



Dose Escalation, Safety and Impact Of A Strain-Specific Probiotic (Renadyl™) on CKD Stages III and IV Patients



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Abstract

The human gut has been utilized as an adjunct for the extraction of toxins in patients suffering from CKD and ESRD. Recent metagenomic studies have queried and confirmed that the microbiome within the gut also gets altered in disease states such as Type 2 Diabetes, a disease of global epidemic proportions.

Our probiotic bacterial formulation Renadyl™ consists of three distinct microbial strains (30 Billion CFU/cap), which have shown the ability to metabolize various uremic nitrogenous wastes, thus helping to promote healthy kidney function.



Streptococcus thermophilus
KB 19

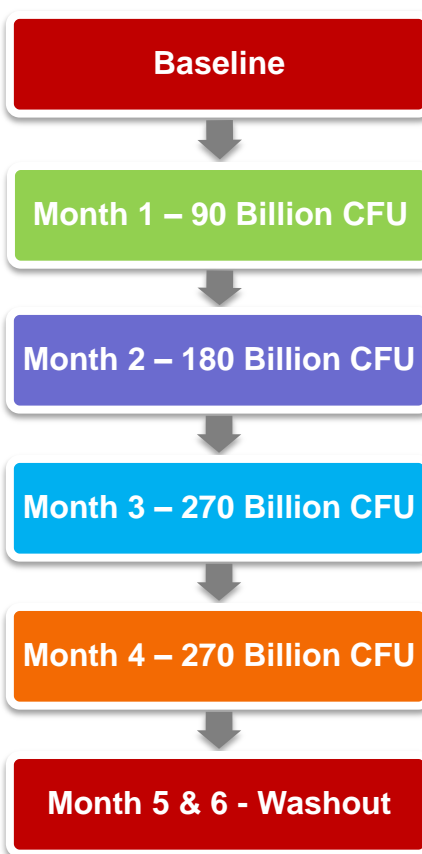


Lactobacillus acidophilus
KB 27



Bifidobacterium longum
KB 31

Methods



An open label, dose escalation study was carried out in CKD Stage 3 and 4 patients. Renadyl™ (*S thermophilus* KB 19, *L acidophilus* KB 27 and *B longum* KB 31) was administered orally, as vegetarian enteric coated gel capsules.

Following baseline data, patients were given Renadyl™ in escalating doses starting from 90 Billion CFU per day in Month 1 to 180 Billion CFU per day at Month 2 and 270 Billion CFU per day during Months 3 and 4. This was followed by a 2 month washout phase.

Routine physicals and blood draws were done at baseline, Months 1 through 4 and Month 6 (washout). A Quality of Life (QOL) questionnaire was also administered at baseline, Month 4 and 6. All data were analyzed using SAS system software, and mixed model methodology for repeated measurements.

Results

Parameter	Treatment period	Amount of reduction	P value
BUN (mg/dL)	Baseline vs Month 4	- 4.55	0.03
	Month 1 vs Month 4	- 4.75	0.03
Creatinine (mg/dL)	Month 2 vs Month 6	- 0.32	0.005
Potassium (mEq/L)	Month 2 vs Month 6	- 0.26	0.03

- 24 (80%) out of 31 patients completed the study till the date of submission of the abstract.
- No significant adverse effects were noted with dose escalation.
- Reduction in levels of BUN (p=0.03), creatinine (p=0.005) and potassium (p=0.03) was seen.
- Improvement was seen in phosphorus, hemoglobin and CRP though it was not statistically significant.
- Serum levels of pentosidine, indoxylsulphate, B-2 microglobulin and p-cresylsulphate varied widely and were difficult to conclude.
- QOL indicated improvement in physical functioning. No significant change was seen in pain, physical, mental, emotional and social well-being.

Objectives

Primary aim was to explore the maximum tolerable dose and duration of Renadyl™ administration, sufficient to extract other known uremic toxins in addition to urea.

Secondary aims were to investigate whether quantifiable Quality of Life (QOL) improvement occurred, as well as to confirm the safety and efficacy of the product.

Conclusions

Administration of Renadyl™ for 4 months in CKD stage 3 and 4 patients at a very high dose of 270B CFU per day, seems to be safe and well tolerated. Statistically significant improvements were noted in BUN, creatinine, potassium and physical well-being.