

Cholestatic Liver Disease Consortium (CLiC)

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Research Areas



Product Development

Device, Drugs, Other

At a Glance

- Status: **Completed Consortium**
- Year Launched: **2003**
- Initiating Organization: **National Institute of Diabetes and Digestive and Kidney Diseases**
- Initiator Type: **Government**
- **Rare** disease
- Location: **North America**

Abstract

The Cholestatic Liver Disease Consortium (CLiC) is now part of ChiLDREN, the Childhood Liver Disease Research and Education Network. The new and expanded network combines CLiC and the Biliary Atresia Research Consortium, as well as new studies on cystic fibrosis liver disease. This consolidation seeks to facilitate the discovery of new diagnostics, etiologic, and treatment options for children with rare liver diseases, and those who undergo liver transplantation, and to train the next generation of investigators in rare pediatric liver diseases.

Mission

ChiLDReN is a collaborative team of doctors, nurses, research coordinators, medical facilities, and patient support organizations. The ChiLDReN Network has clinical sites and research labs in the U.S. and Canada, and also includes a research lab in London. These sites are working together to improve the lives of children and families dealing with rare liver diseases.

One of the primary goals of the Network is to provide a way for patients to join with doctors and researchers by participating in research studies. The greater the collaboration between doctors and patients and their families, the more can be learned about rare liver diseases. This important first step is necessary to find new and better treatments.

Infants, children, and young adults with cholestasis (blockage of bile flow from the liver) who receive their medical care at one of the participating ChiLDReN centers may be eligible to enroll in current ChiLDReN studies. Patients who receive their medical care at other clinical facilities may also be eligible for ChiLDReN studies if they are able to visit a ChiLDReN site for regular research visits.

ChiLDReN is currently studying the following diseases.

Structure & Governance

The ChiLDReN Data Coordinating Center (DCC) is located at the University of Michigan and Arbor Research Collaborative for Health in Ann Arbor, Mich., and operates under the direction of co-Principal Investigators John C. Magee and Robert M. Merion. The DCC provides scientific, statistical, and project management for the network. The DCC collaborates with clinical investigators on study design and analysis and provides leadership in the operational aspects of the study.

Financing

The ChiLDReN Network is sponsored by the National Institute of Diabetes and Digestive and Kidney Diseases, a division of the National Institutes of Health. The Network also receives funding for specific studies from the Cystic Fibrosis Foundation and the Alpha-1 Foundation.

Impact/Accomplishment

Natural History Studies

PROBE: A prospective study of infants and children with cholestasis.

Eligibility: Infants up to 6 months of age that have been diagnosed with cholestasis (direct

hyperbilirubinemia).

ClinicalTrials.gov Study NCT00061828

BASIC: A prospective database study of older children with biliary atresia.

Eligibility: Children and adults age 6 months and older that have been diagnosed with biliary atresia, both before and after liver transplantation.

ClinicalTrials.gov Study NCT00345553

LOGIC: A longitudinal study of genetic causes of intrahepatic cholestasis.

Eligibility: Children and adults ages 6 months through 25 years diagnosed with Alagille Syndrome, alpha-1 antitrypsin deficiency, progressive familial intrahepatic cholestasis, or bile acid synthesis defects, both before and after liver transplantation.

ClinicalTrials.gov Study NCT00571272

MITOHEP: A longitudinal study of mitochondrial hepatopathies.

Eligibility: Children and adults through age 18 years that have been diagnosed with (or are strongly suspected to have) a mitochondrial liver disease.

ClinicalTrials.gov Study NCT01148550

PUSH: A longitudinal study of the risk of hepatic cirrhosis in Cystic Fibrosis.

Eligibility: Children ages 3 through 12 years of age with Cystic Fibrosis and pancreatic insufficiency who are enrolled in the CFF or Toronto CF registry studies.

ClinicalTrials.gov Study NCT01144507

Clinical Therapy Trial

START: A clinical trial to test the efficacy and safety of corticosteroids in the treatment of biliary atresia following hepatic portoenterostomy at a ChiLDREN study site.

Eligibility: Infants up to 6 months of age that have been diagnosed with biliary atresia and have undergone hepatic portoenterostomy within 72 hours at a ChiLDREN study site.

ClinicalTrials.gov Study NCT00294684

ITCH: A clinical trial to test the efficacy and safety of the Intestinal Bile Acid Transport (IBAT) Inhibitor LUM001 in the treatment of Pruritus in Alagille Syndrome Patients.

Eligibility: Children and adults between the ages of 2 and 18 years of age that have been diagnosed with Alagille Syndrome and Pruritus.

ClinicalTrials.gov Study NCT02057692

PRIME: This is a multi-center open label phase I/IIa clinical trial of high dose IVIG in infants with biliary atresia to determine if the administration of intravenous immunoglobulin (IVIG) in these infants is feasible, well tolerated and safe, to determine if there is a trend towards improved clinical outcomes, and to examine mechanisms that might explain the effects of IVIG in this disease.

Eligibility: Infants up to 4 months of age that have been diagnosed with biliary atresia and have undergone hepatic portoenterostomy within 72 hours at a participating ChiLDREN study site.

ClinicalTrials.gov Study NCT01854827

Links/Social Media Feed

Homepage

<https://childrennetwork.org/default.aspx>

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