

## **Randomized Trial of Intravenous Ketorolac Versus Oral Ibuprofen for Painful Crisis**

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Sickle cell disease (SCD) is a common disorder among African-Americans and other minority populations that is characterized by chronic anemia and episodic “vaso-occlusive” crises. The most common of these crises is the painful crisis. The treatment of painful crisis is supportive, including rest, hydration, and analgesia, and therapy is guided by evidence from only a few rigorous clinical trials. Morphine is the cornerstone of analgesia for moderate to severe painful episodes, but it has significant toxicities, such as somnolence, respiratory depression, constipation, dysphoria, and pruritus. Adjuvant analgesics, including non-steroidal anti-inflammatory drugs (NSAIDs), may improve pain control and decrease the requirement for opioids; however, most have not been studied rigorously in patients with SCD, including the elucidation of disease-specific toxicities. This clinical investigation compares a potent parenteral NSAID, ketorolac, with the commonly used oral NSAID, ibuprofen, for the adjuvant treatment of painful crisis. The aims of this project are to show that ketorolac, relative to ibuprofen, is both more effective and equally safe. These aims are achieved by a prospective, randomized, double-blind, placebo-controlled clinical trial. Subjects will receive standard opioid and supportive therapy, and they will be randomly assigned to receive either (1) intravenous ketorolac and oral placebo or (2) intravenous placebo and oral ibuprofen. Efficacy will be assessed by three measures: the duration and degree of intensity and relief determined by validated pain scales; the duration of hospitalization for parenteral opioid therapy; and the utilization of parenteral opiates during hospitalization. All subjects will be monitored for potential adverse effects of the study medications by laboratory measurements and clinical assessments.

### Specific Aims:

1. To determine whether ketorolac decreases the time to a 50% reduction in reported pain intensity more quickly than oral ibuprofen.
2. To determine whether ketorolac is safe for children with SCD.
3. To determine whether secretory phospholipase A<sub>2</sub> (sPLA<sub>2</sub>) predicts impending acute chest syndrome.