Enteral Supplementation of LCPUFAs to Extremely Preterm Infants in the Prevention of Morbidities – An Interim Analysis of Serum Fatty Acid Levels

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Background and aim

Infants born extremely preterm are at risk of developing deficiency of the long-chain polyunsaturated fatty acids (LC-PUFAs) arachidonic acid (ARA) and docosahexaenoic acid (DHA) associated with long-term effects on cognition and visual acuity. The Mega Donna Mega study is a randomized clinical multicentre trial to determine the role of fatty acid supplementation in preventing morbidities in infants born with a gestational age <28 weeks. First patient of the study was enrolled in December 2016 and last patient is expected to leave the study in spring 2019.

Methods

Infants are randomized to receive enteral supplementation with Formulaid™ (DSM Nutritional Products, Inc.), an oil containing ARA and DHA in 2:1 proportions. Supplementation is given from birth to 40 weeks postmenstrual age at 100 and 50 mg/kg/day for ARA and DHA respectively. Parenteral nutrition with Clinoleic (Baxter Medical AB) as clinical routine is given to all infants. Serum fatty acid derived from phospholipids are analysed by GC-MS longitudinally during the treatment period.

Interim study population

Flow chart of the study population. Forty-four infants, of which 23 received treatment with Formulaid™, were included in the interim study. N indicate infants included in interim/complete study. GA, gestational age (weeks + days).

Results 1. Formulaid increases the *relative* concentration of ARA and DHA

Longitudinal development of ARA and DHA in infants receiving Formulaid™ and conventional care. Means and 95% CI are shown. *p-value<0.05, Mann-Whitney U test. The Holm-Bonferroni Method was used to correct for multiple comparisons. CB, cord blood; PNA, postnatal age; PMA, postmenstrual age.

Results 2. Formulaid increases the *absolute* concentration of ARA and DHA

Longitudinal development of ARA and DHA in infants receiving Formulaid™ and conventional care. Means and 95% CI are shown. *p-value<0.05, Mann-Whitney U test. The Holm-Bonferroni Method was used to correct for multiple comparisons. CB, cord blood; PNA, postnatal age; PMA, postmenstrual age.

Conclusions

Enteral supplementation of DHA and ARA using Formulaid™ appears to be a feasible strategy to increase levels of these fatty acids in serum of extremely preterm infants and thus potentially preventing morbidities.

Clinical characteristics of the 44 infants included in the interim analysis. No significant differences were found between groups.

	Control	Formulaid™
Male, n (%)	12 (57)	14 (61)
Gestational age (wks), mean (SD)	25.3 (1.4)	25.7 (1.7)
Birth weight (g), mean (SD)	778 (190)	828 (231)

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References: This work is a part of the Mega Donna Mega Study. The protocol for the study is available at clinicaltrial.gov (Clinical trial NCT 02760472).

More information: www.rop.gu.se