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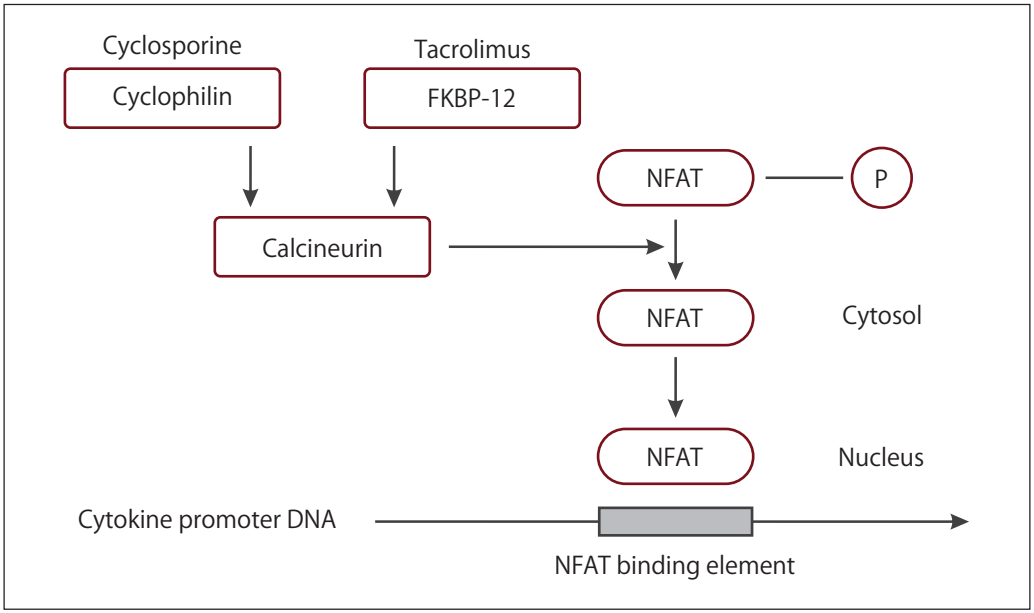
TACROREN

Tacrolimus Capsules 0.25 mg/0.5 mg/1 mg

BACKGROUND :

- Tacroren belongs to a group of medicines called immunosuppressants. Following your organ transplant (e.g. liver, kidney, heart), your body's immune system will try to reject the new organ.
- Tacroren is used to control your body's immune response enabling your body to accept the transplanted organ.
- Tacroren is often used in combination with other medicines that also suppress the immune system.

MECHANISM OF ACTION OF TACROLIMUS :



- Calcineurin inhibitors (Tacrolimus) down regulate immune responses by inhibiting the production of IL-2 in activated T cells.
- IL-2 is a key driver of many immune responses and especially important in mediating organ transplant rejection.
- The calcineurin inhibitor tacrolimus bind to FK binding protein, and the drug-immunophilin complex binds to calcineurin.
- This leads to dephosphorylation of nuclear factor for activated T cells (NFAT) and prevention of its translocation to the nucleus, causing down regulation of cytokine transcription.

CLINICAL STUDY :

Late Conversion of Kidney Transplant Recipients from Ciclosporin to Tacrolimus Improves Graft Function : Results from a Randomized Controlled Trial.

BACKGROUND -

Tacrolimus (TAC) to ciclosporin A (CSA) conversion studies in stable kidney transplant recipients have reported varying effects on graft function. In this study graft function (eGFR) trajectories using linear mixed models was done, which provide effect estimates on both slope and baseline level of GFR and offer increased statistical power.

METHODS -

Secondary analysis of a randomized controlled trial of CSA treated kidney transplant recipients with stable graft function assigned to receive 0.1 mg/kg/day TAC (target 5-8 ng/ml) or to continue CSA based immunosuppression (target 70-150 ng/ml) at a 2:1 ratio. Renal graft function was estimated via the MDRD (eGFRMDRD) and CKD - EPI (eGFRCKD - EPI) formulas.

RESULTS -

45 patients continued CSA and 96 patients were converted to TAC with a median follow up of 24 months. Baseline demographics (except for recipient age) including native kidney disease, transplant characteristics, kidney graft function, medication use and comorbid conditions did not differ between groups. In respect to long-term renal graft function, linear mixed models showed significantly improved eGFR trajectories in the TAC versus CSA group over 24 months of follow up. Estimated eGFRCKD - EPI group differences between TAC and CSA were -3.49 at 3 months, -5.50 at 12 months, and -4.48 ml/min/1.73m^2 at 24 months of follow up. Baseline eGFR was a significant predictor of eGFR trajectories. Significant effects for randomization group were evident despite short-term trough levels in the supratherapeutic range (27% (n = 26) of TAC patients at week one). Median TAC trough levels were within target range at week 4 after conversion.

CONCLUSION -

Conversion of CSA treated kidney transplant recipients with stable graft function to TAC (target 5-8 ng/ml) showed significantly improved long-term eGFR trajectories when compared to CSA maintenance (target 70 - 150 ng/ml).

DESCRIPTION :

- Tacrolimus is an immunosuppressive drug used mainly after allogeneic organ transplant to lower the risk of organ rejection.
- It achieves this by inhibiting the production of interleukin-2, a molecule that promotes the development and proliferation of T cells, which are vital to the body's learned (or adaptive) immune response.

INDICATION :

- TACROREN is a calcineurin-inhibitor immunosuppressant indicated for Prophylaxis of organ rejection in patients receiving allogeneic liver, kidney or heart transplants.
- Use concomitantly with adrenal corticosteroids; in kidney and heart transplant, use in conjunction with azathioprine or mycophenolate mofetil (MMF).

MECHANISM OF ACTION :

- Tacrolimus inhibits T - lymphocyte activation. Tacrolimus binds to an intracellular protein, FKBP - 12.
- A complex of tacrolimus-FKBP-12, calcium, calmodulin and calcineurin is then formed and the phosphatase activity of calcineurin inhibited.
- This effect may prevent the dephosphorylation and translocation of nuclear factor of activated T-cells (NF-AT), a nuclear component thought to initiate gene transcription for the formation of lymphokines (such as interleukin-2, gamma interferon). The net result is the inhibition of T lymphocyte activation (i.e., immunosuppression).

DOSAGE :

Patient Population	Recommended Initial Oral Dosage (2 divided dose every 12 hours)	Observed Whole blood Trough Concentration
Adult Kidney Transplant In combination with azathioprine	0.2 mg/kg/day	Month 1-3: 7-20 ng/mL Month 4-12: 5-15 ng/mL
In Combination with MMF/IL-2 receptor antagonist	0.1 mg/kg/day	Month 1-12: 4-11 ng/mL
Adult Liver Transplant Pediatric Liver Transplant	0.10-0.15 mg/kg/day 0.15-0.20 mg/kg/day	Month 1-12: 5-20 ng/mL Month 1-12: 5-20 ng/mL
Adult Heart Transplant	0.075 mg/kg/day	Month 1-3: 10-20 ng/mL Month ≥ 4: 5-15 ng/mL

PRESENTATION :

TACROREN 0.25/0.5/1 mg are available as a strip of 10 Capsules in Alu - Alu strip packing.

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