Titel des Beitrags:
12-month safety and efficacy of everolimus with reduced exposure cyclosporine in de novo renal transplant recipients.

Abstract:
The proliferation signal inhibitor everolimus (Certican), has demonstrated efficacy with full-dose cyclosporine (CsA) (Neoral). Two multicenter randomized controlled studies were performed to compare 12-month efficacy and safety of everolimus 1.5 and 3.0 mg/day with reduced-dose CsA. Study 1 enrolled 237 de novo renal allograft recipients, randomizing 222 nonblack patients to either everolimus 1.5 or 3.0 mg/day, with the Neoral) dose guided by C(2) (monitoring of CsA concentration 2 h after dosing). Study 2 had a similar protocol, with basiliximab included, enrolling 256 recipients and randomizing 243 nonblack patients. In Study 1, there was a lower incidence of acute rejection in nonblack patients on 3 mg/day (16.4%) compared with 1.5 mg/day (25.9%), P = 0.08. In Study 2, the inclusion of basiliximab lowered the overall incidence of acute rejection; 14.3% of nonblack patients (3 mg/day) and 13.6% of nonblack patients (1.5 mg/day) had acute rejection by 12 months (P =0.891). Renal function was preserved throughout the study, with no differences observed between groups within studies. Everolimus was well tolerated with no significant differences between doses. Everolimus, in combination with reduced-dose Neoral), demonstrated...
efficacy and was well tolerated. Basiliximab allows for utilization of lower doses of everolimus with reduced dosing of Neoral).