ABSTRACT BOOK ABSTRACTS



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INFECTIOUS DISEASES (BACTERIAL, FUNGAL, VIRAL, PARASITIC, INFESTATIONS)

A RANDOMIZED CONTROLLED TRIAL OF ANTI-TNF ALPHA BIO-SIMILAR ADALIMUMAB VERSUS PREDNISOLONE IN THE MANAGEMENT OF LEPROSY PATIENTS WITH NEW TYPE 1 LEPRA REACTION

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Background: Leprosy Type 1(T1R) reactions are immune-mediated events leading to nerve damage and preventable disability affecting hands, feet and eyes which are treated with corticosteroids. There is little evidence on alternative treatments for patients who don't respond to steroids or experience steroid adverse effects. We report the results of a randomized controlled trial testing the efficacy and adverse effect profile of Adalimumab and prednisolone(A+P) in comparison to prednisolone only(P) in patients with new T1R in a tertiary hospital. Adalimumab is a TNF-Alpha blocker and the levels of TNF-Alpha were correlated before and after the clinical intervention.

Objective: To assess outcomes using clinical severity score, recurrence rate, adverse events and quality of life in patients treated with a Biologic drug versus a conventional drug like Prednisolone.

Material & Methods: 73 patients with new T1R were randomized to receive A+P or P for 20 weeks. The base line TNF-Alpha was recorded and compared.

Results: Recovery rates in skin signs was similar in both groups(91%vs88%). Improvements in nerve function both, new and old, sensory(66%vs49%) and motor(75%vs74%) loss were higher (but not significantly so) in the patients on A+P. Recurrences rates of T1R(85%) were high in both groups, and recurrences occurred significantly earlier(8 weeks) in patients A+P, who needed 10% more additional prednisolone. Serious adverse events rates were similar in both arms of the study. Both groups had significant improvement in quality of life after the study, measured by the SF-36.

Conclusions: This is the first double-blind RCT assessing Adalimumab, in management of T1R. Adalimumab could be a safe alternative second-line drug for patients with T1R who are not improving with prednisolone or are experiencing adverse events related to prednisolone. This study illustrates the difficulty in switching off leprosy inflammation. This is











a first study highlighting the safe use of a Biologic drug in a chronic granulomatous infectious disease.



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