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Short Communication

Pharmacological Activities in Therapies for TB and HIV

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DESCRIPTION

There are an extraordinary number of experimental medications being developed to treat tuberculosis. HIV co-infection is common in tuberculosis patients, and treating both conditions at the same time is currently considered best practice. Selected pharmacokinetic studies based on knowledge of their metabolic pathways and their capacity to induce or inhibit metabolizing enzymes of companion drugs must be carried out in order to ensure that combinations of anti-tuberculosis medications and antiretrovirals are safe and tested at doses most likely to be effective. To more thoroughly assess safety and pharmacodynamics, investigations in larger populations should be conducted after drug interaction studies [1].

Early inclusion of HIV patients in TB medication trials improves the knowledge obtained from the trials and ensures that HIV patients have access to promising new TB medicines as soon as possible. Future priorities for tuberculosis-HIV pharmacokinetic, pharmacodynamic, and drug-drug interaction studies are recommended. Special research is being done on children and expectant mothers who are HIV and TB positive [2-4].

In less developed nations, Tuberculosis (TB) is the leading cause of mortality for people with HIV, accounting for 22% (350,000) of all HIV-related fatalities worldwide. The expansion of HIV has also fueled the TB epidemic. Of the 8.8 million incidents TB cases reported worldwide, 1.1 million involved HIV-positive individuals. There is now convincing evidence that treating HIV and TB patients concurrently, as opposed to starting Antiretroviral (ARV) medications after TB treatment is finished, and lowers mortality. Because of this, treatment has become the norm for the majority of patients [5].

While the current pipeline of new TB drugs is stronger than ever, advanced planning and active promotion of Pharmacokinetic (PK) and Pharmacokinetic Interaction (PKI) studies with other antimicrobials and ARV drugs are critical to accelerating development and access of new drugs for HIV co-infected populations. These studies are required to investigate the pharmacologic compatibility and tolerability of future combination drug regimens for HIV-TB co-infected patients. While some PKI studies can be conducted initially in healthy HIV-seronegative volunteers, especially when metabolic drug interactions are expected to necessitate dose adjustments, follow-up studies in patients with HIV and/or TB are required to fully explore variability in PK and Pharmacokinetic/Pharmacodynamic (PK/PD) relationships [6].

However, given the increased number of drugs in the development pipeline and promising results in preclinical and early clinical studies of regimens involving existing and investigational drugs, advances in the treatment of drug-sensitive and drug-resistant TB are likely in the near future. Studies evaluating the safety, pharmacokinetics, and efficacy of co-administered anti-retrovirals and antituberculosis drugs must be conducted to ensure that patients with HIV can fully benefit from new and currently available TB regimens, especially when metabolic drug interactions or overlapping toxicities are likely. Consideration and advanced planning of the most relevant studies should begin early in the course of drug development, with guidance from preclinical studies, and should be completed before the drug is released.

CONCLUSION

While Phase I studies with crossover designs may be used for drugs with shorter half-lives, nesting PKI studies in Phase II a treatment trials will be the most informative strategy. PKI studies must be conducted in the relevant populations, including high-burden settings, for drugs whose concentrations are highly dependent on environmental and host factors, including genetics, rather than extrapolating results from trials involving a small subset of participants, such as healthy volunteers. Advocacy, as well as funding from industry, government, and public-

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private partnerships, will be required to ensure that PKI involving investigational TB drugs and relevant ARVs is carried out, especially PK studies to determine the age-appropriate dose of investigational agents for children should be carried out as soon as an adult dose is determined, with special attention paid to drug formulation. Finally, in all large clinical trials of new TB drugs or regimens, sparse PK sampling will help define the PK/PD parameters that correlate best with treatment response and determine PK targets to ensure optimized dosing. Concurrent HIV/TB treatment saves lives, and careful evaluation of the pharmacology of administered Antiretrovirals and anti-tuberculosis drugs will help ensure that new or improved TB regimens benefit those patients who need them the most.

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