

A Prospective Database of Infants With Cholestasis

Status: RECRUITING

Eligibility Criteria

Sex: ALL

Age: Up to 6 month(s) old

Healthy Volunteers: This study is NOT accepting healthy volunteers

INCLUSION CRITERIA

- Infant's age less than or equal to 180 days at initial presentation at the ChiLDReN clinical site.
- Diagnosis of cholestasis defined by serum direct or conjugated bilirubin greater than or equal to 2 mg/dl and suspected biliary atresia.
- The subject's parent(s)/guardian(s) willing to provide informed written consent.

EXCLUSION CRITERIA

- Acute liver failure.
- Previous hepatobiliary surgery with dissection or excision of biliary tissue.
- Diagnoses of bacterial or fungal sepsis (except where associated with metabolic liver disease)
- Diagnoses of hypoxia, shock or ischemic hepatopathy within the past two weeks (If the cholestasis persists beyond two weeks of the initiating event, the infant can be enrolled).
- Diagnosis of any malignancy.
- Presence of any primary hemolytic disease (except when diagnosed with biliary atresia or another cholestatic disease being studied by ChiLDReN).
- Diagnosis of any drug or Total parenteral nutrition (TPN)-associated cholestasis (except when diagnosed with biliary atresia or another cholestatic disease being studied by ChiLDReN).
- Diagnosis with Extracorporeal membrane oxygenation (ECMO)-associated cholestasis.
- Birth weight less than 1500g (except when diagnosed with biliary atresia).

Conditions & Interventions

Conditions:

Biliary Atresia

More Information

Description:

Biliary atresia, idiopathic neonatal hepatitis, and specific genetic cholestatic conditions are the most common causes of jaundice and hyperbilirubinemia that continue beyond the newborn period. The long term goal of the Childhood Liver Disease Research Network (ChiLDReN) is to establish a database of clinical information and plasma, serum, and tissue samples from cholestatic children to facilitate research and to perform clinical, epidemiological and therapeutic trials in these important pediatric liver diseases.

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Phase:

IRB Number:

System ID: NCT00061828

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