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

<table>
<thead>
<tr>
<th>Barrier</th>
<th>Level of Difficulty*</th>
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</thead>
<tbody>
<tr>
<td>Enrollment and engagement of patients/subjects</td>
<td>X</td>
</tr>
<tr>
<td>Engagement of clinicians and health systems</td>
<td>X</td>
</tr>
<tr>
<td>Data collection and merging datasets</td>
<td>X</td>
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<tr>
<td>Regulatory issues (IRBs and consent)</td>
<td>X</td>
</tr>
<tr>
<td>Stability of control intervention</td>
<td>X</td>
</tr>
<tr>
<td>Implementing/delivering intervention across healthcare organizations</td>
<td>X</td>
</tr>
</tbody>
</table>

*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