May 16th, 11:30 AM - 1:30 PM

Racial/Ethnic Demographics of Participants in Clinical trials of Biologics Used for Asthma

Susamita Kesh
Children's Mercy Hospital Department of Pediatrics

Racial/Ethnic Demographics of Participants in Clinical trials of Biologics Used for Asthma

Submitting/Presenting Author (must be a trainee): Susamita Kesh
(Of note, would not be able to do a presentation on May 16th)
Primary Email Address: skesh@cmh.edu

X Resident/Psychology Intern
☐Fellow

Primary Mentor (one name only): Bridgette Jones, MD MS
Other authors/contributors involved in project:

IRB Number: NA

Describe role of Submitting/Presenting Trainee in this project (limit 150 words):

Presenting Trainee worked on data collection, abstract write up, and poster creation for the project.

Background, Objectives/Goal, Methods/Design, Results, Conclusions limited to 500 words

Background:

African American (AA) and Hispanic patients suffer disproportionately from severe asthma, however are often under-represented within clinical trials of asthma therapies. Monoclonal antibody therapies are shown to be effective in trials to treat patients with severe asthma phenotype.

Objectives/Goal:
We aimed to describe the racial/ethnic makeup of FDA approved biological therapies for asthma.

Methods/Design:

We identified clinical trials in ClinicalTrials.gov of Omalizumab, Mepolizumab, and Reslizumab that assessed safety/efficacy for asthma. The search strategy included the terms “asthma,” drug name, and “United States” . We determined frequency (%) of studies where study participant racial/ethnic demographics were reported; and among these studies the % of racial/ethnic minority inclusion.

Results:

Among the n= 29 studies, racial/ethnic demographics were reported in ClinicalTrials.gov for 25% (3 out of 12 studies), 100% (11 out of 11 studies), 83% (5 out of 6 studies) for Omalizumab, Mepolizumab, and Reslizumab respectively. For Omalizumab, mean% (SD) of racial demographics for study participants were: 40.2% (32.8) AA, 41% (40) Caucasian, 6.65% (14.6) Hispanic. Mepolizumab study demographic mean% (SD) were: 5.4 % (5.8) were (AA), 83.9 (10.5) were Caucasian, 0% (0) were Hispanic. Among the Reslizumab studies, mean% (SD) of ethnic/racial demographics were: 9.22% (10.1) AA, 74% (4.62) Caucasian, 13.5% (37.9) Hispanic.

Conclusions:

Racial/ethnic demographic data are reported for the majority of clinical trials of biological therapies to treat asthma. However, the racial/ethnic makeup of these trials are often not representative of the US asthma population. Future trials to establish asthma therapeutic efficacy/safety should be conducted amongst a representative population.