

THE LANCET HIV

Supplementary appendix

This appendix formed part of the original submission and has been peer reviewed. We post it as supplied by the authors.

Supplement to: Jongen VW, Wit FWNM, Boyd A, et al. Effectiveness of bi-monthly long-acting injectable cabotegravir and rilpivirine as maintenance treatment for HIV-1 in the Netherlands: results from the Dutch ATHENA national observational cohort. *Lancet HIV* 2024; **12**: 40–50.

Supplement to

Effectiveness of injectable long-acting cabotegravir and rilpivirine for the treatment of HIV-1: results from the Dutch ATHENA national observational cohort

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Supplementary Table 1. Restricted mean survival time and time lost until loss of virologic control

	Exposed		Unexposed		Between group contrast			
	Estimate	95% CI	Estimate	95% CI	Difference ³	95% CI	Ratio ⁴	95% CI
Restricted mean survival time¹	2.964	(2.296-3.002)	2.938	(2.898-2.977)	0.026	-0.029 - 0.080	1.009	0.990-1.028
Restricted mean time lost²	0.070	(0.032-0.108)	0.096	(0.056-0.135)	NA	NA	0.730	0.370-1.443

1. Indicates the expected survival time until virological failure for a patient using CAB/RPV or a standard ART regimen
2. Indicates the survival time lost up to the minimum largest observed event time (i.e., 3.034 years)
3. Calculated as $RMST_{exposed} - RMST_{unexposed}$
4. Calculated as $RMST_{exposed}/RMST_{unexposed}$ or $RMT_{exposed}/RMT_{unexposed}$

Supplementary Table 2. Reasons for switching ART

	Exposed (n=57)		Unexposed (n=136)	
	<i>n</i> ^a	(%) ^a	<i>n</i> ^a	(%) ^a
Loss of virologic control	7	12%	0	0%
Adverse events¹	28	49%	48	35%
Return to previous ART regimen	5	9%	0	0%
Patient wish	5	9%	2	1%
Interaction with co-medication	0	0%	6	4%
Regimen simplification	0	0%	51	38%
Pregnancy related	0	0%	3	2%
Precaution	3	5%	17	13%
Adherence problems	1	2%	1	0.7%
Other/unknown reason	8	14%	8	6%

1. Two individuals who experienced loss of virologic control re-suppressed spontaneously but later switched to an oral ART due to an adverse event.

Supplementary Table 3. Characteristics of patients using CAB/RPV with loss of virologic control

	#1	#2	#3	#4	#5	#6	#7	#8	#9	#10	#11	#12	#13	#14
Age, years	45	56	39	57	33	50	37	49	75	31	36	49	36	31
Gender	Male	Male	Male	Male	Male	Male	Transgender female	Male	Male	Male	Male	Male	Male	Male
Region of origin	Caribbean/Latin America	Caribbean/Latin America	Caribbean/Latin America	Caribbean/Latin America	Sub-Saharan Africa	The Netherlands	The Netherlands	Caribbean/Latin America	The Netherlands	The Netherlands	Europe/North America/Australia	Sub-Saharan Africa	Other	Caribbean/Latin America
HIV transmission category	MSM	MSM	MSM	Heterosexual	Heterosexual	Heterosexual	MSM	MSM	Heterosexual	MSM	Unknown	MSM	MSM	MSM
BMI >30 kg/m² at start follow-up	No	No	Yes	No	No	Yes	No	Yes	No	No	No	No	Yes	No
BMI >30 kg/m² around moment of loss of virologic control	No ⁴	No	Yes	No	Not available	Yes	Not available	Yes	Yes	Yes	No	No	Yes	No
Longer needles used	No	No	Yes	No	No	Yes	No	No	No	Yes	No	No	No	No
HIV subtype A6¹	No	No	Not available	No	Not available	Not available	Not available	No	No	No	No	No ⁶	Yes	No ⁷
Years since start ART	13	18	15	16	8.5	7.5	6.7	7.6	5.2	5.2	2.4	12	7.2	1.9
Nadir CD4	260	90	350	10	320	70	270	140	130	1,250	290	Unknown	Unknown	440
CD4 at start follow-up	757	780	920	397	800	810	670	1,010	410	1,220	730	670	270	440
Blips before start follow-up^{2,3}	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Blips during follow-up²	1	0	0	1	0	2	1	0	0	0	0	0	0	0
Oral lead-in	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes
IM injections within window	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Time since last viral load measurement, months	8.0	5.5	6.0	7.2	5.7	1.9	7.0	5.8	7.3	0.2	15.1	4.8	4.7	1.8
HIV RNA at loss of virologic control, c/mL	331	261 2 months later 614,761	338	275	334 4 days later 503	200	15000	94,230 1 month later 14,510	215	600	1,471	3,750	635 13 days later 814	1,738 5 days later 1,413
Time until loss of virologic control, days	422	123	494	600	551	384	269	278	280	116	1,173	86	234	144
Re-suppression without ART change	Yes	No	Yes	Yes	No	Yes	No	No	Yes	Yes	No	Yes	No	No
Follow-up available after re-suppression, days	35	NA	0	0	NA	35	NA	NA	441	0	0	66	NA	NA

