Preventive anti-infectious vaccinations in patients with rheumatoid arthritis under immunosuppressive treatment

The vaccination safety and efficacy has not been systematically analyzed in RA patients receiving immunosuppressive treatment, thus the aim of this study is to evaluate the immunogenicity of influenza virus and 13-valent conjugate pneumococcal vaccines (Prevenar 13) in patients with Rheumatoid Arthritis, in treatment with DMARDs and/or TNFα blockers. The secondary objective is to determine vaccine safety and efficacy.

Vaccine efficacy will be assessed by monitoring any influenza-like-illness episodes in order to explore the possible influenza etiology and indirectly by the ability of the vaccines to prevent clinical or serological pneumococcal disease. The immunogenicity will be evaluated with the antibody titre increase. The safety will be monitored by the appearance of vaccine side effects, by testing clinical and laboratory parameters (autoantibodies, inflammatory markers) and by evaluating possible exacerbations of the inflammatory rheumatic disease though clinimetric indices periodically repeated.
STATE OF THE ART

The immunosuppressive therapy in patients with autoimmune diseases has reached considerable progress. Patients with autoimmune diseases have a double risk to developing infections, compared to the general population. Therefore, prevention by specific available vaccinations is crucial and safe, as suggested by different studies\(^1\)\(^-\)\(^7\). The growing availability of drugs and biologicals, able to very selectively hit the immune system, but also to induce broad functional consequences, allows to more and more effectively treat the patients, but in parallel exposes them to an increased infection risk. The very nature of the disease and the heavy immune suppression cast doubts on safety and immunogenicity of anti-infectious vaccinations in these patients. Vaccination, however, is the only tool to prevent infections, thus improving the prognosis of these patients.

\(^1\) EULAR recommendations for vaccination in adult patients with autoimmune inflammatory rheumatic diseases. Ann Rheum Dis. 2011;70:414-22


