

## RESEARCH STUDY FOR SICKLE CELL DISEASE

### Clinical Importance of Treating Iron Overload in Pediatric & Adult Sickle Cell Patients

Study ID: CCI-08-00274

Valid from - to N/A

Patients with sickle cell anemia often require blood transfusion as part of the treatment for their disease. Each teaspoon of packed red blood cells contains about 5 mg of iron. Since humans have no way to get rid of excess iron, the levels of iron in sickle cell patients increase rapidly with each transfusion. While iron is necessary for many functions in our body, too much iron can be very dangerous and can cause damage to your blood vessels, red blood cells, liver, hormone producing glands (pancreas, pituitary and thyroid) and heart. The damage from iron overload can take years before the problem is severe enough to make you sick. Treatments to remove iron from the body can take months to years to work. It is very hard to know exactly what damage to your organs is caused by your sickle cell disease or by the iron overload.

The purpose of this research study is to see if there has been any damage to your body that may have occurred because of too much iron (iron overload). And if you do have iron overload we want to know whether treatment can take away any of that damage.

This study is being conducted by Dr. Thomas Coates at CHLA. Other investigators on this study are: Dr. Thomas Hofstra and Dr. Susan Cluster of Hematology, Dr. John Wood and Dr. Jon Detterich of Cardiology, Dr. Hollie Jackson of Radiology and Dr. Roberta Kato of Pulmonary.

The following is a description of the requirement for the study. If you are interested in being a part of this study please contact the study coordinator below.

#### **Study Participation Requirements:**

Patients who decide to participate in this study will be scheduled for the baseline/screening exams as required for the study. These exams are: MRI to measure cardiac and liver iron, medical history and physical exam, blood tests, hearing and eye exam and a special test called a red cell survival test. You will learn more about all these procedures when the consent is given to you.

If you qualify to be treated for iron overload then your participation in this study will last up to 1 year and you will be required to take the medication Exjade®. This medication removes iron from the body.

#### **Eligibility Criteria:**

- Must have sickle cell disease
- Must not be on a frequent transfusion program
- Must be at least 14 years of age
- Must not require blood transfusions more than 3 times a year
- Must have labs within the normal range per CHLA standards
- Must not have any severe uncontrolled chronic illnesses

#### **Payment:**

There will be participant reimbursement for your time. This money is to cover any expenses you may incur while participating in the study. The details of the reimbursement are in the informed consent.

#### **Contact Person:**

Anne Nord, RN, BSN, CCRP  
Clinical Research Nurse-Hematology

#### **Study Location:**

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