Interim Week 48 Results in Young South Africans on Long-Acting Injectable ART: the AFINAty Study

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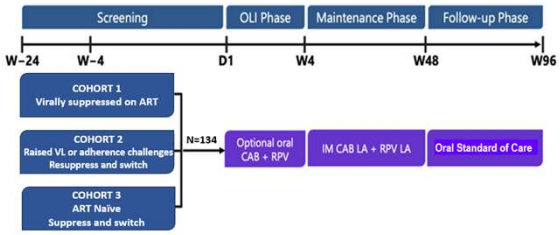
BACKGROUND

- South Africa has the largest population of people living with HIV (PLWH), with young people being disproportionately affected.
- Adolescents and young adults living with HIV (YLHIV) are a population who face antiretroviral therapy (ART) adherence challenges, particularly with oral tablets.
- Long-acting injectable (LAI) formulations, such as cabotegravir and rilpivirine, have the potential to address some of these challenges, including pill fatigue, stigma and disclosure.

We conducted a study to determine the acceptability and feasibility of delivering LAI ART to YLHIV in a community setting in Cape Town, South Africa.

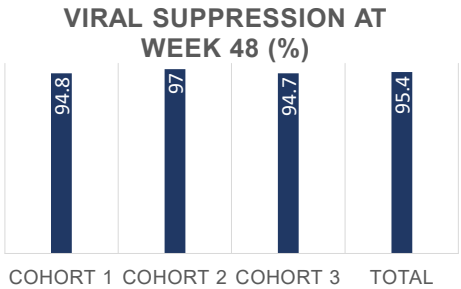
METHODS

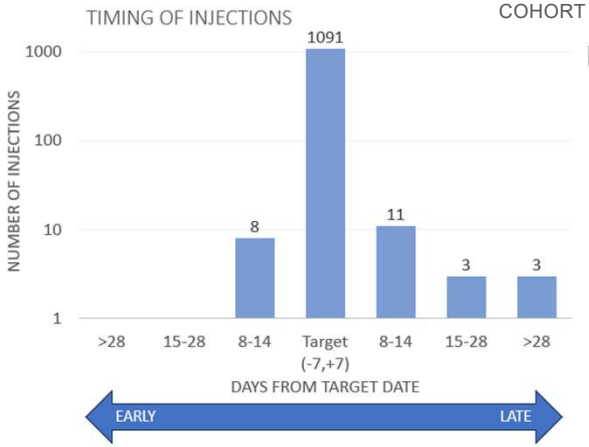
- We enrolled YLHIV, on or starting first-line ART, aged 12-24 years in 3 cohorts: 1) those who are virally suppressed (<50 copies/mL) and adherent to ART; 2) those who are virally unsuppressed or have evidence of recent adherence challenges, and 3) those who are ART naïve.
- We allowed for up to 24 weeks of screening during which viral suppression (<50 c/mL) could be achieved on first-line oral ART.
- When virally suppressed, YLHIV were offered a switch to cabotegravir and rilpivirine LAI administered every 8-weeks, with an optional oral lead-in.
- Viral load was measured at Week 24 and Week 48 after switching.
- Qualitative assessments were made through serial individual interviews.

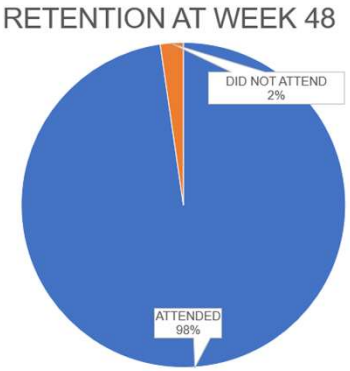


Long-acting injectable ART is an effective, acceptable, and feasible treatment option for youth living with HIV in Cape Town, South Africa

Age & gender	Cohort 1	Cohort 2	Cohort 3
Total	59	35	40
Female sex at birth: n(%)	37 (63.8)	15 (42.86)	31 (81.6)
Age (years): mean (SD)	19.1 (15.7-22.5)	19.3 (16.5-22.2)	20.3 (18.3-22.4)
Under 18 years: n(%)	18(31)	9(25.1)	4 (10.3)







RESULTS

- 172 participants were enrolled across 3 cohorts, of which 134 were virally suppressed after screening and switched to LAI.
- As of 24 February 2025, 130 participants were expected to have reached Week 48.
- 128/130 **(97.7%) attended the Week 48 visit.**
- There was one lost-to-follow-up and one transferred out of the study area.
- At Week 48, 124/130 **(96.9%) suppressed** to <50 copies/mL.
  - There were 4 participants with VL >50 copies/mL.
  - All had low-level viraemia [254(C1), 261(C1), 60(C3), and 54(C2) copies/mL].
  - All resuppressed prior to the next injection.
- 25/1116 (2.2%) of follow-up injection visits have been conducted outside of the window.
- There have been no drug-related severe or serious adverse events to date.
- Qualitative assessments have confirmed this regimen is highly acceptable to YLHIV.

CONCLUSIONS

- High retention and high viral suppression rates at Week 48 have been demonstrated in this community-based cohort of YLHIV in Cape Town, South Africa.
- Long-acting cabotegravir and rilpivirine LAI are an effective, acceptable and feasible treatment option.
- **LAI should be considered a priority in national ART programs for adolescents and young adults living with HIV.**

ADDITIONAL KEY INFORMATION

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