



Evaluation of the clinical safety and beneficial effects of a fish oil containing lipid emulsion (Lipoplus[®], MLF541)

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Background: Recent findings suggest that provision of omega-3 fatty acids contained in fish oil may have favourable influence on patients post operative stress response if provided as a component of a parenteral nutrition regimen. It is under debate whether an increased availability of omega-3 fatty acids may cause this effect by serving as precursors of biologically less active and non-inflammatory eicosanoids. This study supports the idea that improved availability of omega-3 fatty acids can cause a shift in eicosanoid production and result in a better clinical outcome in patients.

Method: 256 cancer patients after major abdominal surgery with a post operative need for parenteral nutrition for at least five days were assigned to either receive a parenteral nutritional regimen with (Lipoplus[®], N=127 treatment group) or without omega-3 fatty acids (Intralipid[®], N=129 control group). Changes of membrane fatty acid composition were assessed in a subset of patients (N=2x16). Changes in mediators of inflammatory stress response were evaluated by assessment of the LTB₄/LTB₅ (Leukotriene **B₄/B₅**) ratio on day 6 after surgery. Safety was routinely monitored.

Results: While both regimen can be considered save patients receiving parenteral nutrition with omega-3 fatty acids left the hospital earlier than those in the control group (17 days, 95%-CI 14.8, 19.6 vs. 22 days, 95%-CI 19.5, 24.3; p = 0.00607). Increased availability of omega-3 fatty acids in plasma phospholipids was proven in the Lipoplus[®] group compared to controls (p = 0.0012), counting for the significant group difference (p = 0.0023) in EPA/AA (Eicosapentaenoic acid/Arachidonic acid) ratio by explaining the increase in the Lipoplus[®] group. Leukotriene B₅ (LTB₅) synthetic capacity was significantly increased under Lipoplus[®] treatment (p = 0.0035). Corresponding LTB₅/LTB₄ ratio increased in the Lipoplus[®] group showing significant (p = 0.0017) shift in eicosanoid composition due to the nutritional regimen.

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