Evaluation of fleroxacin (RO 23-6240) as single-oral-dose therapy of culture-proven chancroid in Nairobi, Kenya

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Abstract:

Chancroid is gaining importance as a sexually transmitted disease because of its association with transmission of human immunodeficiency virus type 1 (HIV-1). Effective, simply administered therapy for chancroid is necessary. Fleroxacin is effective against Haemophilus ducreyi in vitro. We performed an initial randomized clinical trial to assess the efficacy of fleroxacin for treatment of chancroid in Nairobi, Kenya. Fifty-three men with culture-positive chancroid were randomly assigned to receive either 200 mg (group 1) or 400 mg (group 2) of fleroxacin as a single oral dose. Groups 1 and 2 were similar with regard to severity of disease, bubo formation, and HIV-1 status. A satisfactory clinical response to therapy was noted in 23 of 26 patients (88%) in group 1 and 18 of 23 patients (78%) in group 2. Bacteriological failure occurred in 1 of 26 evaluable patients (4%) in group 1 and 4 of 23 evaluable patients (17%) in group 2. Two of 37 HIV-1-seronegative men (5%) and 3 of 11 HIV-1-infected men (27%) were bacteriological failures. Fleroxacin, 200 or 400 mg as a single oral dose, is efficacious therapy for microbiologically proven chancroid in patients who do not have concurrent HIV-1 infection. Among HIV-1-infected men, a single dose of 200 or 400 mg of fleroxacin is inadequate therapy for chancroid. PIP: In Kenya, researchers enrolled 53 men aged 18-60 years with chancroid who enrolled in the Nairobi City Council Special Treatment Clinic in a clinical trial to test the efficacy of fleroxacin in clinical Haemophilus ducreyi infections. They randomly allocated the men to the group receiving 200 mg of oral fleroxacin or the group receiving 400 mg of oral fleroxacin. 88% of the men receiving 200 mg oral fleroxacin (group 1) experienced either improvement in their clinical status or healing compared to 78% of the men receiving 400 mg oral fleroxacin. 2 of 7 (29%) patients who experienced delayed healing tested positive for HIV-1. 2 of 22 patients (9%) who healed right away were HIV-1 positive. The size of the genital ulcer had the most significant effect on healing time. The mean widest ulcer diameter was 9.5 mm in men who healed quickly while it was 18.5 mm in men who experienced a delay in healing (p = .005). Microbiological cure occurred in 92% of men from group 1 and in 83% of those in group 2. The difference in microbiological failure rates of HIV-1-seropositive men and HIV-1-seronegative men approached significance (27% vs. 5%; p = .07). These results showed that a 200 or 400 mg single dose of oral fleroxacin is an efficacious treatment for men with microbiologically confirmed chancroid who are not HIV-1 infected. On the other hand, a single dose of neither 200 or 400 mg of oral fleroxacin adequately treats chancroid in HIV-1 infected men. Further study of chancroid treatment in HIV infected patients is needed, especially since chancroid may facilitate HIV transmission.