



Epratuzumab is Safe and Effective for Treatment of Lupus in Phase II Trials

- Wallace DJ, Kalunian KC, Petri MA, Strand V, Kilgallen B, Kelley L, and Gordon CP. (2010). Epratuzimab demonstrates clinically meaningful improvements in patients with moderate-to-severe systemic lupus erythematosus (SLE): Results from EMBLEM™, a Phase IIb study. American College of Rheumatology Abstracts 1452.

What is the topic?

Epratuzumab is an investigational agent for the treatment of lupus. It is an antibody that binds to a protein called CD22 on B cells, which are white blood cells known to be hyperactive in many people with lupus. Epratuzumab reduces the number of B cells by about 35% and may also affect those B cells that remain in the bloodstream by sending them signals to behave differently. Since B cells are responsible for the autoantibodies seen in lupus (such as ANA, anti-dsDNA, anti-cardiolipin, etc.), one way this treatment might work is to help decrease autoantibodies.

What did the researchers hope to learn?

The researchers hoped to learn whether epratuzumab could be a safe and effective treatment for people with moderate-to-severe lupus. They also wanted to find the best way to give the treatment (which dose and how often to give it) to get the best possible effects. Once identified, this would give them more confidence about how they will be testing the treatment in later studies and what would be the best way to use the treatment should it be proven to work later on.

Who was studied?

227 people with moderate-to-severe lupus were included in the study.

How was the study conducted?

The patients in the study were given either intravenous placebo or one of the following: a) a total of 200, 800, 2400, or 3600 mg of epratuzumab, with half the dose given at each of two time points two weeks apart, or b) 2400 mg of epratuzumab divided into four intravenous infusions given one week apart.

After twelve weeks, the patients were evaluated to see if they were getting better. A clinically meaningful improvement required the patients to have decreased lupus activity (as defined by a responder index that included several different measurements of improvement or flares), as well as no increases in steroids, immune-suppressing or anti-malarial drugs.

What did the researchers find?

The participants had significantly active lupus when they entered the study. Most of them were women with an average age of 38.8 years.

Disease activity was decreased in all epratuzumab groups compared to the placebo group. People in either of the groups that got a total of 2400 mg were the most likely to have reduced disease activity and, in these cases, this was found to be significant by statistical testing as compared to the results in the placebo group.

Epratuzumab was well-tolerated and the numbers of side effects and infusion reactions were similar among placebo and epratuzumab groups.

What were the limitations of the study?

This is a phase II study and was quite small. The next step is to study larger numbers of patients for a longer period

of time. However, an important thing about this study is that it gave some strong clues about how best to give the treatment in order to optimize the effects of the treatment.

What do the results mean for you?

These preliminary results support further study of epratuzumab in larger phase III clinical trials, and provide useful information about how it might be best to give the treatment