25/38) considered the time spent in clinic as extremely or very acceptable for patients (≥12/18 somewhat acceptable).

Figure 1. Time Spent in Clinic/Practice (Expectation at Baseline and Estimate at M6)

- Most patients could return to their daily activities immediately following treatment, with HCPs identifying multiple techniques to minimize pain during injection and giving advice to reduce soreness after injection.
- Although some concerns surrounding LA therapy remained during the first 6 months, the overall feeling about CAB + RPV LA implementation was positive for the majority of HCPs.

Methods

- Implementation questionnaires were completed by HCPs at baseline and M6.
- Questionnaires related to the following aspects: prior experience, barriers to and facilitators of implementation, as well as experiences and impressions of implementing CAB + RPV LA.
- Up to four staff members per site could complete the questionnaires.
- Staff members included physicians, nurses/administering the injections, or other office staff involved in the care of PLHIV on CAB + RPV LA.
- This interim M6 analysis includes quantitative data from HCPs at 22 sites.

Pain-Reducing HCP Techniques and Advice Reported at Month 6

- Figures 3 and 4 show HCP techniques used to minimize pain during injection and HCP advice for reducing soreness after the injection.

Figure 3. Techniques to Minimize Pain During Injection (n=38; Multiple Responses Possible)

- Slow speed of pushing intramuscular injections
- Having patient relax and rest prior to injection
- Assuring medication being at room temperature
- Distraction during injection
- Using pain reliever prior to injection

Figure 4. Advice Provided for Reducing Soreness After the Injection (n=38; Multiple Responses Possible)

- Taking over-the-counter pain relievers
- Using cold compresses
- Avoiding prolonged sitting
- Light stretching/overexertion
- Using a hot compress

Implementation Concerns Over the Course of 6 Months

- Of the implementation concerns listed in Figure 5, patients’ ability to comply with injections and the potential risk of developing resistance were most commonly raised by HCPs.
- Most concerns identified at baseline showed slight numeric decreases in mean score at M6.

Figure 5. HCP Concerns Regarding the Implementation of CAB + RPV LA Therapy in Clinical Routine at Baseline and M6

- Risk of resistance for patients not adherent to the injection
- Ability to identify and flag missed injections/appointments
- Receiving missed injections
- Scheduling of appointment reminders
- Patients’ ability to keep appointments every 2 months
- Enough staff to administer injection on a daily basis
- Time to administrate the injection
- Patients experiencing adverse drug reactions
- Compelling clinic priorities
- Patients’ tolerability of injection pain
- Understanding when/how to reinitiate treatment
- Getting proper medication being at room temperature

Limitation

- The comparison of HCP assessments at baseline and M6 was made at the center level (vs. at the level of the individual); individual respondents may have been different between baseline and M6, leading to possible bias in the comparison.

Conclusions

- In this real-world cohort, HCPs had an overall positive opinion on CAB + RPV LA implementation, with most concerns from baseline decreasing at M6.
- The estimated time patients spent in the clinic/practice for injection visits was <40 minutes for the majority of HCPs.
- These results support the real-world implementation of CAB + RPV LA as a complete regime for the maintenance of HIV-1 virologic suppression.


Table 1. HCP Occupation and Clinical Trial Experience

- Investigator/physician | 20 (47) | 18 (42) |
- Prior experience with CAB + RPV LA | 12/20 (60) | 9/16 (56) |
- Administrators | 11/20 (55) | 9/16 (56) |
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- Prior experience with CAB + RPV LA | 5/7 (71) | 6/8 (75) |
- Administrators | 0/7 | 0/8 |

HCP, healthcare provider; LA, long-acting; M, month; M6, 6-months; RPV, rilpivirine; CAB, cabotegravir; HCP, healthcare provider; n, number.