

Efficacy of single-dose chemotherapy (rifampicin, ofloxacin and minocycline-ROM) in PB leprosy patients with 2 to 5 skin lesions, India: randomised double-blind trial.

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Abstract

We conducted randomized double-blind trial for single-dose of Rifampicin, Ofloxacin and Minocycline (ROM) compared to WHO-PB-MDT among paucibacillary (PB) leprosy patients with 2-5 skin lesions. We enrolled 1526 patients from five centres (ROM=762; WHO-PB-MDT=764) and followed them for 36 months post treatment during 1998-2003. We generated information on clearance of skin lesions and relapse rates per 100 person-years (PY) for all the five centres. At base-line, the patients in the two arms were comparable. Complete clearance of skin lesions was similar (72% vs. 72.1%; $p=0.95$) in both the arms. Clinical scores declined steadily and equally. Difference in relapse rates was statistically highly significant (ROM=1.13 and WHO-PB-MDT=0.35 per 100 PY; mid- p exact=0.001016). Twenty eight of 38 of these relapses occurred within 18 months. In all, 10 suspected adverse drug reactions were observed (ROM=2; WHO-PB-MDT=8). We extended the follow-up to 48 months for 1082 of 1526 patients from two programme-based centres. No further relapses occurred. Decline in clinical score was not dependent on age, gender, number of lesions or affected body parts. Single dose ROM, though less effective than the standard WHO-PB-MDT regimen conceptually offers an alternative treatment regimen for PB leprosy patients with 2-5 lesions only when careful follow-up for relapse is possible.

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