Clinical Trials

Organ Function Preservation by the Combination Treatment of the ptImuM dose of CalcineUrin Inhibitor and Mycophenolate Sodium in Kidney Recipients: OPTIMUM Study

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Most of kidney recipient receive the calcineurin inhibitor (CNI)-based immune suppression for the prevention of renal allograft rejection. Introduction of the CNIs, namely cyclosporine and tacrolimus, has significantly increased 1-year renal allograft survival in the last two decades. However, the CNIs have not extended long-term allograft survival. Chronic allograft nephropathy (CAN) is the leading cause of graft loss after the first year post-transplantation. CNIs are well known as nephrotoxic agents, and their long-term use plays a crucial role in the development and progression of the CAN. Currently, tacrolimus has become the predominant CNI used for maintenance immunosuppressive agent instead of cyclosporine, but designed randomised controlled trials about tacrolimus-sparing therapy are rare. Here, we have hypothesized that tacrolimus-sparing regimen with minimal tacrolimus dose together with mycophenolate sodium (MPS) dose increment will preserve renal allograft function without rising adverse effects (eg., biopsy proven acute rejection, opportunistic infection etc.) compared with the usual tacrolimus dose in the recipients with stable graft function more than one year post-transplantation. The study design is open label and 1:1 randomization (regular dose of tacrolimus+usual dose of MPS versus reduced dose of tacrolimus+maximum dose of MPS). Primary endpoint is estimated GFR using abbreviated MDRD equation 12 months after randomization.