

New drug for kidney transplant recipients effective in humans

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Initial results of a study conducted at 100 centers worldwide indicate that belatacept, a first-in-class costimulation blocker can prevent the immune system rejecting new organs. The results also suggest that it may provide similar patient and graft survival to cyclosporine but with fewer side effects and superior kidney function after 12 months. The study, published today in the *American Journal of Transplantation*, provides the first findings to come from BENEFIT (Belatacept Evaluation of Nephroprotection and Efficacy as First-line Immunosuppression Trial).

Although advances in transplantation have reduced rates of [organ rejection](#) and improved outcomes after one-year, corresponding improvements in long-term [survival rates](#) have not been observed. The kidney allograft (transplant from another human donor with different genes) survival rate is 95% for transplants from living donors and 89% for transplants from deceased donors during the first year. BENEFIT is a three-year, randomized, active-controlled, parallel-group, set up to evaluate the efficacy of belatacept for post-transplant maintenance immunosuppressive management.

"Our findings show that this will be a novel and more specific way of suppressing the immune system with less toxicity," said lead researcher Dr. Flavio Vincenti, of the University of California, San Francisco Medical Center. "It will target the specific responses that cause rejection of transplanted organs with less damage to other systems of the body."

Belatacept is different from calcineurin inhibitors (CNI), such as

cyclosporine, which is the class of drugs most commonly used to suppress the immune system in transplant patients, because it does not cause the toxicities associated with CNI - such as nephrotoxicity and aggravating cardiovascular risk factors. Belatacept selectively blocks T-cell activation (which plays a key part in immune response) and the results suggest that this selectivity allows effective immunosuppression, better preservation of renal function and an improved cardiovascular/metabolic risk profile.

The researchers found that treatment with belatacept was generally safe, although there was a higher incidence of post-transplant lymphoproliferative disorder in belatacept patients with known risk factors.

686 patients 18 years or older who were expected to receive a kidney transplant from a standard criteria donor were included in BENEFIT, and were randomized into three groups; more or less intensive regimens of belatacept, or cyclosporine. 666 patients eventually received a transplant and of these, 527 patients completed the initial 12 month treatment phase, with an even spread of discontinuation between the groups.

"Although belatacept was associated with a higher early rejection rate than patients treated with [cyclosporine](#), it was also associated with better [kidney function](#) and thus has the potential of extending the life of the renal graft," added Vincenti. "Of course, only time will tell how many patients may benefit from this new drug."

Alongside the BENEFIT study is BENEFIT-EXT, which included 543 recipients of extended criteria donors (defined as donors over 60 years old, over 50 years and with two other risk factors, or donation after cardiac death, or more than 24 hours with no blood supply to the organ). 394 patients completed the initial 12 months of this trial with similar

results. The initial results of this study are also published today in the [American Journal of Transplantation](#).

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