ART switch after loss of virologic control	No	Yes	No	No	Yes	No	Yes	Yes	Yes ⁵	Yes ⁵	Yes	No	Yes	Yes
RAMs detected after loss of virologic control¹	Not done	INI: 155H RT: 101E+13 8K+ 230L	Not done	Not done	RT: Y188L	Not done	INI: 148R RT: 101E+138K	INI: 140CS+148 R RT: 101E	Not done	Not done	Attempt failed ⁹	Not done	INI: 155S RT: 138K	INI: L74I+ V165I RT: Y181C+H 221Y
CAB concentration at loss of virologic control	Not done	Not done	Not done	Not available ⁷	1.31 mg/L	1.86 mg/L	2.50 mg/L	Not done	Not done	Not done	Not available ⁷	Not done	0.91 mg/L	Not done
RPV concentration at loss of virologic control	Not done	Not done	Not done	Not available ⁷	0.115 mg/L	0.085 mg/L	0.005 mg/L	Not done	Not done	Not done	Not available ⁷	Not done	0.026 mg/L	Not done

1. HIV-1 sequence analysis interpreted with IAS-USA resistance tables and Comet subtype tool
2. Blip was defined as a viral load between 50-199 copies/mL.
3. Presented as the number of blips in the 2 years prior to start of follow-up.
4. BMI measured 16 months before virological failure
5. Change in ART regimen was due to an adverse event, after viral load was undetectable.
6. Individual had HIV subtype CRF18_CPX
7. Individual received injections in the leg
8. CAB and RPV plasma concentrations were not yet available at the time of writing
9. Genotypic resistance results were not available. Two attempts for sequencing by two different laboratories failed.

Supplementary Table 4. Characteristics of patients using CAB/RPV off-label with loss of virologic control

	#1	#2	#3	#4	#5	Patient #6	Patient #7	Patient #8	Patient #9
Age, years	45	27	49	46	40	48	26	43	40
Gender	Female	Female	Female	Female	Female	Male	Female	Female	Male
Region of origin	The Netherlands	Caribbean/Latin America	Sub-Saharan Africa	Caribbean/Latin America	Caribbean/Latin America	The Netherlands	Sub-Saharan Africa	Sub-Saharan Africa	The Netherlands
HIV transmission category	Heterosexual	Pediatric	Heterosexual	Heterosexual	Heterosexual	Heterosexual	Heterosexual	Heterosexual	MSM
BMI >30 kg/m² before start CAB/RPV	No	No	No	No	Yes	No	Yes	No	Yes ⁵
BMI >30 kg/m² at loss of virologic control	No	No	Not available	No	Yes	No	Yes	No ⁴	Yes ⁵
Longer needles used	No	No	No	No	No	No	No	No	No
HIV subtype A6¹	No	No	Not available	No	No	No	No	No	No
Known RPV associated RAMS at baseline	No	No	Not available	No	No	No	No	No	No
Years since start ART	20	24	17	13	11	8	2	10	0
ART regimen before start CAB/RPV	TAF/FTC/DRV/D TG/COB	TAF/FTC/BIC	RPV/DTG	TAF/FTC/BIC	TAF/FTC/DRV/COB	TAF/FTC/DTG	TAF/FTC/DRV/COB	TAF/FTC/DRV/D TG/COB	TAF/FTC/BIC
Nadir CD4	20	140	240	98	40	69	280	Not available	Not available
CD4 at start follow-up	120	270	630	19	1070	393	340	152	Not available
Time since last HIV-1 RNA measurement, months	1.4	1.1	1.4	1.6	0.6	3.0	4.8	4.1	2.1
HIV-1 RNA at start follow-up	100	Undetectable	Undetectable	Undetectable	Undetectable	Undetectable	Undetectable	Undetectable	Undetectable
Blips before start follow-up^{2,3}	4	0	1	0	0	5	2	1	1
Blips during follow-up²	3	3	2	0	0	1	0	4	0
Oral lead-in IM injections within window	Yes	No	Yes	Yes	Yes	No	Yes	No	Yes
HIV RNA at moment of failure, c/mL	200	962	753	2,230	231	8,310,000	200	3,122	220
Time until loss of virologic control, days	18	243	213	23	332	82	678	152	121

