A Phase 1 Adaptive, Multiple Dose Pharmacokinetic and Safety Assessment of Valacyclovir in Infants At Risk of Acquiring Neonatal Herpes Simplex Virus Disease

Status: Recruiting

Eligibility Criteria

Sex: Male or Female
Age Group: Up to 18 years old
This study is NOT accepting healthy volunteers

Inclusion Criteria:

1. Mother has a history of genital HSV infection 2. Mother is receiving oral acyclovir, valacyclovir, or famciclovir suppressive therapy for 7 or more days before delivery 3. Gestational age 38 or more weeks at birth 4. Infant is no more than 2 days of age at study enrollment 5. Weight at study enrollment at least 2,000 grams

Exclusion Criteria:

1. Evidence of neonatal HSV infection 2. Evidence of sepsis 3. Kidney anomalies or dysfunction 4. Maternal genital lesions suspicious for HSV at the time of delivery 5. Infants known to be born to women who are HIV positive (HIV testing is not required) 6. Infant currently receiving acyclovir, ganciclovir, famciclovir, or any investigational drugs

Conditions & Interventions

Conditions:
Infectious Diseases, Children's Health
Keywords:
herpes simplex virus, neonatal herpes, HSV

More Information

Description: The purpose of this study is to determine the dose of medication (Valacyclovir) needed to prevent an infant from developing herpes simplex virus (HSV) if the infant was potentially exposed to HSV at the time of delivery as they passed through the birth canal.
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