

Lupus Update with Dr. Robert Katz

What's New in Lupus Research?

Benlysta, the new lupus drug, was determined to be effective through clinical trials. There is a website called clinicaltrials.gov that lists the ongoing lupus studies, which drugs are being tested to attempt to gain FDA approval.

There are different phases of drug studies. Phase One studies are testing the drug in healthy nonlupus volunteers to be sure that it is safe. Phase Two studies are testing to obtain the optimal dose and be certain there are no serious side effects. Phase Three studies are big national and international research efforts, in which lupus patients try the new medication at the recommended dosage. Based on the Phase Three clinical trials, the FDA then makes a decision as to whether the drug can be approved for treating lupus. The FDA looks at both the efficacy and the toxicity of the new medications.

Without clinical trials we would not have new medications. There have been revolutionary changes in drug treatment of lupus and autoimmune disease as well as various systemic inflammatory conditions. Rheumatoid arthritis, a cousin of lupus, has been very successfully treated for years with a variety of relatively new biological monoclonal antibodies and other drugs.