Title of Research
Identifying Trajectories of Disease Activity States in Juvenile Idiopathic Arthritis (JIA) Early After Treatment: Shortening Time to Decision to Change Treatment

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Summary of Research
Juvenile idiopathic arthritis (JIA) affects approximately 1 in 1000 children in the United States, making this the most common pediatric rheumatic disease. The treatment of JIA has been revolutionized by introduction of biological therapies, which have resulted in improved disease control and decreased joint damage. However, patients' response times to biologics vary. While some may respond more slowly to therapy yet eventually attain good disease control, others may not respond. There are currently no data to distinguish these groups of patients early on, so physicians must wait for a response, while these children continue to experience ongoing active disease and potential joint damage.

Current trial designs commonly lead in with 16 weeks of trial medication. The researchers hypothesize that it will be possible to identify individuals who will not respond at an earlier point than 16 weeks, by studying their treatment response trajectories. They plan to identify the non-responders using baseline clinical phenotype, biomarkers and demographic predictors.

Study Design
This study will involve secondary analysis of data on subjects with polyarticular course JIA –defined by the presence of more than four affected joints during the first six months of illness1–recruited into several completed, randomized trials. These include the Trial of Early Aggressive Therapy (TREAT), CHERISH (tocilizumab), and AWAKEN (abatacept) trials.

The primary aims are to: measure the probability of attaining clinically significant therapeutic responses before week 16; measure the average time spent by a patient in each of the various response states; and identify predictors for the probability of attaining the various levels of clinically significant therapeutic responses. The results from this study will help inform the design of future JIA trials.

Study Population
Subjects with polyarticular course JIA recruited into the above randomized trials.

Funding Source of Research
None

Requested Study
NCT00095173: A Phase III, Multi-Center, Multi-National, Randomized Withdrawal Study to Evaluate the Safety and Efficacy of BMS-188667 in Children and Adolescents With Active Polyarticular Juvenile Rheumatoid Arthritis (JRA)