



Getting Involved in an RA Clinical Study

by BRENDA VANTA

What You Need to Know About Participating in RA Clinical Studies

If you suffer from Rheumatoid Arthritis and are thinking about participating in a clinical study that evaluates a new drug, you should learn as much as you can about that research study.

The FDA must approve all studies before it begins, and always before the participants of the study receive the treatment. The FDA takes this measure because its goal is to provide a new drug to the community after it is tested and deemed safe and effective through clinical studies. The FDA requires that a drug pass three phases before it is approved and becomes available on the market.

In the first stage, or Phase I trial, the drug is tested on people. This phase typically involves a small number of healthy volunteers; researchers begin to learn how the drug behaves in humans, they evaluate possible side effects and determine optimal dosage. Since the subjects of the study are healthy, they won't directly a benefit, but they will contribute to the development of this new drug and potentially help many RA sufferers.

If Phase I is passed successfully (the intervention/drug appears safe), the next step is Phase II. A larger group of individuals will be involved in the second phase and these people have been diagnosed with RA. This study aims to help scientists assess whether or not the drug is safe for a sufferer of Rheumatoid Arthritis, and to gain a deeper understanding of its effectiveness. During this phase, the optimal dosage of the drug is also evaluated.

If Phase II demonstrates the safety and efficacy of the new drug, a third phase will be ordered. During this phase, the drug or intervention is tested on a larger group of individuals with RA. The goal of Phase III is to compare the new drug with an old standard therapy, with placebo (a dummy pill), or with both.

In the News

A June 2014 study featured in 'Medical News Today' describes a Phase III trial for a drug combination for Rheumatoid Arthritis. It evaluated the efficacy and safety of Cimzia (certolizumab pegol) injections, combined with methotrexate for patients diagnosed with RA. According to the results, this combination was found to be significantly more effective than the combination methotrexate and placebo. Scientists believe that this drug therapy is highly beneficial in the treatment of RA, especially for people who had been diagnosed within one year, and who don't respond well to standard medication or have poor prognostic factors. The complete results will become available in 2016.

Considerations

If you have a wide variety of studies that are available for your participation, consider a drug that has already been tested and is in Phase III or IV to minimize potential risks. Always read the documentation carefully, as well as the informed consent, to learn about the entire procedure and the risks and benefits of the drug.

For more information about getting involved in a study visit: [What Participants Need to Know About Clinical Trials](#)