

Supporting human milk feeding in preterm infants:

A new Human Milk Fortifier with lipids

Preterm birth is a global concern. The World Health Organisation (WHO) estimates that 15 million infants are born prematurely every year – equating to 1 preterm birth every 2 seconds.¹ Infants born prematurely may face significant health challenges, which are usually more pronounced the earlier they are born. The quality of care and nutrition received at birth, and the period that follows, can have a significant impact on preterm health outcomes.

Preterm infants have increased nutrient requirements to achieve the growth velocity of a child growing in utero.^{2,3} Whilst breastfeeding is the best source of nutrition for all babies (WHO), as the desired rate of growth in preterm babies may be up to five times higher than term born infants, the composition of breastmilk alone may not meet the unique requirements to support preterm growth and development.^{3,4}

The European Society for Gastroenterology, Hepatology, and Nutrition (ESPGHAN) address these requirements by giving specific recommendations for preterm infants and advocates the use of human milk as the preferred nutrition for preterm infants <1800g “provided it is fortified with added nutrients where necessary to meet requirements”.^{2,5} The use of Human Milk Fortifier (HMF) is associated with improved growth and brain development.⁶

Most commercially available fortifiers contain varying amounts of protein, carbohydrates, calcium, phosphate and other vitamins and minerals with the primary source of energy coming from the carbohydrate content.⁷ In this randomised, double-blind, controlled study, the

aim was to compare and assess the growth, tolerance and safety of a new nutripem HMF with added lipids (including docosahexaenoic acid (DHA) and arachidonic acid (ARA), medium chain fatty acids, and anhydrous milk fats), more protein and less carbohydrate compared to a conventional HMF in very low birth weight (VLBW) preterm infants receiving human milk.⁸

The study was conducted across 9 neonatal intensive care units (NICU) and 4 European countries including the UK, with VLBW infants (gestational age <32 weeks, birth weight <1500 g) randomised to receive HM fortified with either Nutricia’s current commercially available HMF (Control HMF: 15 kcal, no lipids, 1.1 g protein, and 2.7 g carbohydrates per 100 ml fortified HM) or the new nutripem HMF with lipids (Test HMF: 17 kcal, 0.7 g lipids, 1.3 g protein, and 1.7 g carbohydrates per 100ml fortified HM). Fortification of human milk was started according to the local feeding protocol in each NICU and continued for a minimum of 21 days whilst infant characteristics and data on anthropometrics, digestive tolerance, and safety were collected between birth and the end of intervention. The primary outcome parameter assessed was weight growth velocity between baseline and day 21 of intervention to ensure adequate growth, with an adequate growth considered as weight growth velocity between 15-20 g/kg/day. The aim of this study was to demonstrate that weight growth velocity would be non-inferior with the new nutripem HMF in comparison to the Control group.


A total of 205 VLBW infants were included in the study from March 2018 to July 2020, with 102 VLBW infants in the Test group and 103 in

the Control group. These infants were born at a mean gestational age of 27.8 weeks (SD: 2.2) and had a mean birth weight of 967g (SD: 261) with just over one infant in ten (12.7%) being growth restricted at birth. On average, the infants in the study started the intervention at 10.6 days (SD: 5.6) after birth.

Both groups of infants demonstrated an appropriate growth of between 15-20 g/kg/day – with those receiving the new nutripem HMF with lipids and the conventional HMF having a mean weight growth velocity of 18.4 g/kg/day and 18.5 g/kg/day respectively during the 21 days of intervention. With a predefined non-inferiority margin of -1.6 g/kg/day, this demonstrates the non-inferior and appropriate growth of the new nutripem HMF compared to the conventional, commercially available HMF in line with the aims of the study. In addition to the primary study parameter for growth, there were no significant differences observed in length, head circumference, or anthropometric Z-scores gains during the 21 days of intervention, demonstrating appropriate growth.

Importantly the new, nutripem HMF with lipids was demonstrated to be safe for use in these vulnerable infants, with the percentage of infants with episodes of digestive intolerance (vomiting, regurgitation, clinically significant gastric residuals), as well as stool frequency and consistency being not significantly different between the 2 study groups. Neonatal morbidities including necrotising enterocolitis (Test: 2.9%, Control: 6.9%), serious neonatal infections (Test: 12.6%, Control: 13.9%) and metabolic acidosis (Test: 1.0%, Control: 2.0%) were also not significantly different between groups.

Overall this study demonstrates the safety and tolerance of nutripem’s new HMF with lipids, whilst showing it supports appropriate growth in vulnerable VLBW preterm infants.

As such its use in clinical practice can support human milk feeding, whilst promoting growth and development by meeting the nutritional needs of VLBW preterm infants. 

IMPORTANT NOTICE: Breastfeeding is best. nutripem human milk fortifier is a food for special medical purposes for the dietary management of preterm and low birthweight infants. It should only be used under medical supervision, after full consideration of the feeding options available including breastfeeding. It is not suitable for use as the sole source of nutrition. Refer to the label for details.



PAUL RIGBY
Global Medical & Scientific
Affairs Manager – Preterm &
Faltering Growth, Nutricia

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