

ORAL PRESENTATION

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# Early (2 weeks) vs. late (8 weeks) initiation of highly active antiretroviral treatment (HAART) significantly enhance survival of severely immunosuppressed HIV-infected adults with newly diagnosed tuberculosis: results of the CAMELIA clinical trial

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## Background

Tuberculosis (TB) remains the largest cause of death among people living with HIV/AIDS, especially among those with profound immunosuppression. Case-fatality among co-infected patients occurs mainly in the first months after the TB treatment initiation. Therefore, robust data regarding optimal timing of HAART initiation within this early period is critically needed.

## Methods

The CAMELIA (CAMBodian Early vs. Late Introduction of Antiretroviral drugs) clinical trial is an open-labelled randomized clinical trial designed to compare the impact upon mortality of early (2 weeks) vs. late (8 weeks) HAART initiation after TB treatment onset in treatment-naïve adults with newly diagnosed acid-fast bacilli (AFB) positive TB and CD4+ cell count  $\leq 200$  cells/mm<sup>3</sup>. Patients received standard 6-month TB treatment plus stavudine, lamivudine and efavirenz in 5 hospitals in Cambodia, 2 in Phnom Penh and 3 in province. Patients were followed for 50 weeks after the last

patient's enrollment. A log-rank test was used to compare Kaplan-Meier survival curves.

## Results

661 patients (early, n=332; late, n=329) were enrolled with a median age of 35 yrs, body mass index of 16.7 kg/m<sup>2</sup>, CD4+ cell count of 25 cells/mm<sup>3</sup> and viral load of 5.64 log copies/ml. All AFB-positive samples including sputum in 538 (81.4%) patients, were cultured. As of May 13, 2010, 149 patients were known dead (59, early arm; 90, late arm). Enhanced survival was observed in the early arm (p=0.004, see figure). At week 50, median CD4+ gain was 114 cells/mm<sup>3</sup> and was not statistically different across arms (p=0.22); 96.5% of patients had an undetectable viral load and again no difference across arms was found (0.82). Figure 1.

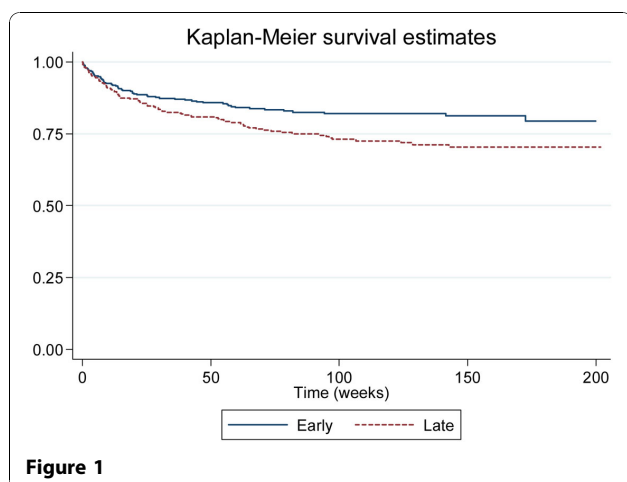
## Conclusion

Initiation of HAART 2 weeks after onset of TB treatment significantly improves survival in severely immunosuppressed HIV-infected adults with newly diagnosed tuberculosis.

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