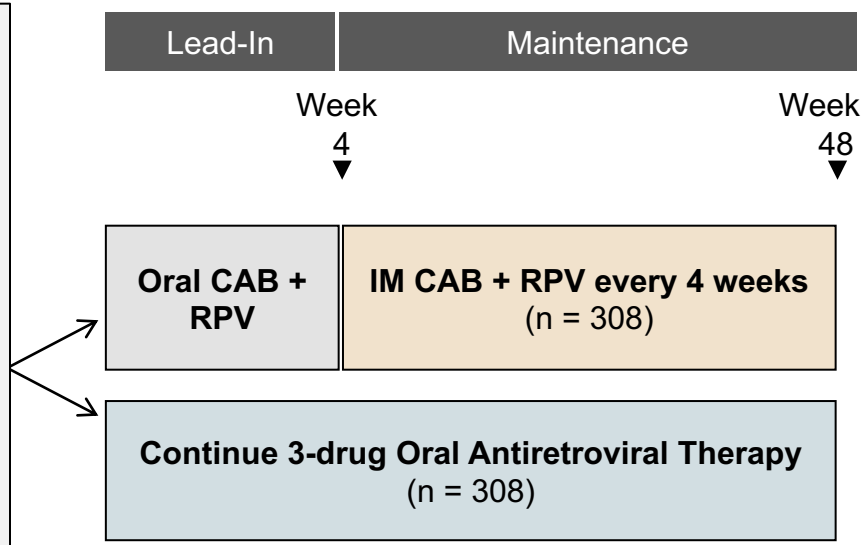
Long-Acting IM Cabotegravir and IM Rilpivirine for HIV Maintenance

ATLAS Study

National HIV Curriculum

Long-Acting IM Cabotegravir and IM Rilpivirine for HIV Maintenance ATLAS Study: Design

- **Background**: Phase 3, randomized, open-label trial assessing IM cabotegravir plus IM rilpivirine after oral induction for adults taking a 3-drug oral antiretroviral therapy regimen
- **Inclusion Criteria**
  - Age ≥18 years
  - Taking 2NRTIs+INSTI, NNRTI, or PI
  - Stable ARV regimen ≥6 months
  - HIV RNA <50 copies/mL ≥6 months
  - No history of virologic failure
  - No INSTI or NNRTI resistance, except that K103N mutation allowed
  - No chronic hepatitis B



Abbreviations: CAB = cabotegravir; RPV = rilpivirine

Source: Swindells S, et al. N Engl J Med. 2020;382:1112-23.

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ATLAS Study: Baseline Characteristics

ATLAS: Baseline Characteristics

Characteristic	IM CAB + RPV (n = 308)	Oral ART (n = 308)	Overall (n = 616)
Age, years, median	40	43	42
Female, n, %	99 (32)	104 (34)	203 (33)
White, n, %	214 (69)	207 (67)	421 (68)
Black, n, %	62 (20)	77 (25)	139 (23)
Median body-mass index	26	26	26
CD4 count <350 cells/mm^3, n, %	23 (7)	27 (9)	50 (8)
Time since first ART (months), median, range	52 (7-222)	52 (7-257)	52 (7-257)
Third class agent, n, %	6	6	6
NNRTI	155 (50)	155 (50)	310 (50)
INSTI	102 (33)	99 (32)	201 (33)
PI	51 (17)	54 (18)	105 (17)

