# Effect of Kibow Probiotic Renadyl™ on sCD30 Levels in Hemodialysis Patients

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## Abstract

Our prior studies in patients with CKD 3-4 (n=31) given RenadylTM, a safe proprietary dietary supplement, which metabolizes various nitrogenous wastes in the bowel, at a dose of 180-270 B CFU, over a 6 month period showed that BUN, creatinine and K+ levels declined. How azotemia impacts QoL is unknown, though increased inflammation is a postulated mechanism. We now report on the effects of Kibow Probiotic RenadylTM on 26 hemodialysis patients where we detected a reduction in their WBC counts, C-reactive protein (CRP) and total indoxyl glucuronide levels. In order to link the reduction to markers of inflammation, we looked at one biomarker of T cell activation, sCD30. This marker has previously been shown to be elevated in patients with CKD and lower levels of sCD30 have been associated with better prognosis in kidney transplant patients. We conducted a prospective, double blind crossover trial with placebo and RenadylTM for 8 weeks, followed by an 8-week washout period. Patient's serum was taken at 3 time points (baseline, after probiotics, and after placebo) and sCD30 levels were measured by ELISA (Bender MedSystems). Patient adherence was assessed by pill count and stool culture to verify probiotic growth during study and absence during placebo period. Data were analyzed with ANOVA for a crossover design with a mixed model methodology in SAS to detect differences in least square means in treatment, period and sequence effect. Mean sCD30 levels were 94.74ng/ml and decreased to 89.84ng/ml with probiotic administration. This difference is not statistically significant (p= 0.49). Our results show that sCD30 levels are not affected with the administration of probiotics, which suggests that patients do not become immunocompromised by this treatment. Larger population studies or longer term studies might be needed to give a better insight into the role of T cell modulation by Probiotics in this population.

## Objectives

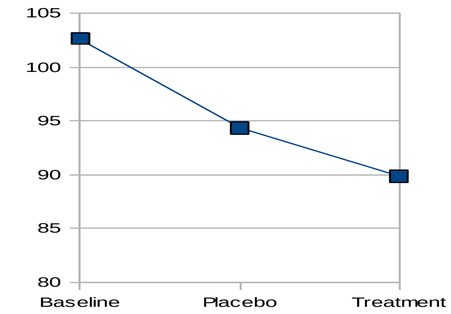
Previous studies had shown that Renadyl was able to improve quality of life and decrease BUN in patients with ESRD. However, the mechanism of action is unknown. Our goal is to measure markers of inflammation to determine how probiotics mediate their protective effects, We looked at sCD30 levels to determine if it is involved in Renadyl's anti-inflammatory effects. We hypothesized that the levels would decrease after treatment with Renadyl compared to the placebo trials.

## Methods

Patients were assigned to take either the placebo or Renadyl™ first for 8 weeks, followed by a washout period of 8 weeks and finishing with 8 weeks of the placebo or Renadyl™ (depending on which was taken first). Each patient's blood samples were taken at the first visit, after finishing 8 weeks of palcebo, and after finishing 8 weeks of Renadyl™. The serum was extracted from the blood and this was used to determine the sCD30 levels.

The sCD30 assay kit was purchased from eBioscience. The wash buffer, assay buffer, HRP-conjugate solution, and the standards were prepared according to the kit's instructions. The wells in the assay plate were washed with 400uL 1x wash buffer 2 times. Next, 75uL of sample diluent and 25uL of serum were added to each well. 50uL of 1x HRP-conjugate solution was added to each well and the wells were incubated at room temperature for 3 hours with shaking. After incubation, the wells were washed with 400uL 1x wash buffer 3 times. 100uL of TMB-substrate solution was added to each well and the wells were incubated at room temperature until the 100U/L standard well showed a strong blue color (around 10 minutes). 100uL of stop solution was added to each well and the wells were read at 450nm on a plate reader. The data were analyzed using SAS.

## Results




Mean baseline sCD30 levels were 102.6ng/ul. The mean levels after placebo treatment was 94.74ng/ul and the levels after probiotic treatment was 89.84ng/ul. This difference is not statisticaly significant (p=0.49).

## Conclusions

Our results show that sCD30 levels are not affected with the administration of probiotics. This suggests that patients are not immunologically compromised by this treatment. However, since total WBC counts were reduced, markers of T-cell activation might be involved in the probiotics' protective effect. Larger population studies or longer term studies might be needed to give a better insight into the role of T cell modulation by Probiotics in this population

## References

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