A study in pediatric patients with CF introduced high-dose Cystic Fibrosis Foundation Vitamin D replacement guidelines. Insufficient pancreatic enzyme production causes malabsorption of vitamin D. Adequate vitamin D supplementation in CF patients has been linked to reduced fractures, decreased levels of inflammatory markers, improved glucose management, improved FEV1, and decreased acute pulmonary exacerbations.

Cystic Fibrosis Foundation Vitamin D replacement guidelines may inadequately correct vitamin D deficiency in many patients with CF.

A study in pediatric patients with CF introduced high-dose vitamin D3 therapy producing an association with quantitative improvement from deficient to normal vitamin D status without evidence of toxicity.

**Objectives**

**Primary**

- Change in serum 25-hydroxyvitamin D 25(OH)D levels at 1 and 3 months

**Secondary**

- Change in serum 25(OH)D levels at 6, 9, and 12 months
- Association of single, high dose vitamin D3 with improved adherence, depression, anxiety, pain, sleep, and social functioning

**Methods**

**Study Design**

Randomized, double-blind, placebo-controlled trial to examine the difference between single, high-dose vitamin D3 therapy and guideline-driven maintenance dosing.

**Participants**

<table>
<thead>
<tr>
<th>Inclusion</th>
<th>Exclusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients diagnosed with cystic fibrosis seen at the Intermountain Cystic Fibrosis Adult Center or University of Utah Hospital</td>
<td>Pregnancy/ breast feeding</td>
</tr>
<tr>
<td>≥18 years old</td>
<td>Prisoners or wards of the state</td>
</tr>
<tr>
<td>Baseline 25(OH)D levels &lt;30 ng/mL</td>
<td>Patients in the Intensive Care Unit</td>
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<td></td>
<td>Patients unable to swallow</td>
</tr>
<tr>
<td></td>
<td>Received high-dose vitamin D3 therapy in the last 6 months</td>
</tr>
</tbody>
</table>

**Data Collection**

**Laboratory Data Elements**

- Serum 25(OH)D level
- Comprehensive Metabolic Panel
- Spirometry

**Questionnaires**

- Patient Health Questionnaire depressive screens (PHQ-9)
- Generalized Anxiety Disorder 7-item Scale (GAD-7)
- Likert Pain Scale
- Adherence assessment for maintenance vitamin D therapy
- Pittsburgh Sleep Quality Index (PSQI)
- Patient-Reported Outcomes Measurement Information System (PROMIS) Short Form v1.0 - Sleep disturbance 8a
- PROMIS Social Functioning

**Procedures**

**Baseline Appointment**

- Obtain baseline medical history and current medication list
- Collect laboratory data elements
- Complete Questionnaires

**Consecutive Appointments**

- Collect laboratory data elements
- Complete Questionnaires

**Power Analysis**

- Calculated using two-tailed t-tests
- Based on expected difference in a serum 25(OH)D level of 32 ng/mL and SD in measurements of 32
- Expected difference determined from prior study in pediatric patients
- 16-32 patients required to achieve 90% power and an alpha of 0.05 and 0.01

**Intervention and Randomization**

- Total Population
  - N = 40
  - N = 20
  - N = 20

**Data Safety Monitoring Board (DSMB)**

- Members include investigational drug services, pharmacy, and pulmonology
- Assess risks associated with the study:
  1. Blood draws - pain, discomfort, syncope, bleeding or bruising, and can increase the risk of infection
  2. Hypervitaminosis - hypercalcemia, hyperphosphatemia, renal calculi, nausea, vomiting, severe lower abdominal pain

**Results**

- To Be Determined
- Investigational New Drug Application required for high dose vitamin D3 per the Food and Drug Administration

**References**


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- All authors have no relevant conflicts of interest to report
- Funding will be provided by the Intermountain Cystic Fibrosis Adult Center