

Characteristics of participants in a fully decentralized dermatologic clinical trial evaluating the safety and efficacy of topical ruxolitinib monotherapy for atopic dermatitis

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Abstract

A decentralized dermatological clinical trial model can be used to improve participation for populations underrepresented in clinical research.

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Original Manuscript

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Title: Characteristics of participants in a fully decentralized dermatologic clinical trial evaluating the safety and efficacy of topical ruxolitinib monotherapy for atopic dermatitis

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Abstract

A decentralized dermatological clinical trial model can be used to improve participation for populations underrepresented in clinical research.

Introduction

Historical underrepresentation of diverse populations in clinical research may result in skewed or misleading findings about the safety and efficacy of new therapeutics that are not generalizable to all patients. [1] In dermatology, diverse participant representation is particularly important due to 1) clinician reliance upon visual pattern recognition, 2) differences in clinical presentation of disease states across racial and ethnic groups, and 3) varied treatment response among individuals from these groups. Specifically, underrepresentation of skin of color in atopic dermatitis (AD) research and varied disease presentation may contribute to health disparities and clinical mismanagement. [2-5] Telemedicine has been established as a means of providing quality dermatological care to individuals in a remote setting, especially those from underserved populations. [6-8] We sought to determine if a decentralized randomized controlled clinical trial (RCT) model leveraging telemedicine can be utilized to improve participation for populations underrepresented in clinical research on atopic dermatitis.

Methods

Participants were recruited for a Phase 2, RCT evaluating the safety and efficacy of topical ruxolitinib for patients with atopic dermatitis (NCT05127421). The study protocol was approved by the institutional review board (IRB Project #: 20214280). Using an observational study, an online survey was sent to 167 individuals who had completed consent and screening (Fig. 1), with questions related to access to health care, prior participation in clinical research, health insurance status, financial hardship in paying for prescription medication, and race/ ethnicity. Survey response data was analyzed with quantitative and descriptive analyses of key outcome measures.

Results

Of the 167 individuals who completed consent and screening assessment for the RCT, 90 were enrolled in the RCT (RCT enrollment rate: 54%) and 77 were ultimately dosed with either the experimental or vehicle cream. Participants were from 19 states, with 44.2% of patients identifying as Black, 40.3% White, 6.5% Asian, and 9.1% Other (Table 1a).

Table 1. Characteristics of participants and survey respondents in a Phase 2, decentralized, dermatological clinical trial (NCT05127421) studying the safety and efficacy of topical ruxolitinib for atopic dermatitis.

1a. Characteristics of randomized controlled trial (RCT) participants.			
Race, n (%)	Vehicle (n = 23)	1.5% RUX^a cream (n = 54)	Total (N = 77)
Black	10 (43.5)	24 (44.4)	34 (44.2)
White	11 (47.8)	20 (37.0)	31 (40.3)
Asian	1 (4.3)	4 (7.4)	5 (6.5)
Other†	1 (4.3)	6 (11.1)	7 (9.1)
1b. Survey response data for a subset of individuals who were consented and screened for NCT05127421, and subsequently completed an online survey following study completion.			
Question	Response	Number	Percent (%)
Have you been evaluated by a dermatologist for a skin condition in the past 12 months?	Yes	25	50%
	No	24	48%
	Prefer not to answer	1	2%
	Total	50	100%
Have you ever participated in clinical research previously?	Yes	10	20%
	No	39	78%
	Prefer not to answer	1	2%
	Total	50	100%
Have you experienced difficulties in accessing healthcare in the past 12 months?	Yes	32	64%
	No	17	34%
	Prefer not to answer	1	2%
	Total	50	100%
If yes (n=32), why? (check all that apply)	Out of pocket expense	5	16%
	Time off of work	3	9%
	Caregiving coverage (i.e., childcare)	2	6%

	Transportation difficulty	4	13%
	Difficulty obtaining a timely appointment	10	31%
	Difficulty identifying provider within network	8	25%
	Lack of health insurance	4	13%
	Most are too far away	1	3%
	Rude people	1	3%
	Prefer not to answer	1	3%
Are you currently covered by a health insurance plan?	Yes	45	90%
	No	3	6%
	Prefer not to answer	2	4%
	Total	50	100%
If yes (n=45), please select your current health insurance plan(s) (check all that apply).	Medicare	9	20%
	Medicaid	21	47%
	Employer Sponsor / Commercial	13	29%
	Government	4	9%
	Other	2	4%
	Prefer not to answer	1	2%
In the past 12 months, have you ever experienced difficulty paying for a medication that was prescribed to you?	Yes	30	60%
	No	20	40%
	Prefer not to answer	0	0%
	Total	50	100%
What race(s) or ethnicities best describe you (n=50)? (check all that apply)	White	19	38%
	Black / African American	26	52%
	Asian / Pacific Islander	2	4%
	Hispanic / Latino / Latina	4	8%
	Native American	0	0%

	Other	2	4%
	Prefer not to answer	0	0%

† Includes American-Indian/Alaska Native.

