How Real-World Mepolizumab Users in the REALITI-A Study Relate to the Recruitment Criteria Applied in the Randomized, Placebo-Controlled Trials of Subcutaneous Mepolizumab in Severe Eosinophilic Asthma

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Methods

Results

Aims

Mepolizumab is an anti-eotaxin-3 monoclonal antibody treatment approved for use in patients with inadequately controlled severe eosinophilic asthma (SEA), despite use of standard-of-care therapies such as high-dose inhaled corticosteroids (ICS), bronchodilators, and/or requiring maintenance and oral corticosteroids (OCS). *Compared with real-world studies, randomized controlled trials (RCTs) conducted to prove efficacy and safety of new therapies typically have strictly defined and exclusion criteria. The key placebo-controlled studies of salmeterol/fluticasone (SFC) mepolizumab 100 mg in SEA required evidence of meeting the diagnostic criteria of asthma and severe eosinophilic asthma. **In contrast, the REALITI-A study is a multinational, real-world cohort study, which included patients with asthma and severe exacerbations and aimed to assess real-world clinical outcomes of patients receiving treatment with mepolizumab.

Here, we aimed to evaluate participants in the REALITI-A study against the inclusion and exclusion criteria of the previously conducted mepolizumab RCTs, to determine the similarity of one clinical characteristic of real-world participants to those in a controlled clinical trial setting.

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REALITI-A (NCT 00749794) Study Design

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