

Everolimus Versus Azathioprine in a Cyclosporine and Ketoconazole-Based Immunosuppressive Therapy in Kidney Transplant: 3-Year Follow-up of an Open-Label, Prospective, Cohort, Comparative Clinical Trial

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In cyclosporine-based protocols, everolimus is more effective than azathioprine to reduce acute rejection. Ketoconazole may reduce cyclosporine and everolimus requirements. We compared kidney transplant patients treated with everolimus or azathioprine in a ketoconazole- and cyclosporine-based immunosuppressive regimen. This open-label, prospective trial of low immunologic risk patients. Included one group (n = 11) who received everolimus (target blood level, 3-8 ng/mL) and the other (n = 11) azathioprine (2.0-2.5 mg/kg/d). Both received steroids, ketoconazole, and cyclosporine with C0 targets (ng/mL) in the everolimus group of 200-250, 100-125, and 50-65 for months 1 and 2 and thereafter and in the azathioprine group of 250-300 in month 1, 200-250 in month 2, 180-200 until month 6, and 100-125 thereafter. Their baseline characteristics were similar. Two biopsy-proven acute rejections occurred in each group. Three-year graft and patient survival in both groups was 100%. Creatinine clear