^aRUX: ruxolitinib

The overall survey response rate was 30% (n=50). Of all survey respondents, 54% had completed the RCT (n=27), 30% had failed screening (n=15), and 16% had enrolled in but failed to complete the RCT (n=8). Of the individuals who completed consent and screening, 50 responded to the online survey (survey response rate: 30%), with 38% of respondents identifying as White, 52% Black / African American, 4% Asian / Pacific Islander, 8% Hispanic / Latino(a), and 4% “Other” (Table 1b).

48% of survey respondents had not been evaluated by a dermatologist for atopic dermatitis in the past 12 months. 78% of respondents had never participated in a clinical research study previously. 64% of respondents reported experiencing difficulties in accessing healthcare services in the past 12 months. Respondents most frequently cited difficulty in obtaining a timely appointment (31%), difficulty identifying a provider within network (25%), out-of-pocket expense (16%), lack of health insurance (13%), and transportation difficulty (13%) as obstacles (Table 1b).

90% of respondents reported current coverage by a health insurance plan. Of respondents with current health insurance coverage, 47% reported coverage by Medicaid, 29% reported coverage by employer sponsors or commercial plans, 20% reported coverage by Medicare, 9% reported coverage by a government plan, 4% reported other coverage, and 2% preferred not to specify (Table 1b).

Discussion

Lack of diversity among participants in clinical trials contributes to suboptimal research and exacerbates inequities in healthcare access. Numerous barriers exist which may contribute to suboptimal diversity and representation among clinical trial participants generally and specifically

within dermatology, namely, geographic proximity to trial site, the time needed to travel to a trial site, the need to take time off of work or school, the need to secure a caregiver, and the associated costs with each of these. [9] Improving representation in research warrants a multi-faceted approach spanning differentiated recruitment, incentivization, and data collection strategies. We found that a fully decentralized clinical trial model could be used to expediently identify and enroll geographically and racially / ethnically diverse participants, first-time research participants, and publicly insured participants, many of whom had experienced recent difficulties in accessing dermatological care. Increasing diversity of clinical trial participants improves the diversity of dermatologic data available with which to train clinicians in effective diagnosis in skin of color, increases the generalizability of results about the safety and efficacy of emerging therapeutics in all populations, and helps to connect individuals from marginalized groups with the latest therapies to which they might not otherwise have had access (Figure 1). Further use and development of the decentralized clinical trial model in dermatology may provide opportunities to address the historical lack of diversity in dermatologic clinical trials.

