

Promising kidney drug fails in large clinical trial

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What was hoped to be a promising new drug to protect the kidneys has failed to benefit diabetes patients with kidney disease, according to a study appearing in an upcoming issue of the *Journal of the American Society Nephrology (JASN)*. The results call into question the usefulness of the drug sulodexide.

Kidney disease due to diabetes is the most common cause of kidney failure in developed countries. The number of patients with type 2 diabetes is expected to double and reach 366 million individuals worldwide by 2030. Kidney disease cases are sure to rise in parallel.

Investigators have wondered whether sulodexide, which belongs to a class of drugs called glycosaminoglycans, may protect the kidneys. The drug is actually a naturally occurring compound and has been used for more than 20 years to treat various heart conditions. Previous research indicates that sulodexide reduces excretion of protein in the urine, which is a hallmark of kidney disease.

To test the effects of sulodexide on the kidneys in a large and extensive trial, David Packham, MD (Melbourne Renal Research Group, in Australia) and his colleagues within the Collaborative Study Group (a large clinical trial group comprised of various kidney care centers) conducted a randomized, double-blind, placebo-controlled study in patients with diabetes and kidney disease. The investigators planned to enroll 2,240 patients in the Sun-MACRO trial over a period of two years, but they stopped the study early after enrolling 1,248 patients because they did not detect any significant differences between sulodexide and placebo for preventing kidney failure. Also, the trial did not confirm the potentially beneficial effect of sulodexide in reducing urinary protein excretion that was previously reported in smaller studies.

"In view of the negative results of Sun-MICRO trial

and the data analysis from this study, it is tempting to conclude that sulodexide has no therapeutic benefit in type 2 diabetic nephropathy," the authors wrote.

More information: The article, entitled "Sulodexide Fails to Demonstrate Renoprotection in Overt Type 2 Diabetic Nephropathy," will appear online at jasn.asnjournals.org/ on Thursday, October 27, 2011, doi:10.1681/ASN.2011040378

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