Study shows mortality rate halved by early initiation of ARVs for people living with HIV and TB

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The combination of antiretroviral (ARV) and tuberculosis (TB) treatments could more than halve the mortality rate among patients coinfected with HIV and TB, according to a randomised open-label trial by the Centre for the AIDS Programme of Research in South Africa (CAPRISA).

The Starting Antiretroviral therapy (ART) in Three Points in Tuberculosis therapy (SAPIT) trial compared three treatment strategies of ARV initiation in HIV/TB co-infected patients. The trial examined differences in treatment outcomes depending on when patients initiated ARV treatment in conjunction with TB treatment.

The first group started ARVs within the first two months of starting TB treatment; the second group started ARVs after the two-month intensive phase of TB treatment (the integrated treatment arms) and the third group started ARVs only after completing their TB treatment (the sequential treatment arm). A standardised once a day ARV regimen of ddI, 3TC and efavirenz was given to the 645 patients participating in the trial, all of whom had smear-positive pulmonary TB and HIV infection with CD4 counts of less than 500.

The mortality rate (the ratio of deaths in a group to the entire population of that group) was 55% lower in the in the integrated treatment arms when compared to the sequential treatment arm. This means that deaths can be more than halved by combining ARVs with TB treatment. Of significance is that the reduction in mortality in the integrated arms was significant for patients with a CD4 count below 200, as well as those with CD4 counts between 200 and 500.

These trial results show that TB and ARV treatment should be integrated. In South Africa, this requires that all TB patients are tested for HIV and that all HIV positive people are screened for TB every six months. If a patient?s CD4 count is less than 500, they should be offered ARVs two months at most after they have started TB treatment.

This trial data shows the need for South Africa, as well as the World Health Organisation (WHO) to review their TB and ARV treatment guidelines. Currently the South African TB guidelines state that patients with a CD4 count above 200 should not start ARV treatment; patients with a CD4 count of less than 200 are recommended to start ARV treatment after two months of TB treatment and patients with a CD4 count of below 50 should start ARVs after 2 weeks of TB treatment.

According to the trial data, an additional 100 000 to 150 000 TB patients with CD 4 counts below 500 would need to be initiated on ART. This would prevent about 10 000 deaths each year.

Given the above data coming out of the study, the sequential arm has been stopped and all patients in this arm will be given ARVs as soon as possible. The two integrated care arms will continue as per the original protocol with the aim of determining when ARV treatment should be initiated during the course of TB treatment, the results of which will be available in 2010.

The Treatment Action Campaign calls on the WHO and the South African Department of Health to integrate these findings into their TB/HIV treatment guidelines by providing ARVs to patients not more than two months after they

have started TB treatment if their CD4 count is less than 500. The Department of Health must put measures in place to prepare for the increased demand in ARVs that would arise from TB patients needing to start ARV treatment earlier. We look forward to the final results of the study which will provide clarity more precisely when ARVs should be initiated for patients on TB treatment.

For more information about the trial please visit CAPRISA's website .

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