HIGH PROTEIN MEALS DURING HEMODIALYSIS TREATMENT TO INCREASE SERUM ALBUMIN WHILE CONTROLLING PHOSPHOROUS: PRELIMINARY RESULTS FROM THE FREDI STUDY


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INTRODUCTION

- There is a known and consistent association between higher serum PHOSPHORUS levels and increased death risk in dialysis-dependent patients.
- Traditional approach to phosphorus control in dialysis patients including dietary restriction, since higher protein intake may lead to higher serum phosphorus level.
- However, higher protein intake may also be associated increasing serum albumin level and improving survival in hypoalbuminemic hemodialysis patients.
- We hypothesized that high protein diet including during hemodialysis treatment, if combined with effective phosphorus control using lanthanum carbonate, is effective.

RESULTS

- We successfully recruited 110 hypoalbuminemic (<4.0 g/dL) hemodialysis patients from several DaVita dialysis clinics in Southern California (see flow chart).
- Upon inclusion/exclusion criteria qualification and 1:1 randomization:
  - The “intervention” group received 8 weeks of high protein food in the form of cold meal boxes (51 g protein, 850 Cal, phosphorus to protein ratio <10 mg/gm) during each hemodialysis treatment along with 0.5 to 1.5 g Fosrenol (titrated as needed) plus dietary counseling to maintain a high dietary protein intake at home.
  - The “control” group received salad meal boxes with low calorie (<50 Cal) and very low protein (<1 g) during each hemodialysis treatment and continued non-Fosrenol binders as needed.
- The main outcome measure included:
  - Combined rise in serum albumin of >0.2 g/dL while maintaining in-target phosphorus 3.5 – <5.5 mg/dL
  - Both achieved by the end of the intervention period analyzed according to intention-to-treat (ITT) principle.
- Data from 106 patients were eligible for the ITT analyses.
- Results: Combined rise in albumin while maintaining phosphorus in the target range was achieved in 25.5% and 9.8% of the 51 intervention and 55 control subjects, respectively (χ² p=0.036).
- No serious adverse event were observed, and patients reported satisfaction with high protein meals during HD.

METHODS

- The “Fosrenol for Enhancing Dietary Protein Intake in Hypoalbuminemic-mic Dialysis Patients” (FREDI) pilot/feasibility randomized controlled trial (ClinicalTrials.gov # NCT0111694) was designed and conducted to examine the following hypothesis:
  - Provision of food with high protein content including during hemodialysis treatment combined with a potent phosphorus binder such as lanthanum carbonate (Fosrenol™) to simultaneously control phosphorus burden of high protein diet will improve clinical outcomes.
- The FREDI study sample size was based on 110 adult hypoalbuminemic (albumin<4.0 mg/dL) hemodialysis patients from dialysis clinics in Southern California.

CONCLUSIONS

- We conclude that in hemodialysis patients with albumin <4.0 g/dL, providing high protein meals combined with Fosrenol™ during hemodialysis treatment in the dialysis clinic is safe and may increase serum albumin levels while controlling serum phosphorus.
- These findings may have important clinical implications in dialysis patient care management and need to be examined in additional studies.

KEY LEARNINGS

- The traditional approach of restricting dietary protein to control phosphorus in dialysis patients may not be the most appropriate method especially in hypoalbuminemic dialysis patients.
- High protein diet including during hemodialysis treatment may be a feasible approach and associated with favorable outcomes but additional studies are necessary.

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