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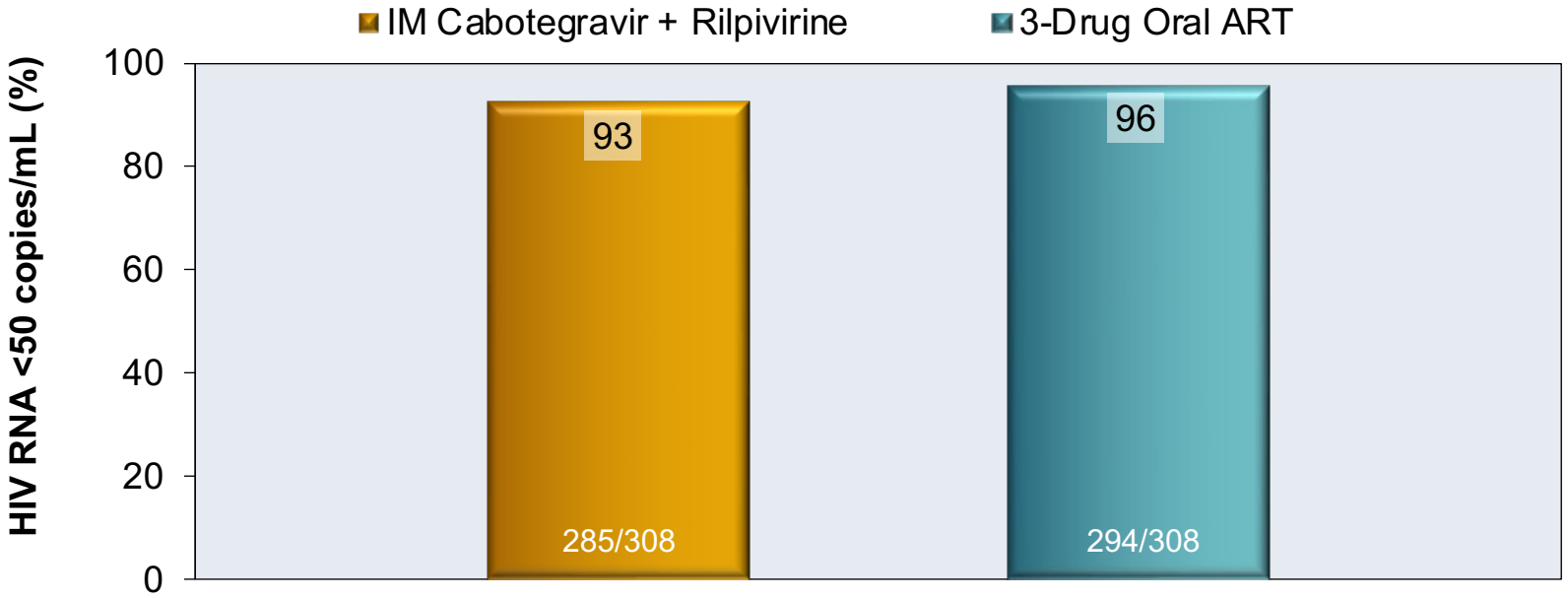
Long-Acting IM Cabotegravir and IM Rilpivirine for HIV Maintenance ATLAS Study: Results

Weeks 48: Virologic Response by FDA Snapshot Analysis



HIV RNA ≥50 copies/mL at 48 weeks: 2 % CAB + RPV, 1% 3-drug oral ART

Source: Swindells S, et al. N Engl J Med. 2020;382:1112-23.

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ATLAS Study: Results

Participants in the IM CAB-RPV arm with Viral Rebound Meeting Protocol-Defined Criteria for Genotype Resistance Testing

Country, HIV-1 Subtype	At Baseline		At Virologic Failure	
	INSTI RAMs	NNRTI RAMs	HIV RNA	INSTI RAMs
Russia, A/A1	L74I	E138E/A	25,745 copies/mL	L74I
F, France, AG	None	V108V/I, E138K	258 copies/mL	None
M, Russia, A/A1	L74I	None	1841 copies/mL	N155H, L74I

There were also 4 virologic failures in the oral ART arm; new RAMs detected included one G190S, one M184I, and one M230M/I.

Abbreviations: RAMs = resistance associated mutations

Source: Swindells S, et al. N Engl J Med. 2020;382:1112-23..

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ATLAS Study: Adverse Events

Injection Site Reactions (ISRs)	
Type of Reactions	**Participants (%) with Reaction**
Participants who received injections, n	303
Any reaction, n (%)	250 (81)
Pain, n (%)	231 (75)
Grade 3 pain, n, (%)	10 (3)
Pain leading to withdrawal	4 (1)
Nodule, n (%)	37 (12)
Induration, n (%)	30 (10)
Swelling, n (%)	23 (7)
Median duration of reaction, days	3
The majority of ISRs (99%) were grade 1-2; 88% resolved within 7 days.	

Source: Swindells S, et al. N Engl J Med. 2020;382:1112-23.

Long-Acting IM Cabotegravir and IM Rilpivirine for HIV Maintenance
ATLAS Study: Conclusions

Conclusions: “Monthly injections of long-acting cabotegravir and rilpivirine were noninferior to standard oral therapy for maintaining HIV-1 suppression. Injection-related adverse events were common but only infrequently led to medication withdrawal.”

Source: Swindells S, et al. N Engl J Med. 2020;382:1112-23.

Acknowledgments

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AETC AIDS Education & Training Center Program

National HIV Curriculum

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