Diversity & Equality in Health and Care
ISSN: 2049-5471

Open access Commentary

A Cross-sectional Analysis of Diversity in Lichen Planus Clinical Trials

Anika Pulumati[1,2*], Yanci A Algarin[2,3], Melanie Hirsch[3], Keyvan Nouri[3]

[1]*Deaprtment of Dermatology, University of Missouri-Kansas City School of Medicine, USA*
[2]*Deaprtment of Dermatology, Eastern Virginia Medical School, USA*
[3]*Department of Dermatology and Cutaneous Surgery, University of Miami Leonard M. Miller School of Medicine, USA*

DESCRIPTION

Lichen Planus (LP) is a chronic inflammatory condition that may affect the skin, nails, hair, and oral mucosa with a global estimated prevalence ranging from 0.5% to 1% [1]. The classic presentation involves flat-topped, violet papules on the skin, exhibiting various morphological variants; however, over 20 different clinical manifestations of LP are described [2]. LP manifests across all skin types, but preferentially affects middle-aged adults, with no known gender predisposition. Although the disease is often self-limiting, the relentless pruritus and painful mucosal erosions cause significant morbidity. Additionally, LP patients are more likely to experience depression and reduced quality of life [3]. Diagnosing LP in Skin of Colour (SOC) populations poses challenges due to potential dermoscopic variations in this population. Notably, a lack of confidence has been reported in managing SOC populations [4]. Data on the racial and ethnic distribution of U.S. LP clinical trials are limited. Thus, we aim to assess the current demographic composition of U.S. LP clinical trials compared to 2022 U.S. Census data [5]. In November 2023, the authors searched the "https://clinicaltrials.gov" database using the following filters: Condition: Lichen Planus, Country: United States, Recruitment: Complete, Study Type: Interventional (Clinical Trial), Study Results: With Results. Of the 11 identified clinical trials, 9 met our inclusion criteria with a total of 341 participants (**Table 1**).

Table 1: Demographic makeup of United States lichen planus clinical trials

Racial Representation of Lichen Planus Clinical Trials (n=341)							
American Indian or Alaska Native	Asian	Native Hawaiian or other Pacific Islander	Black or African American	White	More than one race	Unknown or not reported	Other
0.29% (1)	2.35% (8)	0.00% (0)	8.78% (30)	71.55% (244)	0.00% (0)	17.01% (58)	0.00% (0)

Ethnic Representation of Lichen Planus Clinical Trials (n=341)		
Hispanic or Latino	Not Hispanic or Latino	Unknown or not reported
7.62% (26)	25.51% (87)	66.86% (228)

Of the participants, 74.2% (n=253) identified as female and 25.8% (n=88) as male. Furthermore, 71.55% (n=244) of participants identified as White, 17.01% (n=58) as unknown or not reported, 2.35% (n=8) as Asian, 8.78% (n=30) as Black or African American, 0.29% (n=1) as American Indian or Alaska Native, 0% (n=0) as other, 0% (n=0) as more than one race, and 0% (n=0) as Native Hawaiian or Other Pacific Islander. Regarding ethnicity, 7.62% (n=26) of participants identified as Hispanic or Latino, 25.51% (n=87) as not Hispanic or Latino, and 166.86% (n=228) as unknown or not reported. As compared to census data, Black or AA (8.78% vs. 13.6%), Hispanic or Latino (7.62% vs. 19.1%), Asian (2.35% vs. 6.3%), American Indian or Alaska Native (0.29% vs. 1.3%), and Native Hawaiian or Other Pacific Islander (0.0% vs. 0.3%) groups were underrepresented. White (71.55% vs. 75.5%) was closely represented. Our study demonstrates the underrepresentation of multiple minority groups in LP clinical trials when compared to U.S. census data. This issue is particularly crucial due to the distinct variations in the "classic" clinical presentation of lichen planus across different skin complexions. The misalignment between trial demographics and the diverse population affected by LP highlights the potential for misdiagnoses or delayed diagnoses in SOC patients. Bridging this gap by increasing the diversity of clinical trial participants is crucial for developing

Received:	29-February-2024	**Manuscript No:**	IPDEHC-24-19110
Editor assigned:	04-March-2024	**PreQC No:**	IPDEHC-24-19110 (PQ)
Reviewed:	18-March-2024	**QC No:**	IPDEHC-24-19110
Revised:	25-March-2024	**Manuscript No:**	IPDEHC-24-19110 (R)
Published:	01-April-2024	**DOI:**	10.35248/2049-5471-21.2.11

Corresponding author Anika Pulumati, Department of Dermatology, University of Missouri-Kansas City School of Medicine, USA, E-mail: alpc97@umsystem.edu

Citation Pulumati A, Algarin YA, Hirsch M, Nouri K (2024) A Cross-sectional Analysis of Diversity in Lichen Planus Clinical Trials. Divers Equal Health Care. 21:11.

comprehensive insights and tailored interventions that address the full spectrum of LP among all patients.

DATA AVAILABILITY AND SHARING

The data that support the findings of this study are openly available at https://clinicaltrials.gov/. Data will be shared upon inquiry.

FUNDING

The authors have no funding sources to disclose.

ETHICAL APPROVAL

IRB approval was not required.

PATIENT CONSENT

Not applicable.

ACKNOWLEDGEMENT

The authors would like to thank the Dr. Phillip Frost Department of Dermatology and Cutaneous Surgery.

CONFLICT OF INTEREST

The authors have no financial or non-financial conflicts of interest to disclose.

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