

Addressing Disparities: A Cross-Sectional Analysis of Diversity in Merkel Cell Carcinoma Clinical Trials

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Background

- Merkel cell carcinoma (MCC) ranks as the second most lethal form of skin cancer, surpassed only by melanoma, frequently manifesting with metastatic spread upon diagnosis.¹
- Five-year survival rates are 51% for localized disease, 35% for regional nodal, and 14% for distant metastases.²
- Despite over 90% of patients being non-Hispanic Whites (NHW), disparities in outcomes exist across different racial and ethnic groups.¹

Objectives

1. Evaluate whether the demographic composition of U.S. MCC trials aligns with the U.S. incidence rates from 2000 to 2018, as reported by the National Cancer Institute's Surveillance, Epidemiology, and End Results Program (SEER).
2. Compare the demographic characteristics of participants in MCC trials with the population demographics outlined by SEER.
3. Emphasize the importance of enhancing minority representation in clinical trials to mitigate disparities and improve outcomes.
4. Explore the potential implications of increased minority participation in MCC trials for addressing existing disparities and optimizing management strategies.

Methods

- In November 2023, the authors searched the "https://clinicaltrials.gov" database using the following filters³:
 - Condition: Merkel Cell Carcinoma
 - Country: United States
 - Recruitment: Complete
 - Study Type: Interventional (Clinical Trial)
 - Study Results: With Results
- Of the 18 identified clinical trials, 9 met our inclusion criteria with a total of 502 participants (Table 1.)

Results

Racial representation of Merkel cell carcinoma trials (n = 502)

American Indian/ Alaska Native	Asian	Native Hawaiian/ Other Pacific Islander	Black or African American	White	Multiple races	Unknown / not reported	Other
0.2% (1)	2% (10)	0%	0.8% (4)	81% (409)	0%	16% (78)	0%

Ethnic representation of Merkel cell carcinoma trials (n = 502)

Hispanic or Latino	Not Hispanic or Latino	Unknown/ not reported
7% (37)	76% (381)	17% (84)

Table 1. Demographic Makeup of United States Merkel Cell Carcinoma Clinical Trials

Gender Breakdown:

- Identified as female → 51% (n = 255)
- Identified as male → 49% (n = 247)

Comparison to U.S. Incidence Data:

- **Underrepresented** populations
 - White- 81.0 vs 89.9%
 - Black/AA- 0.8 vs 1.5%
 - Asian American or Pacific Islander (AAPI)- 2.0 vs. 2.3%
 - Other (American Indian or Alaska Native (AI/AN) and unknown origin)- 0.2 vs. 0.6%
- **Overrepresented** populations
 - Hispanic or Latino- 7.0 vs. 5.7%

Discussion

- Underrepresentation of minority groups in MCC trials is evident, except for Hispanic or Latino individuals, which is attributed to MCC's high prevalence in NHWs.
- Despite this, skin of color (SOC) patients are still affected, often presenting with more advanced disease.
- Variation in racial and ethnic group categorization across studies—some distinguishing between Hispanic and non-Hispanic Whites, others between White and non-White—may skew incidence rates and overreport White representation.
- Underreporting of demographic data challenges comprehensive MCC outcome analysis and complicates efforts to address minority representation.
- Lack of data in a significant proportion of participants (n= 84) adds to uncertainty and potential bias of our study's findings.

Conclusion

- Improved demographic data collection and enrollment from diverse populations are necessary steps.
- Enhanced understanding of prognosis variations between NHWs and SOC groups is critical.
- Improved treatment outcomes hinge on addressing the disparities in demographic representation in clinical trials.
- **Strategies for future clinical trials:**
 - Tailored recruitment methods such as community engagement and culturally sensitive outreach can overcome participation barriers.
 - Diverse representation is vital for generating comprehensive and applicable data reflecting the entire MCC patient population.
- **Addressing health disparities in clinical research:**
 - Actively recruiting participants from various racial, ethnic, and socioeconomic backgrounds enhances understanding of intervention impacts and tailors treatments to diverse patient needs.
 - Collaborative efforts among researchers, physicians, advocacy groups, and policymakers are crucial for promoting diversity in research and improving health outcomes for all MCC patients.

