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AN OPEN-LABEL TRIAL OF ADJUNCTIVE TOCILIZUMAB IN SCHIZOPHRENIA

B. Miller[1], J. Dias[2], P. Buckley[3]

[1]Psychiatry and Health Behavior, Georgia Regents University, Augusta, USA ; [2]Biostatistics and Epidemiology, Georgia Regents University, Augusta, USA ; [3]Medical College of Georgia, Georgia Regents University, Augusta, USA

Schizophrenia is associated with impaired cognition, which persists despite current treatments, and is an important determinant of quality of life and overall function. Converging lines of evidence suggest that interleukin-6 (IL-6) may play a role in the pathophysiology of schizophrenia. We previously found that higher blood IL-6 levels were a significant predictor of greater cognitive impairment in schizophrenia after controlling for multiple potential confounding factors. We are conducting an 8-week open-label trial of adjunctive tocilizumab in schizophrenia. Tocilizumab is a humanized monoclonal antibody against the IL-6 receptor, approved by the US FDA for the treatment of adults with moderately to severely active rheumatoid arthritis. Tocilizumab is administered as an intravenous infusion every 4 weeks. Subjects in the trial are age 18-55, taking a non-clozapine antipsychotic, stable based on clinical judgment and no psychiatric hospitalizations in the past 3 months, and on the same psychotropic medications for at least 1 month. Following a screening visit, subjects receive a 4 mg/kg infusion of tocilizumab at baseline and again at 4 weeks. Cognition, as measured by the Brief Assessment of Cognition in Schizophrenia (BACS, using alternate forms) is assessed at baseline, and 2, 4, and 8 weeks. In the first 3 subjects, tocilizumab infusions were well tolerated without significant adverse effects. The mean improvement was 16% on the BACS composite score, including a significant mean 35% improvement (12 points) on digit symbol coding (p=0.03). These preliminary data suggest that anti-cytokine therapy may be a viable adjunctive treatment for cognitive impairment in schizophrenia.

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