Development of novel manufacturing methods may achieve safe 20% PFO parenteral emulsions, but by established formulation methods, these emulsions were clinically suboptimal despite meeting pharmacopeial standards" Fell et al (2016).

Abstract:

Background: Fat emulsions are important components of parenteral nutrition (PN). Fish oil (FO) emulsions reverse cholestasis in PN-associated liver disease. There are 2 FO monographs. One is "FO; rich in omega-3 fatty acids" (NFO). The other, "omega-3 acids," (PFO), is enriched in omega-3 fatty acids, particularly eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA). The purpose of this study is to compare the effects of 20% NFO and PFO emulsions produced in the laboratory in a murine model.

Methods: Emulsions were compounded containing different oils: soybean oil (SO), NFO, and two PFOs differing in percentage of fatty acids as triglycerides (PFO66 and PFO90). Chow-fed mice received saline, one of the above emulsions, or a commercial FO (OM) intravenously (2.4 g/kg/day) for 19 days. On day 19, animals were euthanized. Livers, spleens, and lungs were procured for histologic analysis.

Results: OM, SO, NFO, and PFO90 were well-tolerated clinically. PFO66 resulted in tachypnea and lethargy for ~1 minute following injections. At euthanasia, PFO66 and PFO90 groups had organomegaly. Histologically, these groups had splenic and hepatic fat-laden macrophages, and lungs had scattered fat deposits. Other groups had normal organs.

Conclusions: PFO emulsions present an attractive possibility for improving inflammation in PN-dependent patients by concentrating anti-inflammatory EPA and DHA. However, 20% PFO emulsions were poorly tolerated and precipitated adverse end organ sequelae, suggesting that they may not be safe. Development of novel manufacturing methods may achieve safe 20% PFO parenteral emulsions, but by established formulation methods, these

emulsions were clinically suboptimal despite meeting pharmacopeial standards.

Reference:

Fell, G.L., Cho, B.S., Pan, A., Nose, V., Anez-Bustillos, L., Dao, D.T., Baker, M.A., Nandivada, P., Gura, K.M. and Puder, M. (2016) A Comparison of Fish Oil Sources for Parenteral Lipid Emulsions in a Murine Model. JPEN. 18th March. .

doi: 10.1177/0148607116640275

Thank you to our partners for supporting IVTEAM