The Effect of Reduction of Uremic Toxin for Chronic Kidney Disease Progression; Kremezin Study Against Renal Disease Progression in Korea (K-STAR)

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Considering the increasing number of end-stage renal disease patients (1,000 ppm in Korea) and socioeconomic burden, the prevention of chronic kidney disease (CKD) progression into ESRD is a project with top priority. Although many interventions are provided, un-met needs are still existing. Here, we conduct a multicenter, randomized, parallel, controlled study to re-evaluate the efficacy and safety of AST-120 (Kremezin) in inhibiting the progression of renal failure in patients with CKD stage III-IV (NCT 00860431). Study objectives are; to evaluate the effects of AST-120 on the progression of CKD (primary endpoints; doubling of serum creatinine, 50% decrease in MDRD eGFR and initiation of maintenance renal replacement therapy): secondary endpoints; to evaluate the effects of AST-120 on renal function (eGFR and proteinuria), to evaluate the effects of AST-120 on health related quality of life, to evaluate the safety and side effects of AST-120 in long term use, and to evaluate all-cause death and hospitalization). Patient enrollment was completed at the end of August, 2010. A total of 579 patients were recruited from 11 centers and randomized either to control or treatment groups. The patients will be followed for 3 years after randomization. Mean age is 57+13.3 year-old and 32% were female patients. Half of the study subjects have diabetic kidney disease and eGFR at the time of enrollment is 27+7.4 ml/min/1.73m^2. Thirty per cent of patients were CKD stage III. BMI was 24.7 kg/m^2. Patients on CKD stage IV had higher serum levels of indoxyl sulfate and beta-2 microglobulin than patients on CKD stage III at the time of enrollment. Medication compliance rate was more than 90% at the time of each visit. The one year analysis of the efficacy and safety of AST-120 on CKD progression will be presented.