

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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ABSTRACT

BACKGROUND

Studying the link between hypovitaminosis D and prostate cancer outcomes, particularly in Black individuals, requires understanding factors influencing vitamin D levels, given their increased risk and survival rates. In response to FDA guidance on remote clinical trials, Mayo Clinic initiated the Clinical Trials Beyond Walls program, allowing decentralized trials focused on Black men with CaP.

OBJECTIVE

Assess the effectiveness of decentralized remote clinical trial services in engaging Black men with CaP, examining the relationship between hypovitaminosis D and cancer outcomes, with a focus on culturally sensitive adaptation of study protocols.

METHODS

The trial studies vitamin D insufficiency and its immunological effects in Black patients with CaP. Remote screening and consent enable participation from anywhere, with telemedicine for study visits. Biospecimens are collected by mobile phlebotomists or at a commercial lab, then sent to Mayo Clinic for analysis. Cholecalciferol is prescribed and dispensed by a contracted pharmacy.

RESULTS

CT is currently ongoing with decentralized capabilities. Estimate enrollment through 2025 with national campaign

CONCLUSIONS

Remote clinical trial services decentralize trials, allowing participants to engage from home or local areas, reducing transportation barriers. The addition of additional decentralized capabilities to address other SDH can be seamlessly integrated. However, ensuring cultural humility is crucial for adapting study protocols, tools, vendors, and strategies to diverse populations. Engagement of institutional collaborators who are willing to drive successful implementation is essential.

OBJECTIVES

- Determine the prevalence of vitamin D insufficiency among black/AA prostate cancer patients.
- Determine the changes in circulating immunological cell function among patients with vitamin D insufficiency and the effects of vitamin D replacement on those changes.
- Determine the acceptability of vitamin D replacement therapy among black/AA prostate cancer patients and potential impact on health-related quality of life.
- Determine if there are differences in the peripheral blood immunological cell function in black/AA patients with metastatic or locally recurrent prostate cancer compared to those with localized prostate cancer.

METHODS

Study Activity	Screening Pre-Registration Screening (<30 days)	Active Monitoring			Clinical Follow-Up
		Baseline/Start of Treatment	Check-in, 4 weeks (+/- 1 week)	End treatment (+/- 1 week)	
Remote Screening Eligibility	X				
Remote Pre-registration consent (via telemedicine)	X				
Serum Vitamin D and Calcium Test (mobile phlebotomy at home scheduled)	X			X	
Baseline Eligibility		X			
Remote Main Study Consent (via telemedicine)		X			
Immunological Lab Studies (Research Study Kit) (mobile phlebotomy at home scheduled)		X		X	
Quality of Life Measure (CDC HROQL-4 Healthy Days Measure) (Electronic questionnaire)		X		X	
AE Assessment (phone call)			X	X	
Medication Compliance Review (phone call)			X	X	
Participant Remuneration (ClinCard electronically delivered)		X		X	
Oncology visit (via telemedicine)		X			X

RESULTS 1

Go-live date for decentralized capabilities: October 1, 2023

Decentralized capabilities implemented:

- Remote consent capturing via Adobe Sign
- Telehealth visits
- Phone visits
- Mail order pharmacy
- Data capturing via REDCap and Qualtrics
- Decentralized phlebotomy via mobile collection and brick-and-mortar collections

RESULTS 2

Participant involvement:

- Total participants in decentralized cohort: 36
- Successful blood draws completed: 60

