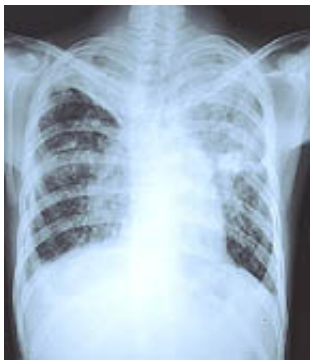
ICAAC: Moxifloxacin regimens are not noninferior for TB

8 September 2014



(HealthDay)—For patients with uncomplicated, smear-positive pulmonary tuberculosis, moxifloxacin-containing regimens over four months are not noninferior to a control regimen, according to a study published online Sept. 7 in the *New England Journal of Medicine* to coincide with the Interscience Conference on Antimicrobial Agents and Chemotherapy, held Sept. 5 to 9 in Washington, D.C.

Stephen H. Gillespie, M.D., D.Sc., from the University of St. Andrews Medical School in the United Kingdom, and colleagues conducted a randomized phase 3 trial to test the noninferiority of two moxifloxacin-containing regimens versus a control regimen in 1,931 patients with uncomplicated, smear-positive pulmonary tuberculosis. Patients were randomized to a control group (isoniazid, rifampin, pyrazinamide, and ethambutol for eight weeks followed by isoniazid and rifampin for 18 weeks); an isoniazid group (replacing ethambutol with moxifloxacin for 17 weeks followed by nine weeks of placebo); and an ethambutol group (replacing isoniazid with moxifloxacin for 17 weeks followed by nine weeks of placebo).

The researchers found that a favorable outcome was reported in fewer patients in the isoniazid and ethambutol groups (85 and 80 percent, respectively) than in the control group (92 percent) in the per-protocol analysis. Similar results were seen in the modified intention-to-treat analysis and all sensitivity analyses.

"Noninferiority for these regimens was not shown, which indicates that shortening treatment to four months was not effective in this setting," write the authors.

Bayer Healthcare provided moxifloxacin, and Sanofi donated rifampin.

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