Impact of Biologic Therapy on the Risk of Arterial and Venous Thromboembolic Events in Chronic Autoimmune Diseases: A Post-Hoc Analysis of RCTs

Objective: Patients with autoimmune diseases are at increased risk of cardiovascular events and venous thromboembolism (VTE), particularly during periods of high disease activity. It is unclear whether biologic therapy modifies this risk. The objective of this proposal was to evaluate the association between biologic therapy and risk of major adverse cardiovascular events and VTE in autoimmune diseases.

Methods: The intended approach was to perform two separate Cox proportional hazard analyses to evaluate the association between (a) receipt of biologics (vs. placebo), and (b) response to therapy (vs. non-response) on cardiovascular and VTE risk, after pooling data from included phase III RCTs of infliximab and golimumab.

Results: During evaluation of the data, the number of cardiovascular events was small in trials in patients with inflammatory bowel diseases, which would have precluded meaningful inferences. Hence, the PI did not prioritize the project for further perusal.

Conclusions: N/A