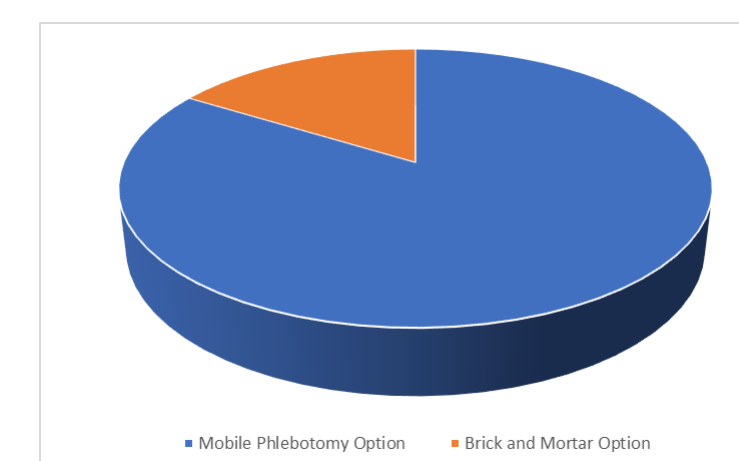
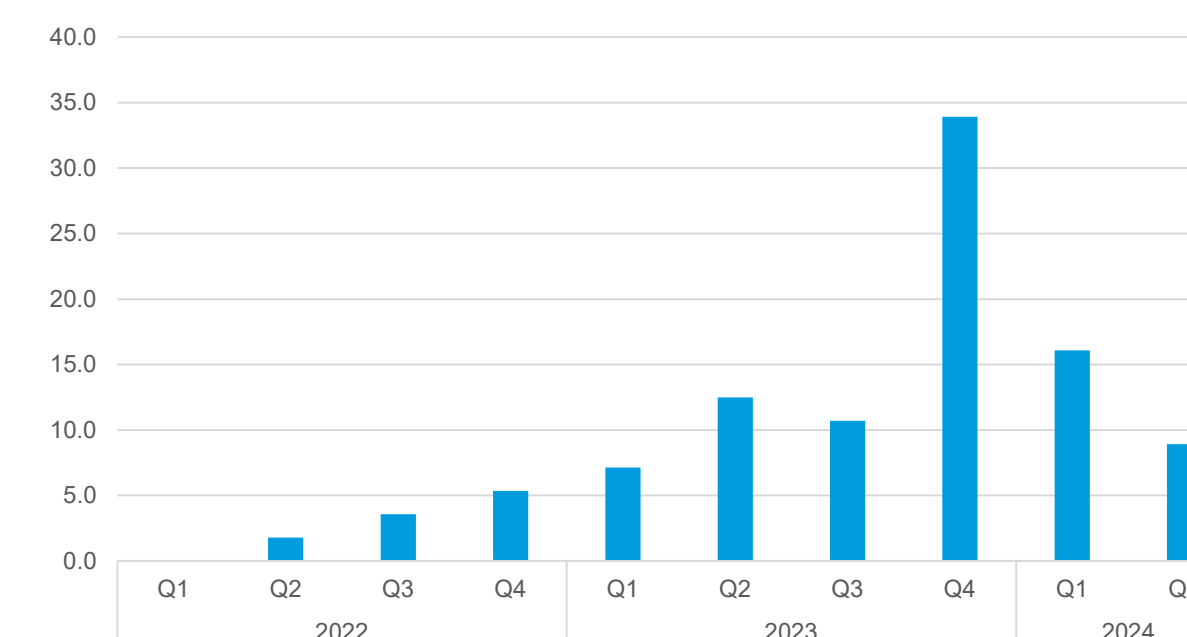
Phlebotomy breakdown:

- 90% blood draws completed via mobile collection
- 10% were completed via brick-and-mortar collection

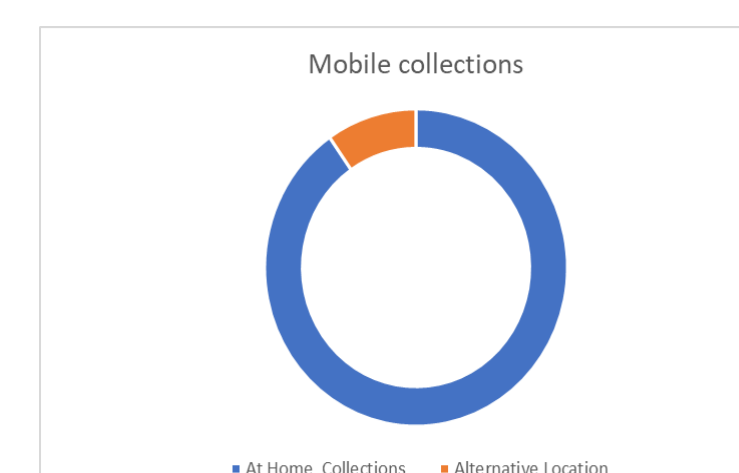
Patient preferences:

- Approximately 90% of patients preferred mobile collection at home
- 10% preferred collection at an alternative location, primarily their workplace.

Percent of Accrued Patients



Comparison of Patient Utilization: Decentralized Phlebotomy with Brick and Mortar vs. Mobile Phlebotomy Options



DISCUSSION

Challenges and Opportunities:

Limited Accessibility of Decentralized Phlebotomy:

- Unavailability of mobile phlebotomy in the state of Nevada.
- Inability to complete brick-and-mortar phlebotomy collections in Arizona and Oklahoma due to contractor's geographical limitations.
- Introduction of brick-and-mortar services occurred three months after go-live date, potentially skewing utilization percentages in patient utilization between decentralized phlebotomy options.

Language Translation Needs:

- Use of phone interpretation via a hotline to provide interpretation services for patients with limited English proficiency, facilitating communication during decentralized phlebotomy and study visits.

CONCLUSIONS

- Patient Preference for Convenience:** Patient preferences favored mobile collection at home, highlighting the importance of convenience and accessibility in healthcare services.
- Future Implications:** Understanding patient preferences and optimizing decentralized strategies can enhance participant engagement and enrollment rates in future studies, emphasizing the importance of flexibility and convenience in healthcare delivery. Geographic digital limitations for inclusion outside of the continental US and international.

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