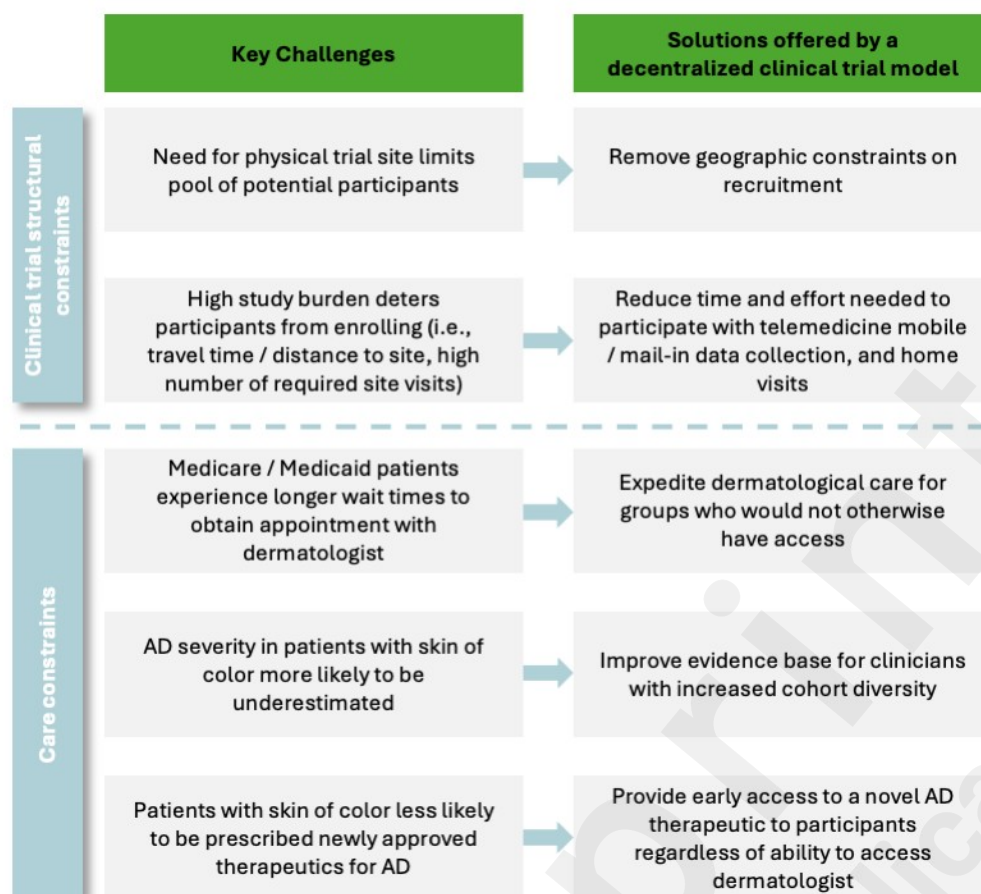


Figure 1. How a decentralized dermatological clinical trial model improves management of atopic dermatitis (AD) for groups typically underrepresented in research.

References

1. Nelson, A. (2003). Unequal treatment: confronting racial and ethnic disparities in health care. *Choice Reviews Online*, 40(10), 40–584340–5843. <https://doi.org/10.5860/choice.40-5843>
2. Brunner, P. M., & Guttman-Yassky, E. (2019). Racial differences in atopic dermatitis. *Annals of Allergy, Asthma & Immunology*, 122(5), 449–455. <https://doi.org/10.1016/j.anai.2018.11.015>
3. Reporting, representation, and subgroup analysis of race and ethnicity in published clinical trials of atopic dermatitis. (2012). *Journal of the American Academy of Dermatology*, 66(4), AB90. <https://doi.org/10.1016/j.jaad.2011.11.382>
4. Fenton, A., Elliott, E., Shahbandi, A., Ezenwa, E., Morris, C., McLawhorn, J., Jackson, J. G., Allen, P., & Murina, A. (2020). Medical students' ability to diagnose common dermatologic conditions in skin of color. *Journal of the American Academy of Dermatology*, 83(3), 957–958. <https://doi.org/10.1016/j.jaad.2019.12.078>
5. Bell, M. A., Whang, K. A., Thomas, J., Aguh, C., & Kwatra, S. G. (2020). Racial and Ethnic Disparities in Access to Emerging and Frontline Therapies in Common Dermatological Conditions: A Cross-Sectional Study. *Journal of the National Medical Association*, 112(6), 650–653. <https://doi.org/10.1016/j.jnma.2020.06.009>
6. Laggis, C., Williams, V., Yang, X., & Kovarik, C. (2019). Research Techniques Made Simple: Teledermatology in Clinical Trials. *Journal of Investigative Dermatology*, 139(8), 1626–1633. <https://doi.org/10.1016/j.jid.2019.04.004>
7. *Study of Efficacy and Safety of CJM112 in Patients With Moderate to Severe Inflammatory Acne*. (2022, July 12). Clinicaltrials.gov; National Library of Medicine. <https://clinicaltrials.gov/study/NCT02998671#publications>
8. Werth, V. P., Joly, P., Mimouni, D., Maverakis, E., Caux, F., Lehane, P., Gearhart, L., Kapre, A., Pordeli, P., & Chen, D. M. (2021). Rituximab versus Mycophenolate Mofetil in Patients with Pemphigus Vulgaris. *New England Journal of Medicine*, 384(24), 2295–2305.

<https://doi.org/10.1056/nejmoa2028564>

9. *Review of the Literature: Primary Barriers and Facilitators to Participation in Clinical Research.* (n.d.). National Institutes of Health. Retrieved December 1, 2023, from https://orwh.od.nih.gov/sites/orwh/files/docs/orwh_outreach_toolkit_litreview.pdf



Supplementary Files

Figures

How a decentralized dermatological clinical trial model improves management of atopic dermatitis (AD) for groups typically underrepresented in research.

