



Efficacy, safety and quality of life of a long-term home parenteral nutrition regimen with either Lipidem or Lipofundin MCT

B. Braun Melsungen AG, Hospital Care, Clinical Development

Background: Long term home parenteral nutrition is indicated in patients who are unable to completely cover their daily caloric requirements by oral/enteral nutrition. By providing lipid emulsions containing n-3 PUFA (**Poly Unsaturated Fatty Acids**) as part of a home parenteral nutrition regimen we like to prove safety and assess valuable information about possible improvements in patients quality of life by stopping or deceleration of processes underlying weight loss.

Method: 66 patients in need of home parenteral nutrition support providing at least 70 % of patients weekly needs will be randomly assigned to receive nutritional support with either Lipoplus® (a Fish Oil containing lipid emulsion) or Lipofundin MCT/LCT® for at least 8 weeks. Patients will visit the hospital in four weeks intervals. During these visits a indirect calorimetry will provide information on **Resting Energy Expenditure (REE)** and a Bioimpedance Analyses as well a MRI will provide on body composition changes. Blood samples will be taken for analysis of safety variable, eicosanoid concentrations and concentration of n-3 PUFA in phospholipids membranes. Quality of life will be monitored by EORTC QLQ C-30.

Principal investigator: Dr. Paul Thul: Charité University Hospital Berlin, Germany

Status: Recruiting

Sponsor: B. Braun Melsungen AG

Register:

<http://www.clinicaltrials.gov/ct2/show/NCT00530738?term=B.Braun+Melsungen+AG&rank=3>