


A Continuing Medical Education Activity

**The 18th Conference on
Retroviruses and Opportunistic Infections (CROI):
Online Expert Poster Review and Discussion**

Jointly sponsored by the Postgraduate Institute for Medicine and ViralEd, LLC

**ACTG A5221 STRIDE: An International Randomized Trial
of Immediate vs Early Antiretroviral Therapy (ART) in
HIV + Patients Treated for Tuberculosis**

D Havlir, P Ive, M Kendall, A Luetkemeyer, S Swindells, J Kumwenda,
J Rooney, S Qasba, E Hogg, J Andersen, I Sanne



**ACTG 5221 (STRIDE): Starting ARV
Therapy in Patients with TB**

HIV+, CD4+cells <250 cells/mm³ Treated for Confirmed or Suspected TB

48 weeks
analysis
▼

**Arm 1
Immediate ART
(N=405)** → **TMP/SMX + TDF/FTC/EFV (2 weeks post TB Tx)**

**Arm 2
Early ART
(N=401)** → **TMP/SMX + TDF/FTC/EFV (8-12 weeks post TB Tx)**

Havlir D, et al. 18th CROI; Boston, MA; February 27-March 2, 2011. Abst. 38.

Baseline characteristics

	Treatment Arm		
	Immediate N=405	Early N= 401	All N=806
Study Site			
Africa	275	279	554
Asia	29	23	52
N. America	21	18	39
S. America	80	81	161
Confirmed TB	48%	45%	46%
Median CD4 cells/mm ³	70	82	77
(IQR)	(34, 146)	(40, 144)	(36, 145)
Median log ₁₀ HIV RNA	5.39	5.50	5.43
EVF/TDF/FTC	98%	96%	97%
Median time to ART	10 days	70 days	n.a.

ACTG 5221: Results

	Immediate ART	Early ART	P value
TB diagnosis confirmed	46%	54%	
Median ART Start Time	10 days	70 days	
AIDS or death by week 48	12.9%	16.1%	P=0.45
AIDS or death by W48 with ≤50 cells/mm ³ (n=285)	15.5%	26.6%	P=0.02
>50 cells/mm ³ (n=521)	11.5%	10.3%	P=0.67

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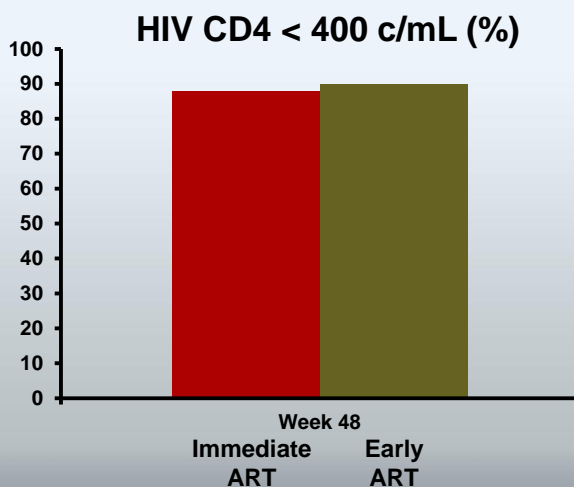
Frequency and Predictors of MTB IRIS

	Frequency ¹ #MTB IRIS	Predictor	Hazard (95%) CI ¹	P Value
Immediate ART	43 (11%)	Immediate ART	2.5 (1.4, 4.2)	0.001
Early ART	19 (5%)	HIV RNA Higher	1.8 (1.2, 2.7)	0.007
		Confirmed TB ²	3.6 (2.0, 6.6)	<0.001

¹P=0.002

¹Cox analysis, multivariate analysis
²Versus probable/not TB

HIV RNA Response





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**When to Start ART in TB
 – Building on Previous Studies**

	A5221/ STRIDE	CAMELIA¹	SAPIT²
N	806	660	429
Sites	Africa, Asia, S Am, N Am	Cambodia	S. Africa
Arms	Imm vs <u>8-12 wk</u>	Imm vs <u>8 wk</u>	Early vs <u>24 wk</u>
Endpt	↓Death/AIDS <50 CD4	↓Death	↓Death
CD4 (IQR)	77 (36, 145)	25 (11,56)	150 (77, 254)

¹Blanc, IAC, 2010

²Abdool Karim, NEJM, 2010