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More is not better: The result from a US government sponsored multi-center randomized international clinical trial to prevent tuberculosis in HIV/AIDS population

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Background: Tuberculosis (TB) and HIV/AIDS have been closely linked since the beginning of AIDS epidemic. TB is the most common co-infection and cause of death among the AIDS population. And yet, there isn't rapid, accurate, and reliable diagnosis methodology for TB testing, especially in resource-limited countries. Treating HIV/AIDS patients with the available 4 TB drugs has been utilized in in some African countries to manage AIDS patients that were potentially afflicted with TB not diagnosed. In order to evaluate this treatment/prevention strategy for such patient population, the Division of AIDS at the National Institute of Allergy and Infectious Diseases, one of the 27 institutes and Centers of the National Institutes of Health, funded/sponsored a multicenter international clinical trial project.

Methods: An open label, randomized clinical trial was conceived in 2008 and the first patient was enrolled in October 2011. The study completed the last patient follow-up in June 2014. The protocol included two arms. Arm A received standard anti-HIV treatment therapy plus four anti-TB drugs, Isonizid (INH), Rifampin (RIF), Pyrozinamide (PZA), and Ethambutol (EMB). Arm B received standard anti- HIV treatment plus isoniazid, a WHO recommended strategy to prevent TB. All participants had CD4 counts less than 50 per μL.

Results & Conclusion: The trial enrolled 850 patients and conducted in 18 clinical trial sites in Malawi, South Africa, Haiti, Kenya, Zambia, India, Brazil, Zimbabwe, Peru, and Uganda. We hypothesized the empirical treatment would reduce the mortality in this patient population. However, the results from the trial showed that the mortality rate was same for both study arms. Furthermore, the TB incident rates in Arm A were significantly higher in the treatment arm compared to control arm (33 versus 19). The results illustrated that that adding RIF, PZA, and EMB were not helpful, and possibly harmful. Drug-drug interactions maybe one of the reasons and the real-time drug concentration tests are among the other measurements to explain these study results.

Biography

Jing Bao is a Medical Officer at the division of AIDS, National Institute of Allergy and Infectious Diseases, Columbus Technologies and Services, Inc., with extensive experience in international clinical trial oversight and global regulations. She manages and oversees the US government (National Institutes of Health) funded/sponsored international multi-center clinical trials on treatment development for HIV/AIDS and co-infections. She received her MD from China and was a Medical Director for two hospitals before she received a PhD from Israel. She has published influential research findings in world leading journals. She is the Member of Asian American Executives Network and will be graduated from its Senior Executive Service Candidate Development Program in April 2017.

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