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Clinical safety and efficacy of Suprimun compared with cellcept in renal transplant recipients

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Background: Immunosuppressive therapies are essential to ensure the acceptance of donated organ. Mycofenolate mofetile (MMF) is an antiproliferative/antimetabolite drug which is widely used from 1995 following a series of clinical trials proving its efficacy being more than Azathioprine in prevention of acute rejection. Suprimun (Actoverco®) is a generic form of cellcept produced by Clausen. It contains MMF and has received EMEA approval. This product has been used since 2003 in most Latin American countries. This study compares the efficacy and safety of suprimun with cellcept in kidney transplant recipients to assess feasibility of recommendation of suprimun considering its lower cost.

Methods: A muti-centre open labeled parallel group randomized clinical trial including 100 kidney transplant recipients from 4 major centres, who were randomly assigned to 2 groups of 50 with cellcept or suprimun, treated in combination with cyclosporine and corticosteroid. Serial serum creatinine levels and acute rejection episodes were measured as main outcomes. Patients were visited 9 times after discharge on pre-defined protocol. At the end of the 6th month, serum levels of MMF were measured by HPLC technique.

Results: Eighty seven kidney transplant recipients have been recruited up to now, with the mean age was 42.1 (13.8) ranged 17-73 y. old of which 41 cases completed the follow-up visits; 19 in suprimun and 22 in cellcept groups. No significant difference s of serum creatinine, BUN levels, and episodes of acute rejection were observed between the two groups. Biopsy proven incidence of acute rejection was reported as 31.5% in both groups (P=0.63). There has been no report of serious adverse effect so far.

Conclusion: According to the data gathered till this stage of study, efficacy and safety of suprimun and cellcept has been comparable with no statistical and clinically important difference between the two groups. With increasing sample size and completing the follow-up a more valid conclusion would be taken.

Biography

Ali Reza Khoshdel graduated as a medical doctor in 1994 and completed his PhD in 2007 from the University of Newcastle, Australia. He did his postdoctoral studies in chronic kidney diseases, diabetes and hypertension as well as renal replacement therapies and is expert in arterial stiffness studies. He is working as an associate professor in clinical epidemiology and is the director of the Modern Epidemiology Research Centre, and is currently the Dean of education in his affiliated university. He has published more than 80 papers and book chapters in reputed journals and serving as an editorial board member and of several international journals.

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