

2020-4341 Project Summary

Objective: The objective of this study was to estimate the risk of key opportunistic infections among participants in randomized clinical trials for two major tumor necrosis factor inhibitors (TNFi), infliximab and golimumab.

Methods: Individual patient-level data on 8,477 participants from 21 randomized clinical trials of infliximab and golimumab were aggregated and provided by Yale Open Data Access Project for meta-analysis. We assessed adverse events for pneumonia, upper respiratory tract infection, gastroenteritis, herpes, hepatitis, fungal infections, and sepsis adverse events in addition to etiologic agents for these categories.

Results: Associations between treatment assignment and infections varied by the analysis used to adjust for treatment arm switching. Under intent-to-treat assumptions, hepatitis and upper respiratory tract infection were associated with TNFi. After adjusting for treatment arm switching, pneumonia had an increased risk associated with TNFi use. Four cases of Legionella pneumonia were diagnosed among participants and one case of histoplasmosis and cryptococcal pneumonia.

Conclusion: Our study confirms that use of TNFi is associated with specific infections and demonstrates the importance of incorporating treatment switching in retrospective analyses. While rare infections were captured in clinical trials, trial length was noted as an important factor for understanding these events prior to post-market surveillance.