

J Infect Dis. 2010 Jun 1;201:1729-35.

A Phase III Equivalence Trial of Azithromycin versus Benzathine Penicillin for Treatment of Early Syphilis.

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BACKGROUND: Syphilis remains an important source of morbidity worldwide. Long-acting penicillin is the only therapy currently recommended for syphilis in much of the world. Because of hesitation to use penicillin for fear of anaphylaxis, there is a need for an effective, well-tolerated alternative to penicillin for syphilis therapy.

METHODS: This multicenter, randomized clinical trial was conducted in clinics for the treatment of persons with sexually transmitted diseases. We compared serological cure rates for human immunodeficiency virus (HIV)-negative persons with early syphilis treated with azithromycin at a dosage of 2.0 g administered orally as a single dose with cure rates for those treated with benzathine penicillin G at a dosage of 2.4 million units administered intramuscularly.

RESULTS: A total of 517 participants were enrolled in the trial. In the intention-to-treat analysis, after 6 months of follow-up, serological cure was observed in 180 (77.6%) of 232 azithromycin recipients and 186 (78.5%) of 237 penicillin recipients (1-sided lower bound 95% confidence interval, 7.2%). Nonserious adverse events were more common among azithromycin recipients than they were among penicillin recipients (61.5% vs 46.3%), and such adverse events were accounted for, in large part, by self-limited gastrointestinal complaints.

CONCLUSIONS: In this trial, the efficacy of azithromycin at a dosage of 2.0 g administered orally was equivalent to that of benzathine penicillin G for the treatment of early syphilis in persons without HIV infection.

PMID: 20402591