Race And Ethnicity In Clinical Trials For Autoimmune Connective Tissue Disease Therapeutic Agents: A Scoping Review

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BACKGROUND

Black, Indigenous, and people of color (BIPOC) are disproportionately affected by autoimmune connective tissue diseases (AICTD)1

Clinical trials can help to address this disparity

- Provide knowledge of disease processes
- Direct future investigational strategies
- Provide access to novel and potentially life-saving therapy for those with refractory disease

- Underpowered or absent groups in clinical trials can be significantly harmed2

- Research question: How well are racial and ethnic minorities represented in clinical trials for novel AICTD therapies?

METHODS

- Query: Randomized clinical trials in human subjects with biologics or small molecule drugs for lupus, dermatomyositis, systemic sclerosis, or morphea
- MEDLINE (Ovid)
- Embase (Ovid)
- Web of Science
- Cochrane Library via Wiley
- Global Index Medicus
- ClinicalTrials.gov
- WHO ICTRP
- Three independent reviewers performed title and abstract screening followed by full text screening

RESULTS

- 6849 studies imported
- 1541 duplicates
- 5308 studies screened
- 4408 studies irrelevant
- 500 studies assessed for eligibility
- 408 studies excluded
  - 244 No subject eligibility data
  - 164 Too much disease data
  - 17 Incorrect outcome measures
  - 80 Non-African American patient population
  - 3 Non-English language
  - 20 Failure to acquire
  - 2 Wrong patient population
- 92 studies included

Figure 1: PRISMA Diagram

Figure 2: Focus, country of study, and year of publication for included clinical trials

Figure 3: Racial and ethnic representation in lupus erythematosus RCTs based in the United States. Data is from 3 United States-based clinical trials involving 1240 patients with lupus erythematosus. United States epidemiological data was based on previous reported meta-analyses of the CDC’s National Lupus Registries. 3,4 *p<0.05

Figure 4: Racial and ethnic representation in dermatomyositis RCTs based in the United States. Data is from 3 United States clinical trials involving 79 patients with dermatomyositis or polymyositis. United States epidemiological data was based on 2020 prevalence mapped onto corresponding US census data. 3,4 *p<0.05

Figure 5: Racial and ethnic representation in systemic sclerosis RCTs based in the United States. Data is from 4 United States clinical trials involving 112 patients with systemic sclerosis. United States epidemiological data was based on 2020 prevalence mapped onto corresponding US census data. 3,4 *p<0.05

Figure 6: Race and ethnicity in US AICTD RCTs over time, comparing the past 5 years to all prior trials. * Includes EMBRACE trial, accounting for over 40% of Black trial participants 2018-2022. 1 American Indian/Alaskan Native, Asian, Black, Hispanic, Native Hawaiian/Other Pacific Islander, Other.

CONCLUSIONS

- Inclusivity in RCTs for AICTD remains problematic, even despite recent pushes for greater diversity in participants.
- BIPOC patients are underrepresented in trials of novel therapies for lupus and systemic sclerosis
- In AICTD RCTs in the last 5 years:
  - American Indian/Alaskan Native and Hispanic involvement has declined.
  - Black involvement has significantly increased due to the EMBRACE trial.
  - Without the EMBRACE trial, BIPOC inclusion overall would have seen a significant decline.
- Lack of diversity in trials serves to exacerbate disparities for BIPOC patients with AICTDs.
- Further targeted efforts are needed to increase inclusivity in RCTs for novel AICTD therapies.

REFERENCES


Table 1: Race/Ethnicity in AICTD RCTs

<table>
<thead>
<tr>
<th>Race/Ethnicity</th>
<th>2017 N = 16479</th>
<th>2018-2022 N = 6069</th>
<th>χ²</th>
<th>p</th>
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<tbody>
<tr>
<td>American Indian or Alaskan Native</td>
<td>7.6%</td>
<td>2.2%</td>
<td>221.97</td>
<td>&lt;0.0001</td>
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<tr>
<td>Asian</td>
<td>19.2%</td>
<td>18.2%</td>
<td>3.04</td>
<td>0.08</td>
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<td>Black</td>
<td>10.3%</td>
<td>16.8%</td>
<td>178.33</td>
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<td>Hispanic</td>
<td>17.3%</td>
<td>13.7%</td>
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<td>Native Hawaiian or Other Pacific Islander</td>
<td>0.1%</td>
<td>0.2%</td>
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<td>0.23</td>
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<tr>
<td>Other</td>
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<td>6.5%</td>
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<td>White</td>
<td>56.0%</td>
<td>55.3%</td>
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<td>BIPOC</td>
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<td>57.3%</td>
<td>3.26</td>
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