Childhood Liver Disease Research and Education Network (ChiLDREN)

A RANDOMIZED, DOUBLE-BLINDED, PLACEBO-CONTROLLED TRIAL OF CORTICOSTEROID THERAPY FOLLOWING PORTOENTEROSTOMY IN INFANTS WITH BILIARY ATRESIA

Manual of Operations (MOO)

1 April 2007 (Version 1)

LAST EDITED on 01 September 2010

4.6 Steroid Pulses

4.7 Tracking Study Medication Use

4.8 Administration Instructions for Study Medications

- 4.8.1 Administration Instructions for Steroid/Placebo
  - 4.8.1.1 Schedule of Dosing
  - 4.8.1.2 Guidelines for Giving a Second Dose if Child Spits Ups/Vomits First Dose
  - 4.8.1.3 Two-Week Drug Adjustment
  - 4.8.1.4 Instructions for the Family Administering Steroid/Placebo
- 4.8.2 Administration Instructions for AquADEK™ and Vitamin K (Mephyton®)
  - 4.8.2.1 Schedule of Dosing
  - 4.8.2.2 Guidelines for Giving a Second Dose if Child Spits Ups/Vomits First Dose
  - 4.8.2.3 Accountability for Vitamins
  - 4.8.2.4 Instructions for the Family Administering AquADEK™ and Vitamin K
- 4.8.3 Administration Instructions for Ursodeoxycholic Acid (Urso 250® or Actigall®)
  - 4.8.3.1 Schedule of Dosing
  - 4.8.3.2 Instructions for the Family Administering Ursodeoxycholic Acid (Urso 250® or Actigall®)
- 4.8.4 Administration Instructions for Trimethoprim-Sulfamethoxazole (TMP-SMZ) (Bactrim)
  - 4.8.4.1 Schedule of Dosing
  - 4.8.4.2 Dose Adjustment
  - 4.8.4.3 Instructions for the Family Administering TMP-SMZ (Bactrim)
- 4.8.5 Administration Instructions for Ranitidine (Zantac®)
  - 4.8.5.1 Schedule of Dosing
  - 4.8.5.2 Instructions for the Family Administering Ranitidine (Zantac®)
- 4.8.6 Administration Instructions for Ranitidine (Zantac®)
  - 4.8.6.1 Schedule of Dosing

4.9 Transferring START Subjects from One Clinical Site to Another

- 4.9.1 Subjects Taking Steroid/Placebo
  - 4.9.1.1 Tasks: ‘From’-Site (study site from which subject is transferring from)
  - 4.9.1.2 Tasks: ‘To’-Site (study site to where subject is transferring to)
  - 4.9.1.3 Tasks: Central Pharmacy
- 4.9.2 Subjects Done Taking Steroid/Placebo
  - 4.9.2.1 Tasks: ‘From’-Site (study site from which subject is transferring from)
  - 4.9.2.2 Tasks: ‘To’-Site (study site to where subject is transferring to)

CHAPTER 5. SPECIMEN COLLECTION

5.1 Vitamin Levels Assessment

- 5.1.1 Schedule
- 5.1.2 Testing
- 5.1.3 Sample Size Requirements