

ARV Therapies and Therapeutic Strategies

REPORTING ON IAS 2015

Comprehensive Expert Review and Discussion of Key Presentations

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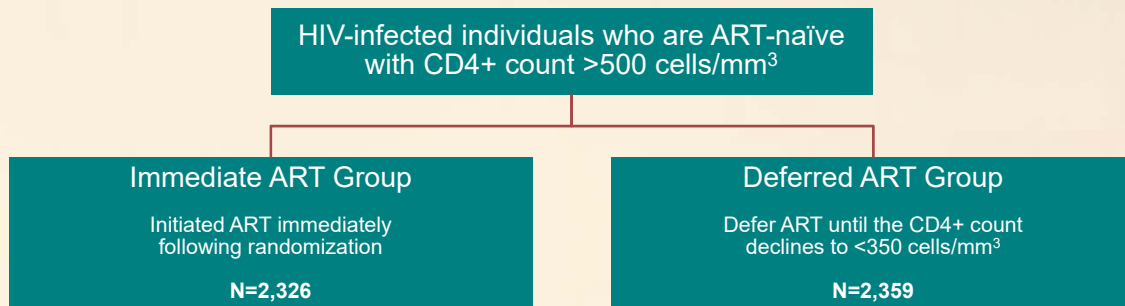
Strategic Timing of AntiRetroviral Treatment (START) Study Primary Results

**Abdel Babiker, PhD, Fred M. Gordin, MD, Jens D. Lundgren, MD,
James D. Neaton, PhD**

Abstract MOSY0301

START Study: Study Design

START Design



Primary Composite Endpoint, Target=213

- ❖ Serious AIDS or death from AIDS
- ❖ Serious Non-AIDS Events and death not attributable to AIDS
 - ◆ CVD, ESRD, decompensated liver disease & non-AIDS defining cancers

DSMB Stopped Study on May 27, 2015

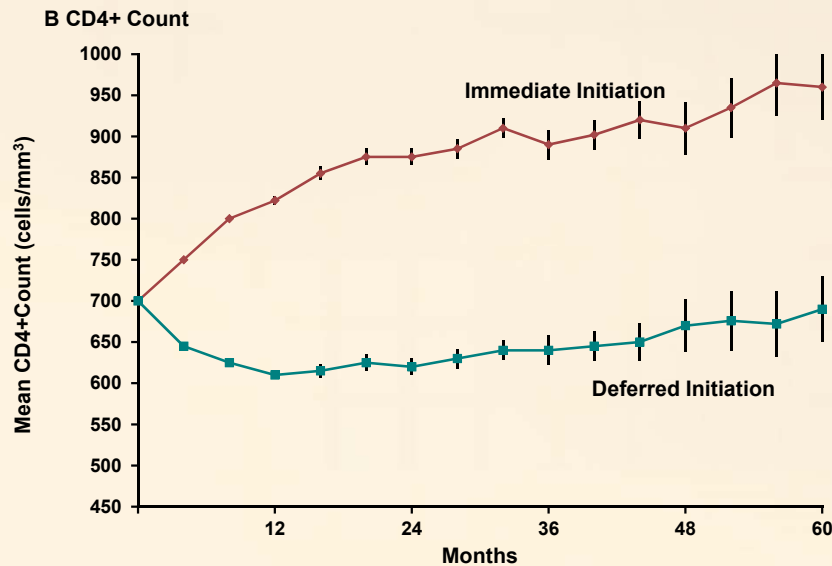
START Study: Baseline Characteristics

Characteristics	Immediate-Initiation Group (N=2326)	Deferred-Initiation Group (N=2359)	All Patients (N=4685)
Median Age (IRQ)-yr	36 (29-44)	36 (29-44)	36 (29-44)
Female Sex – no. (%)	624 (26.8)	633 (26.8)	1,257 (26.8)
Mode of Infection with HIV – no. (%)			
Sexual Contact			
Men Having Sex with Men	1,300 (55.9)	1,286 (54.5)	2,586 (55.2)
With Person of Opposite Sex	873 (37.5)	917 (38.9)	1,790 (38.2)
Injection-drug Use			
	37 (1.6)	27 (1.1)	37 (1.6)
Blood Products, Other, or Unknown			
	116 (5.0)	129 (5.5)	116 (5.0)
Median Time Since HIV Diagnosis (IQR) – yr	1.0 (0.4-3.0)	1.1 (0.4-3.1)	1.0 (0.4-3.0)
Median CD4+ count (IQR) – cells/mm	651 (585-765)	651 (582-764)	651 (585-765)
Median HIV RNA (IQR) – copies/ml	13,000 (3133-43,808)	12,550 (2963-42,567)	13,000 (3133-43,808)
Median CHD Risk at 10yr (IQR) - %	1.9 (0.5-5.0)	1.9 (0.5-5.3)	1.9 (0.5-5.0)

No significant differences between groups

Lundgren J, et al; 8th IAS, Vancouver, Canada, July 19-22, 2015; Abst. MOSY0301.