Re-suppression without ART change	No	Yes	No	No	No	No	Yes	No	No
ART switch after loss of virologic control	Yes	No	Yes	Yes	Yes	Yes	Yes ⁶	Yes	Yes
RAMs detected after loss of virologic control¹	INI: 155H	No	INI: Q148R RT: Y181C	RT: 138K	No	RT: K101EK+V179D+Y181C+V189I	No	No	RT: K101E
CAB concentration at loss of virologic control	Not done	Not done	Not available ⁷	Not done	Not done	0.42 mg/L	Not available	0.84 mg/L	0.95 mg/L
RPV concentration at loss of virologic control	Not done	0.09 mg/L	Not available ⁷	Not done	0.087 mg/L	0.036 mg/L	Not available	0.085 mg/L	0.079 mg/L

1. HIV-1 sequence analysis interpreted with IAS-USA resistance tables and Comet subtype tool
2. Blip was defined as a viral load between 50-200 copies/mL.
3. Presented as the number of blips in the 2 years prior to start of follow-up.
4. BMI measured 13 months before loss of virologic control
5. BMI measured 12 months before loss of virologic control
6. Change in ART regimen was due to a pregnancy wish, after viral load was undetectable.
7. CAB and RPV plasma concentrations were not yet available at the time of writing

Supplementary Table 5. Univariable and multivariable determinants of loss of virologic control

	Exposed individuals		Individuals with previous virological failure	
	HR (95%CI)	aHR (95%CI) ^b	HR (95%CI)	aHR (95%CI)
Age	1.00 (0.96-1.04)		0.96 (0.90-1.02)	
Gender				
	Male	a	REF	REF
	Female		9.95 (2.07-47.90)	15.11 (1.85-123.07)
Migration background				
	No	REF	REF	
	Yes	0.32 (0.10-1.01)	0.58 (0.15-2.33)	
HIV subtype A6^b				
	No	a	a	a
	Yes			
BMI > 30 kg/m²				
	No	REF	REF	
	Yes	2.13 (0.67-6.79)	2.39 (0.44-13.05)	
Known RPV associated RAMS at baseline^c				
	No	a	a	a
	Yes			
Years since HIV diagnosis, median [IQR]	0.97 (0.89-1.06)		0.98 (0.91-1.05)	
Years since start ART, median [IQR]	0.98 (0.90-1.07)		1.00 (0.93-1.08)	
Nadir CD4, median [IQR]	1.00 (1.00-1.00)		0.99 (0.99-1.00)	
Prior AIDS diagnosis				
	No	REF	REF	REF
	Yes	1.93 (0.54-6.91)	5.08 (1.21-21.26)	4.32 (1.03-18.09)
Number of virological failure before start follow-up			1.01 (0.99-1.04)	
Oral lead-in				
	No	REF	REF	
	Yes	0.80 (0.10-6.08)	0.22 (0.06-0.88)	

Abbreviations: aHR, adjusted hazard ratio; AIDS, Acquired Immune Deficiency Syndrome; ART, antiretroviral therapy; BMI, body mass index; CAB, cabotegravir; HIV, human immunodeficiency virus; HR, hazard ratio; IQR, interquartile range; kg, kilogram; m, meters; RAMS, resistance-associated mutations; RPV, rilpivirine

- a. Not taken into account due to 0 observations in one of the cells
- b. No determinants were associated with the outcome in the multivariable model

Acknowledgement list of principal treating physicians at participating HIV treatment centers

Latest update: 17 September 2024

Clinical centres

* denotes site coordinating physician

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Emma Kinderziekenhuis (Amsterdam UMC), Amsterdam:

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