CLINICAL STUDIES

STUDY	ORGAN GROUP	BRAND OF TACROLIMUS	DESIGN	RESULTS
Alloway et al. (2017)[1]	35 RENAL 36 LIVER	Prograf Sandoz Dr. Reddy	Randomized, crossover using pharmacokinetic parameters to establish bioequivalence	Bioequivalence between Prograf and alternate brands using FDA metrics.
Arns et al. (2017)[2]	81 de novo RENAL	44 Prograf 37 TacHexal (Sandoz)	Multicentre, randomized, open-label compared pharmacokinetic data and clinical characteristics of Prograf vs. TacHexal	No relevant difference in pharmacokinetic parameters at 1 month post-transplant and trough concentrations at 3 and 6 months.
Barbour et al. (2018)[3]	17 patients with Glomerulonephritis	Prograf to Sandoz	Conversion study	No difference in the mean tacrolimus levels. Only 2 patients required dose adjustments. No disease flare ups or increased side effects.
Bloom et al. (2013)[4]	68 RENAL (SUBPOPULATIONS: FEMALE, AFRICAN-AMERICAN, DIABETES, USE OF STEROIDS)	Prograf Sandoz	Randomized, crossover using pharmacokinetic data to establish bioequivalence	Sandoz is expected to offer comparable bioavailability to Prograf regardless of patient characteristics.
Naicker et al. (2017)[5]	37 PEDIATRIC RENAL	Prograf to Sandoz	Retrospective, cohort conversion study by measuring 3 pre-conversion tac trough and creatinine and 3 post-conversion levels at day 3,10,X.	Pediatric renal transplant recipients can be converted from tacrolimus Prograf to Sandoz with negligible change metrics or allograft function.
Spence et al. (2012)[6]	234 RENAL, LIVER, HEART	Prograf Alternate	Retrospective analysis	Alternate brand shows comparable trough levels as Prograf. No adverse events reported.

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