START Study: CD4 Cell Counts

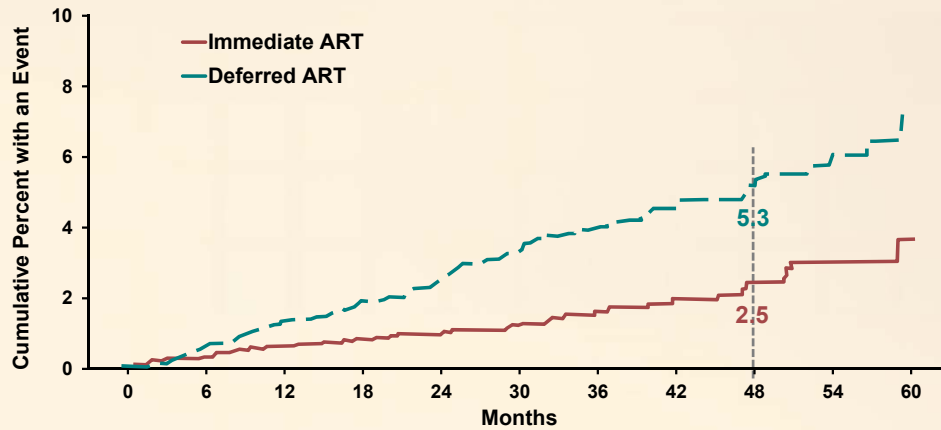


CD4 at the start of ART in deferred. Median 408
Estimated difference 194 cells

Lundgren J, et al; 8th IAS, Vancouver, Canada, July 19-22, 2015; Abst. MOSY0301.

START Study: Primary Endpoint

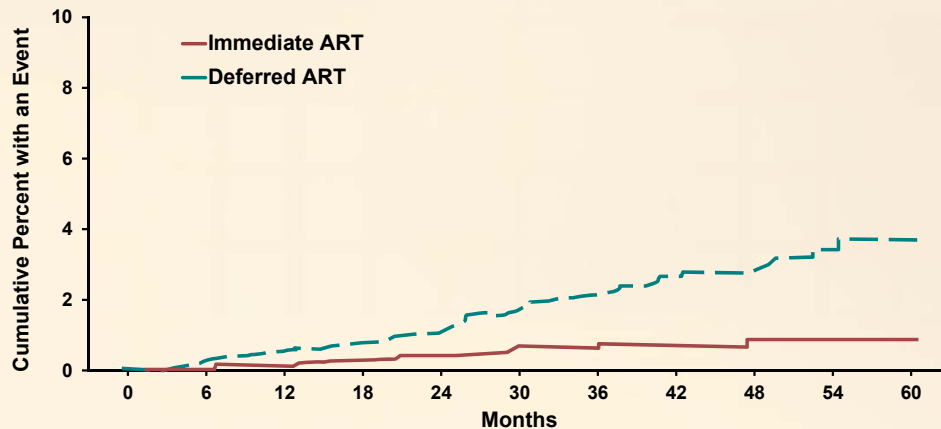
	Immediate ART	Deferred ART
No. with Event (%)	42 (1.8%)	96 (4.1%)
Rate/100PY	0.60	1.38
HR (Imm/Def)	0.43 (95% CI: 0.30 to 0.62, p<0.001)	



Lundgren J, et al; 8th IAS, Vancouver, Canada, July 19-22, 2015; Abst. MOSY0301.

