



Children's Hospital Boston

The Hospital for Children

Division of Immunology  
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### Project Inventory

**Title:** A prospective, randomized, double-blind, active controlled, parallel group, multi-center trial to assess the efficacy and safety of mycophenolate mofetil (MMF) in inducing response and maintaining remission and renal function in subjects with lupus nephritis

**Principal Investigator:** Robert Sundel, MD

**Researchers Involved:** Mary Beth Son, MD - Fatma Dedeoglu, MD - Susan Kim, MD - Irene Borrás-Coughlin, CCRC

**Abstract:** The study is designed as a prospective, randomized, active controlled, parallel group, international multicenter, two arm comparison study of MMF vs. cyclophosphamide during induction (open label), followed by a randomized double-blind comparison of MMF vs. azathioprine during maintenance. After screening and determination of eligibility, subjects with lupus nephritis will enter the induction phase of the study and be randomized to receive, in an open-label fashion, either oral MMF (1.5 g BID) or IVC (monthly bolus doses of 0.5 to 1.0 g per square meter of body surface area) for 24 weeks. At the end of the open-label induction phase, subjects meeting the criteria for response (Section 4.4 of the Protocol) or complete (renal) remission (Section 4.5 of the Protocol) will be re-randomized to receive either oral MMF (1.0 g BID) or azathioprine (2mg.kg.day), in a double-blinded fashion until 144 treatment failures are observed or until the last subject has been followed for 36 months. A protocol amendment will be written extending the maintenance phase duration if any subject is required to be followed beyond 36 months. Dose adjustments for efficacy and safety will be allowed during the maintenance phase. Subjects also will receive concomitant treatment with corticosteroids at specified initial dosing and taper (Section 6.1 of the Protocol). Subjects in selected countries who enter the maintenance phase will also be asked to enter a long-term registry under a separate protocol.

**Funding Sources:** Aspreva Pharmaceuticals Corp. - PPD Inc

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### Project Inventory

**Title:** Trial of Early Aggressive Therapy in Juvenile Idiopathic Arthritis (TREAT JIA trial)

**Principal Investigator:** Robert Sundel, MD

**Researchers Involved:** Mary Beth Son, MD - Fatma Dedeoglu, MD - Susan Kim, MD - Robert Fuhlbrigge, MD - Arturo Borzutzky, MD - Erin Janssen, MD - Andrew Shulman, MD - Lisa Stutius, MD - Bebe Samler, RN - Maria Benoit, RN - Irene Borrás Coughlin, CCRC

**Abstract:** This study is being conducted to determine if treatment early in the disease course of children with polyarticular juvenile idiopathic arthritis (JIA) (within 12 months from onset of disease) with an aggressive combination of medications can result in Inactive Disease (ID) in a greater proportion of children than treatment with one medication. Initial treatment with Methotrexate will be compared to the combination of methotrexate, prednisone and etanercept together. All of these medications are routinely used to treat poly JIA and are all considered to be first-line agents, but are usually added together slowly after the disease has been present for a long time. This trial will study their effectiveness given together very early in the disease process.

**Funding Sources:** NIH/NIAMS; Amgen, Inc.

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