



Double blind, prospective randomized comparison of a MCT/LCT/FO-containing 20% lipid emulsion with a MCT/LCT-emulsion (20 %) during parenteral nutrition in preterm newborn

B. Braun Melsungen AG, Hospital Care, Clinical Development

Background: Eicosapentaenoic and Docosahexaenoic Acid (EPA & DHA) as the most prominent representatives of omega-3 fatty acids are potent modulators of stress induced immune response in humans. Eicosanoides derived from EPA & DHA are non inflammatory derivatives and compete with pro-inflammatory eicosanoids derived from arachidonic acid (omega-6 fatty acid). Preterm newborns per se are under continuous stress caused by their immaturity and their preterm exposure to an inadequate environment. A large variety of noxes challenge the immature organism continuously.

The hypothesis that an improved availability of omega-3 fatty acids as part of a parenteral nutrition regimen provided for a limited post natal period can be achieved without sacrificing the essential contribution of omega-6 fatty acids and safety.

Method: 34 preterm newborns were randomly assigned to a parenteral nutrition regimen either containing omega-3 fatty acids (Lipoplus®) or a standard lipid emulsion (Lipofundin MCT/LCT®). In this double blind, prospective, parallel group phase II trial patients obtained at least 70% of their nutritional requirements during 5 days by parenteral nutrition. Safety was closely monitored. Concentration of EPA and DHA in membranes of serum phospholipids, erythrocytes and buccal mucosa was measured on days 1, 5 and 6. A ¹³C Arachidonic Acid Tracer was provided on day 5 to quantify patients omega-6 status.

Study site(s): Prof. Berthold Koletzko; Childrens Hospital Ludwig-Maximilians University Munich, Germany
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Status: Statistical evaluation

Sponsor: B. Braun Melsungen AG

Register:

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