



Department of Medicine

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Duke Nephrology

The HiLo Trial

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Overview of study design: An 'A' vs. 'B' trial in dialysis

Pragmatic, multicenter, cluster-randomized, open-label, superiority, outcomes trial

- Compare effects of two different phosphate management strategies
 - Liberal P control, targeting 6–7 mg/dl, or
 - Strict P control, targeting <5.0 mg/dl
 - Individual-level randomization
 - N = ~4000 patients being treated with hemodialysis at >100 facilities
- Partners
 1. Large national for-profit dialysis corporation: DaVita, Inc.



Outcomes

1. Primary

- Composite of all-cause mortality and all-cause hospitalization: total counts per person-years of follow-up (continuous)

2. Secondary

- All-cause mortality, time-to-event
- Total inpatient hospital days per person-years of follow-up
- Cause-specific hospitalizations in Medicare beneficiaries based on merging clinical data from HiLo with claims data from the CMS Virtual Research Data Center as in PROVEN
- Diet & nutrition: serum albumin, protein catabolic rate (PCR)
- Patient-reported outcomes (PROs) related to gastrointestinal symptoms

Current Status

1. 31 dialysis units activated under individual randomization design since February, 2022.
2. 140 participants enrolled in the study (40% consent rate)
3. Currently activating the Woodlands and Voyager divisions (northeastern US).
4. Additional 6 divisions in the queue for activation
5. Implementing dietitian champions to support efficient activation and enrollment
6. Providing dietitians rewards for reaching study milestones

Barriers Scorecard

Barrier	Level of Difficulty*				
	1	2	3	4	5
Enrollment and engagement of patients/subjects			X		
Engagement of clinicians and health systems			X		
Data collection and merging datasets		X			
Regulatory issues (IRBs and consent)	X				
Stability of control intervention		X			
Implementing/delivering intervention across healthcare organizations		X			

*Your best guess! 1 = little difficulty 5 = extreme difficulty

Top Challenges

1. Dietitian availability to perform activation and enrollment activities
2. Medical director and/or rounding nephrologist adoption of the protocol

Recent Generalizable Lesson Learned

1. Patient care is team-centric. Need to ensure all staff members and medical providers are informed about the study

Current Data Sharing Plan & Obstacles

1. NIDDK Repository – private archive managed by the NIDDK
2. Patient level: de-identified
3. Facility level: de-identified
4. Provider level: de-identified

Data We're Planning to Share

1. Trial data
2. De-identified data set for all eligible patients in cluster-randomized sites (will be receiving soon)

Questions & Comments

