



Belimumab Allows For Reduction in Steroid Use for People with Lupus

- van Vollenhoven RF, Gallacher A, Navarra S, Ginzler EM, Dooley MA, Cervera R, Li EK, Levy RA, Gúzman R, Zhong ZJ, Cooper S, Pineda L, Hough D, and Wallace DJ, for the BLISS-52 and -76 Study Groups. (2010). Belimumab, a BLYS-specific inhibitor, reduces corticosteroid use in patients with active SLE: results from the Phase 3 BLISS-52 and -76 studies. American College of Rheumatology Abstracts 451.

What is the topic?

One way to test whether a new treatment for lupus is effective is to see whether it allows people to reduce the amount of steroids they are taking.

What did the researchers hope to learn?

The researchers hoped to learn whether treatment with belimumab could reduce the use of steroids in people with active lupus.

Who was studied?

1684 people with active lupus participated in two international clinical trials of belimumab, compared to standard of care, in people with lupus.

How was the study conducted?

Patients received either 1 or 10 mg/kg of belimumab, or placebo, during the study. All participants were kept on standard of care treatments at the same time. If people were not doing well, some temporary increases in the standard of care treatments were allowed during the earlier parts of the study. If people were getting better, steroid tapering was encouraged (but not required). The goal was to compare outcomes in those who did or did not have belimumab added to their treatments. Neither the patients nor the study doctors knew who was getting belimumab or placebo. This is called a “double-blind study.”

What did the researchers find?

1453 patients (86% of the participants) were taking steroids when they started the study. Other features, such as how much steroid was being taken (equivalent to 12.5 mg of prednisone each day), and how long it was since the diagnosis of lupus (average of 6.4 years), were about the same whether a person was assigned to receive belimumab at either dose or placebo.

64% of patients were taking anti-malarial drugs (plaquenil or similar treatments), 50% were taking immune-suppressing drugs (such as Imuran, methotrexate, or CellCept®), and 26% were taking non-steroidal anti-inflammatory drugs.

976 patients (67% of all the patients) were taking at least 7.5 mg of prednisone per day when they started the study. Of those taking 10 mg/kg of belimumab, 18% were able to reduce prednisone use by at least 25% and 54% of them met the rules to be considered a “responder” (using the SLE Responder Index, or SRI). Of those taking 1 mg/kg of belimumab, 20% were able to reduce prednisone use by at least 25% and 50% were responders. In contrast, only 12% of the patients on placebo were able to reduce prednisone use by at least 25% and only 41% were responders.

708 patients (42%) were taking 7.5 mg or less of prednisone per day. Of those taking 10 mg/kg of belimumab, 11% had increased prednisone dose at the end of the study, and this also happened in 14% of those taking 1 mg/kg of belimumab and 18% of those taking placebo. Thus, taking belimumab resulted in more people decreasing steroids

and fewer increasing steroids.

What were the limitations of the study?

These are exploratory studies using information from a clinical trial that already reported other kinds of statistical outcomes. The rules of statistics indicate that firm conclusions cannot be made from exploratory studies, but these findings are very interesting and should be further studied.

What do the results mean for you?

These results suggest that treatment with belimumab may have “steroid-sparing” effects. If this turns out to be the case, after more studies are done, this would be very important to people with lupus since some of the major damage that the disease can cause may arise from side effects of steroids.