Oral Fish Oil to Prevent and Treat Parenteral Nutrition Associated Liver Disease

The Problem

Approximately, one in eight infants is born prematurely in the United States, and one-third of premature infants are born at less than 34 weeks gestation. These infants have a significantly elevated risk of medical complications. One common complication is that premature infants are unable to intake sufficient food orally, necessitating that they be put on parenteral nutrition. Unfortunately extended parenteral feeding is associated with its own significant complication, a severe liver disease named Parenteral Nutrition Associated Liver Disease (PNALD) in which the liver is permanently damaged or fails entirely.

Early evidence from a group at the Boston Children’s Hospital suggested that PNALD may be occurring, at least in part, due to hepatic effects of intravenous administration of Omega-6 long-chain fatty acids. Under a compassionate use protocol, this group in Boston has been able to treat a small number of patients with a parenteral formula containing a primarily omega-3 long-chain fatty acids (derived from fish oil), with promising results, but this formula is not approved by the FDA for use in the United States.

The Technology Solution

In contrast to the unapproved intravenous formula, there are many fish oil supplements available as dietary supplements in the United States. In a potential breakthrough in the prevention and treatment of PNALD, researchers at the University of Tennessee Health Science Center were able to reverse PNALD in 4 of 6 premature infants with short bowel syndrome using an oral formulation of fatty acids derived from fish oil.

The researchers have further developed a supplement with a defined composition, improved handling characteristics and flavoring which can be used to advance enteral tolerance in infants receiving parenteral nutrition. They are also planning another clinical study “Parenteral Nutrition Associated Liver Disease: Early Markers and Therapy With Enteral Omega-3 Supplementation” (see tillman/clinicaltrials/protocol).

The Benefits

Infants can be given the fish oil enterally and not intravenously - allowing parents to administer supplement at home.
Inventors’ fish oil supplement has improved flavoring and smell as compared to commercially available fish oils - this will lead to improved patient compliance.

Supplement has known and consistent amounts of DHA and EPA – many commercially available fish oils vary in their key ingredients.

Supplement has improved viscosity – can be used in feeding tubes.

The Inventors

**Dr. Rich Helms** is Professor and Chair of Clinical Pharmacy at the University of Tennessee Health Science Center. His research interests are amino acid and fatty acid metabolism in the neonate and infant, cysteine dosing in the pre-term neonate, carnitine effects on neonatal morbidities, and amino acid requirements in home parenteral nutrition patients.

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Patent Applications

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The University of Tennessee Research Foundation (UTRF) is a non-profit corporation responsible for commercializing University of Tennessee technologies and for supporting University research. UTRF is seeking parties interested in learning more about this technology and in exploring possible research and/or commercialization arrangements.

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