START Study: Serious AIDS Events

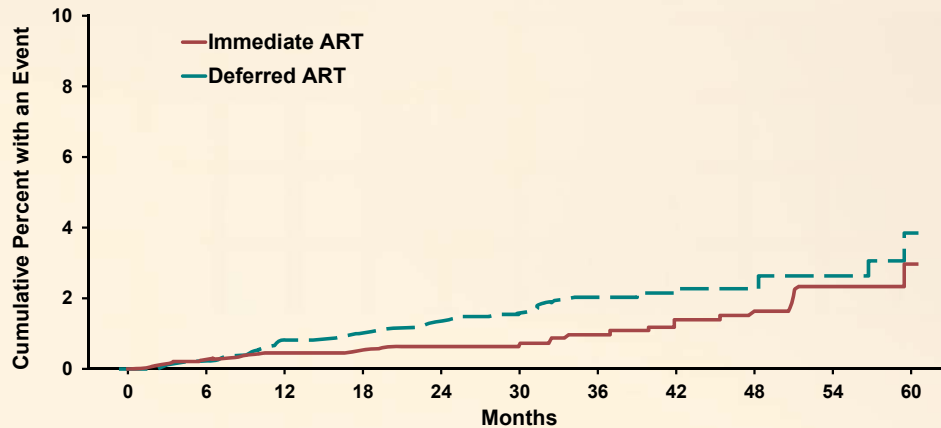
	Immediate ART	Deferred ART
No. with Event (%)	14	50
Rate/100PY	0.20	0.72
HR (Imm/Def)	0.28 (95% CI: 0.15 to 0.50, p<0.001)	



Lundgren J, et al; 8th IAS, Vancouver, Canada, July 19-22, 2015; Abst. MOSY0301.

START Study: Serious NON-AIDS Events

	Immediate ART	Deferred ART
No. with Event (%)	29	47
Rate/100PY	0.42	0.67
HR (Imm/Def)	0.61 (95% CI: 0.38 to 0.97, p=0.04)	



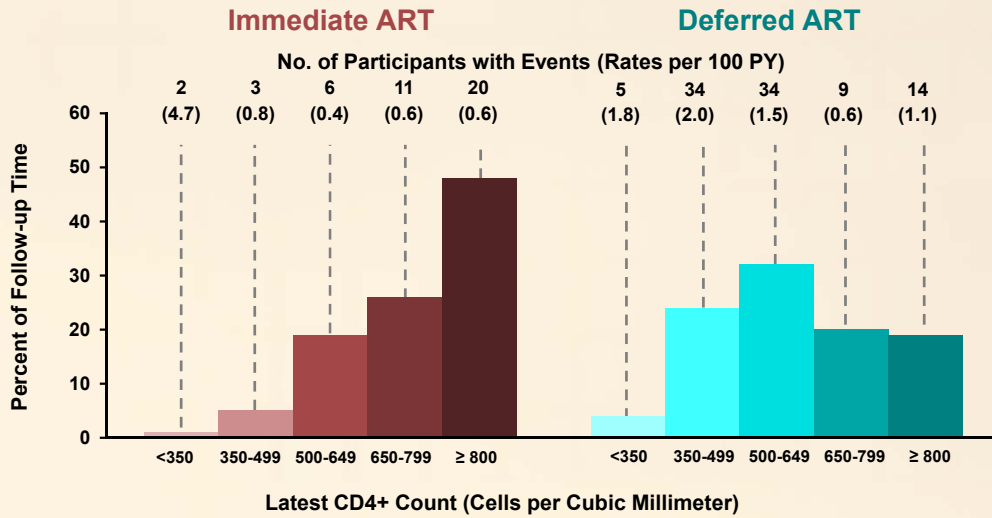
Lundgren J, et al; 8th IAS, Vancouver, Canada, July 19-22, 2015; Abst. MOSY0301.

START Study: Primary and Secondary Endpoints

End Point	Immediate-Initiation Group (N=2326)		Deferred-Initiation Group (N=2359)		Hazard Ratio (95% CI)	P Value
	No.	No. /100 person-yr	No.	No. /100 person-yr		
Composite Primary End Point	42	0.60	96	1.38	0.43 (0.30-0.62)	<0.001
Components of the Primary End Point						
Serious AIDS-Related Event	14	0.20	50	0.72	0.28 (0.15-0.50)	<0.001
Serious Non-AIDS-Related Event	29	0.42	47	0.67	0.61 (0.38-0.97)	0.04
Death From Any Cause	12	0.17	21	0.30	0.58 (0.28-1.17)	0.13
Tuberculosis	6	0.09	20	0.28	0.29 (0.12-0.73)	0.008
Kaposi's Sarcoma	1	0.01	11	0.16	0.09 (0.01-0.71)	0.02
Malignant Lymphoma	3	0.04	10	0.14	0.30 (0.08-1.10)	0.07
Cancer Not Related to AIDS	9	0.13	18	0.26	0.50 (0.22-1.11)	0.09
Cardiovascular Disease	12	0.17	14	0.20	0.84 (0.39-1.81)	0.65

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START Study: CD4 at the Time of Events



Primary Events at Latest CD4 count >500 c/mm ³	Percent Rate (/100 PY)	Immediate	Defer
		88%	59%
0.6	1.1		

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