A Phase 1 Pharmacokinetic and Safety Assessment of Oral Letermovir in Infants with Symptomatic Congenital Cytomegalovirus 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:

- age at enrollment is 90 days or younger - gestational age at birth is 32 weeks or greater - diagnosis or symptomatic congenital CMV (cytomegalovirus) - minimum weight of 2.6kg (5 lb, 12 oz.)

Exclusion Criteria:

- receiving other investigation drug - high bilirubin or ALT

Conditions & Interventions

Conditions:
Infectious Diseases
Keywords:
CMV, congenital, cytomegalovirus, treatment, valgancyclovir

More Information

Description: The purpose of this study is to determine the dose of a new medication being studied for babies who are exposed to cytomegalovirus during birth. This is called congenital cytomegalovirus (cCMV). Cytomegalovirus is the leading cause of hearing loss and the leading viral cause of developmental delays in children. If a baby participates in this study, in addition to the study medication, he/she will still receive the current best treatment for cCMV, which is oral Valganciclovir.
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