

**Drug-specific risk and characteristics of lupus and vasculitis-like events in patients with rheumatoid arthritis treated with TNFi therapy: results from the British Society for Rheumatology Biologics Register for Rheumatoid Arthritis**

***Lay title: Risk and characteristics of lupus and vasculitis-like events in rheumatoid arthritis patients treated with biologic drugs***

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**What was discovered?**

Biologic drugs that are used to treat rheumatoid arthritis (RA) act by targeting inflammatory molecules in the body. They are usually very effective but they can cause serious side effects in patients. Lupus like-syndrome (LLE), an immune disease that can affect several parts of the body, and vasculitis-like syndrome, a group of disorders that causes inflammation of blood vessels, has been associated with these drugs since their launch. Both types of events can range from mild to life threatening. Previous studies have not been able to accurately quantify how frequently such events occur, if there is any difference in risk between different biologic drugs and what factors may be associated with such events.

One of the largest worldwide studies that registers UK patients on biologic drugs was used. After evaluating over 12,000 patients exposed to the biologics, it was found that the absolute risk or the actual risk of developing the disease over a time period was low. The risk of both events was highest in the first year of treatment. After taking into account differences in characteristics of patients receiving treatment, there was no difference in the overall risk of LLE or VLE between patients receiving biologics compared to those receiving standard RA treatment (such as methotrexate). Furthermore there were no differences in the risk of such events between the types of biologic drugs after accounting for such characteristics. Factors associated with lower rates of both events included being on concomitant treatment such as sulfasalazine, whilst having more severe disease at start was associated with higher rates. The majority of patients developed features of the disease limited to skin and were not life threatening.

**Why is this important/clinical benefit?**

The findings are reassuring for patients on biologics as they suggest the overall risk of such events is low and if they do develop, are usually non-life threatening. The study also suggests that patients who are going to develop such events may be more likely to do so in the first year of therapy. Additionally being on certain concomitant anti-rheumatic drugs whilst on a biologic may be associated with lower rates.