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Effect of Rifampin with bio-enhancer in the treatment of newly diagnosed sputum positive pulmonary tuberculosis patients: A double center study

Tuberculosis was declared as global emergency by WHO in 1993. DOTS therapy recommended by WHO is highly effective in an active drug susceptible TB as long as patient completes the course. Adverse effect of anti TB drugs is one of the most common reason for non-adherence eventually contributing to treatment failure, relapse or emergence of drug resistance. The standard treatment for newly diagnosed tuberculosis patients consists of an intensive phase for two months with four drugs (HRZE), followed by continuation phase for four months with two drugs (HR). Rifampicin, which is very effective against *mycobacterium tuberculosis*, in both phase of treatment has certain concerns, which included decreased bioavailability with chronic use and hepatotoxicity. To overcome these concerns a new boosted formulation of Rifampicin (Risorine) with bio-enhancer of Piperine was developed. Piperine has been found to increase bioavailability of several drugs including Amoxicillin, Cefotaxime, Theophylline and Propanolol. Risorine is a fixed combination which contains Rifampicin 200 mg + Isonazid 300 mg + Piperine 10 mg. We conducted study in two centres to validate the therapeutic efficacy and tolerablity of Risorine formulation containing regimen with a conventional regimen. This was a randomized, prospective, parallel group study. All the patients were subjected to sputum examination, biochemical investigations followed by Adverse Drug Event (ADE) monitoring. A Total of 63 patients completed the study. No significant difference was observed in baseline characteristics of patients between the study groups. At the end of the continuous phase, both the groups showed zero bacteria detection. However, in the intervention group, the rate of sputum conversion was much faster than the usual care group. The rate of increase in SGOT and SGPT was much higher in the usual care group ($p<0.0001$) than the interventional group ($p<0.05$). Urea and creatinine have also increased from pre-treatment to end visit. The number of patients reported ADEs was less in the intervention care group (22.22%) when compared to the usual care group (36.84%). Rifampicin 200 mg with Piperine 10 mg FDC is compatible with the usual CAT-1 regimen.

Biography

Arcot Dheenadayalu Nageswari is a Postgraduate in Tuberculosis and Respiratory Diseases. She was trained by Central Govt. of India in TB Control. She has the prestigious Fellowship award by WHO in TB control Training at Japan and Korea 1993. She has published 20 papers in Indexed national and international journals.

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