Category: Community Outreach and Engagement & Diversity, Equity, and Inclusion - Work in progress

Differences in Immunological Effects of Vitamin D Replacement Among Black Prostate Cancer Patients With Localized Versus Metastatic Disease: A Decentralized Clinical Trial

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1. Background
Black men are at increased risk of hypovitaminosis D. Survival rates for men diagnosed with prostate cancer (CaP) vary widely depending on demographic factors. Examining the connection between hypovitaminosis D and CaP outcomes requires an understanding of the variables that alter vitamin D levels, especially in Blacks. In May 2023, the FDA released guidance for the expansion of access to clinical trials using digital health technologies to conduct remote clinical trials.

2. Goals
Aligned with this guidance, Mayo Clinic (MC) developed a Clinical Trials Beyond Walls initiative to enhance capabilities for research teams to reach patients to participate in CT without traveling to a Mayo Clinic location. A fully decentralized CT was implemented with support of the MC Clinical Trials Beyond Walls initiative to exclusively enroll and accrue Black men with CaP.

3. Solutions and Methods
The study is an interventional therapeutic clinical trial evaluating the prevalence of vitamin D insufficiency and the potential beneficial immunological effects of vitamin D replacement in Black patients with CaP (localized and metastatic). Remote screening and consenting were implemented to allow prospective trial participants to complete ICD from anywhere. Study visits were conducted remotely using telemedicine technologies, which reduced the need for participants to travel to the study site. Because of the national geographic reach for recruitment, options for biospecimen collection allowed for participants to have biospecimen collected by trained professionals using mobile phlebotomy vendors, or to use an Uber Health transportation option to travel to a contracted commercial lab. All research samples collected at the commercial lab or collected at a participant's home were mailed to Mayo Clinic and processed, with downstream biospecimen analysis conducted by the Mayo Clinic Biospecimen and Processing Core laboratory. The interventional medication (Cholecalciferol) was similarly prescribed to the CT participant and dispensed by a contracted pharmacy.

4. Outcomes
CT is currently ongoing with decentralized capabilities.

Data Analysis Plan: Models will be controlled for age (years), body mass index (BMI) (continuous), smoking (yes/no). To examine the effects of vitamin D receptor variants, each variant will be added as a covariate in the regression model. Statistical tests will be two-sided and p-values less than .05 will be considered statistically significant. Descriptive analysis on self-reports of vitamin D supplement use since diagnosis, at enrollment, and 8-week follow-up. Results will be stratified by ethnicity and other social factors. Analysis of records describing frequency with which participants' 25(OH)D blood levels assessed post diagnosis, prior to study enrollment and at follow up will be completed. Comparisons between groups will include chi-square and t-tests.

5. Lessons Learned and Future Directions

Remote clinical trial services can successfully be used to decentralize aspects of clinical trials. This enables participants to engage in research in their home environments or local communities. Decentralization of clinical trials can reduce transportation-related barriers for cohorts who are at risk for exclusion from CT trial participation due to geographic constrains. However, the creation and coordination of remote factors must consider a culturally humble approach for the adaptation and modification of study protocols, decentralized tools, linguistically competent vendors, and patient-centric strategies.

Figure

Study Table of Assessments

Study Activity	Prescreening	Baseline/ (Within weeks after prescreening if eligible)*	Start of Treatment (Within 4 weeks of prescribing if eligible)	4 Weeks from Start of Treatment (+/- 1 week) (Phone call)	8 Weeks from Start of Treatment (+/- 1 week)
			0	D28	D56
Prescreening Consent	X				
Prescreening Eligibility	X				
Blood Draw (25-Hydroxy D and Calcium)	X				X
Main Study Consent		X			
Baseline Eligibility		X			
Medication Diary (Dispense)		X			
Blood Draw (Immunological Function Test – Research Kit)		X			X
Administer CDC HRQOL–4 Healthy Days Measure		X			X
Vitamin D Prescription		X			
Virtual visit with PI		X			X
Initiate treatment			X		
AE Assessment		X		X	X
Medication Compliance Review				X	X