Medical College of Georgia
GEORGIA'S HEALTH SCIENCES UNIVERSITY

Department of Medicine
Sickle Cell Center

ONGOING CLINICAL TRIALS:

CICL670A2201 Novartis Pharmaceuticals Corp.
"A Randomized, Multicenter, Open-Label, Phase II Study to Evaluate the Safety, Tolerability, Pharmacokinetics and the Effects on Liver Iron Concentration of Repeated Doses of 10 mg/kg/day of ICL670 Relative to Deferoxamine in Sickle Cell Disease Patients with Transfusional Hemosiderosis"

The major goal of this study is to determine the safety, tolerability, and efficacy of a new oral iron chelator in patients with sickle cell disease with transfusional iron overload.

NO1-HB-07160 NIH/NHLBI/Clinical Trials and Surveys Corp.
"Pediatric Hydroxyurea Phase III Clinical Trial (BABY HUG) Feasibility and Safety Pilot Study Hematology and Biochemistry Core Laboratory"

The major goal of this study is to determine the safety of HU in infants with sickle cell disease, 12-24 months of age, and to determine the efficacy of HU in preventing organ damage.

1U01 HL078787-01A1 NIH/NHLBI/St. Jude Children's Research Hospital
"Stroke with Transfusions Changing to Hydroxyurea (SWiTCH)"

The major goal of this study is to determine if switching patients from a chronic transfusion program to transfusions plus hydroxyurea therapy will prevent recurrence of stroke as well as transfusion only.

CC-4047-SCD-001 Celgene Corporation
"A prospective, multi-center, open-label, dose-escalation study to determine the maximum tolerated dose, effect on induction of fetal hemoglobin, and the safety of CC-4047 in subjects with sickle cell disease"

The major goal of this study is to determine the maximum tolerated dose of CC-4047 and to determine the effect of CC-4047 on the induction of fetal hemoglobin in patients with sickle cell disease.

Neuropsych Study NIH/NHLBI/RhoFed Corporation
"Neuropsychological dysfunction and neuroimaging abnormalities in neurologically intact adult patients with sickle cell disease (SCD)"

The major goal of this study is determine the extent of neurocognitive dysfunction in neurologically asymptomatic adult patients with sickle cell disease and to determine the association between neurocognitive dysfunction and imaging abnormalities.

AN-SCD-1121 Anthera Pharmaceuticals, Inc.
"IMPACTS Trial: Investigation of the Modulation of Phospholipase in Acute Chest Syndrome(Dose Escalation Study: Varespladib Infusion [A-001] for the Prevention of Acute Chest Syndrome in At-Risk Patients with Sickle Cell Disease and Vaso-occlusive Crisis)"

The major goal of this study is to determine the safety, tolerability, and pharmacokinetic profile of A-101 in preventing acute chest syndrome in patients with sickle cell disease.

SCD-001 BioMarin Pharmaceutical, Inc.
"A Phase 2a, Multicenter, Open-label, Dose-escalation Study to Evaluate the Safety, Tolerability, and Efficacy of 6R-BH4 in Subjects with Sickle Cell Disease"

The major goal of this study is to determine the safety of and to evaluate the physiological and biochemical markers of endothelial function in subjects with sickle cell disease receiving 6R-BH4.