

The Medical Letter[®]

on Drugs and Therapeutics

Volume 63

Published online August 23, 2021

Online
Article

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IN BRIEF

A Shorter Treatment Regimen for Tuberculosis

In a clinical trial conducted by the CDC's Tuberculosis Trials Consortium in collaboration with the NIH-funded AIDS Clinical Trials Group, a new 4-month regimen for treatment of drug-susceptible pulmonary tuberculosis was found to be noninferior to 6 months of standard treatment.

STANDARD TREATMENT – Patients with drug-susceptible tuberculosis have typically been treated with rifampin, isoniazid, pyrazinamide, and ethambutol during an initial 8-week intensive phase, and then with rifampin and isoniazid during an 18-week continuation phase. Once-daily treatment is preferred, but twice- or three-times-weekly dosing can be used as an alternative in patients who are HIV-negative and do not have smear-positive or cavitory disease. Directly observed therapy should be used to ensure treatment adherence.¹

THE CLINICAL TRIAL – Study 31/A5349 was a randomized, open-label trial in which 2516 patients ≥ 12 years old with pulmonary tuberculosis were randomized to receive 6 months of standard once-daily treatment or one of two 4-month treatment regimens using high-dose rifapentine, isoniazid, pyrazinamide, and either moxifloxacin or ethambutol. The 4-month regimen that included moxifloxacin was noninferior to standard treatment for the primary endpoint of disease-free survival at 12 months (88% vs 90%) and similar to standard treatment in safety and tolerability. The 4-month regimen with ethambutol did not meet the prespecified criteria for noninferiority compared to standard treatment.²

Table 1. Two Drug Regimens for Drug-Susceptible TB¹

Regimen	Intensive Phase	Continuation Phase
Standard 6-Month Treatment	Rifampin 600 mg + Isoniazid 300 mg ² + Ethambutol 800-1600 mg ³ + Pyrazinamide 1000-2000 mg ⁴ once/day x 8 wks	Rifampin 600 mg + Isoniazid 300 mg ² once/day x 18 wks
Rifapentine-Based 4-Month Treatment	Rifapentine 1200 mg + Isoniazid 300 mg ² + Moxifloxacin 400 mg + Pyrazinamide 1000-2000 mg ⁴ once/day x 8 wks	Rifapentine 1200 mg + Isoniazid 300 mg ² + Moxifloxacin 400 mg once/day x 9 wks

1. SE Dorman et al. *Contemp Clin Trials* 2020; 90:105938.
2. Pyridoxine 25-50 mg once daily is also recommended to decrease the risk of isoniazid-induced neuropathy.
3. Dose is based on body weight (<55 kg: 800 mg; 55-75 kg: 1200 mg; >75 kg: 1600 mg).
4. Dose is based on body weight (<55 kg: 1000 mg; 55-75 kg: 1500 mg; >75 kg: 2000 mg).

CONCLUSION – The positive results with the 4-month regimen have been recognized by the CDC and the WHO as an important development in the effort to improve treatment of tuberculosis.^{3,4} Shortening the required duration of antimicrobial therapy may increase treatment adherence, which could theoretically decrease disease prevalence and the risk for development of drug resistance. ■

1. P Nahid et al. Executive summary: official American Thoracic Society/Centers for Disease Control and Prevention/Infectious Diseases Society of America clinical practice guidelines: treatment of drug-susceptible tuberculosis. *Clin Infect Dis* 2016; 63:853.
2. SE Dorman et al. Four-month rifapentine regimens with or without moxifloxacin for tuberculosis. *N Engl J Med* 2021; 384:1705.
3. CDC. Landmark TB trial identifies shorter-course treatment regimen. 2020. Available at: <http://bit.ly/38BdSMb>. Accessed July 15, 2021.
4. WHO. New study 31/A5349 on the treatment of drug-susceptible TB. October 22, 2020. Available at: <http://bit.ly/3eVlk4w>. Accessed July 15, 2021.

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