

Title of the Study: The effect of various doses of Lipid-Based Nutrient Supplement (LNS) on energy intake from complementary foods of 9-month old infants in rural Malawi

Investigators

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Background and design

This study is designed as a sub-study within a larger randomized controlled trial (called “iLiNS-DOSE”) that we are currently conducting in rural Malawi to evaluate the effect of daily consumption of a micronutrient-fortified, energy dense, lipid-based nutrient supplement (LNS) on growth and development in infants.

Undernutrition, especially in developing countries, is one of the greatest predictors for morbidity and mortality, especially among children. In Malawi, prevalence of undernutrition, and in particular stunting, is high, with just over half of all children under five years of age stunted (HAZ < -2 SD) (Kothari and Abderrahim, 2010, reporting from 2004 DHS). High levels of stunting result from some combination of small maternal size and maternal under-nutrition, repeated infections during infancy, poor breastfeeding or care practices, and inadequate quantity and/or quality of complementary food. Provision of LNS, in the form of a paste that can be added directly to complementary foods prepared in the home beginning at 6 mo of age, may help prevent growth faltering in early childhood. Preliminary results from Malawi and Ghana suggest that daily consumption of 20-50 g of LNS for 6-12 months increases linear growth and markedly reduces the incidence of severe stunting before the age of 18 months.

The iLiNS-DOSE trial aims to identify the lowest daily dose of LNS that promotes growth in infants when given between the ages of 6 and 18 months (see full trial protocol at ClinicalTrials.gov, NCT00945698). Specifically, we will assess the growth-promoting effects of LNS given daily to infants at a dose of 10 g, 20 g or 40 g, from 6 to 18 months of age; a comparison group will not receive any study supplement until after 18 months (when they will receive fortified maize-soy porridge). The daily doses of 10 g, 20 g or 40 g of LNS will provide 56 kcal/d, 118 kcal/d and 243 kcal/d, respectively.

To understand mechanisms by which LNS may impact growth, we need to know if infants receiving LNS consume more energy and nutrients than those not receiving LNS, and we need to know if LNS displaces either breast milk, complementary foods, or both. Further, if there is displacement of food, to understand impact of LNS on diets we need to identify which foods are displaced. Within iLiNS we have undertaken two sub-studies, one focused on breast milk intakes, and the study described here, focused on complementary food intakes.

In this sub-study, we will assess the energy intake from complementary foods (and from LNS if the infant is randomized to one of the three groups who receives LNS) among 9 month old infants consuming 10g, 20g, 40g LNS per day and in the comparison (delayed intervention) group. We will also describe diets and diet patterns among infants in the various groups.

Specific objective

To estimate energy intakes from all non-breast milk sources of energy (LNS + complementary foods) in 9 and 15 month-old infants and assess whether there is a difference between the comparison group and the 10g, 20g and/or 40g of LNS supplementation groups.

Hypothesis

The mean energy intakes (kcal/day) from all non-LNS sources of energy will not be >75 kcal/d lower; and from LNS plus all non-LNS sources of energy it will be >60 kcal/d higher comparing infants receiving 20g or 40g to those receiving no LNS. A similar trend will be observed comparing the 10-g to the no LNS group. That is, LNS will not displace complementary foods to a great extent, but instead will result in higher overall energy intake.

Study procedures and research methods

Selection of subjects: Infants are randomly selected concurrently from each of the four study groups in the larger intervention trial at the time of enrolment (6 mo of age); procedures for the sub-study do not begin until infants are 9 months of age. Enrolment will be on-going during a one-year period. A total of 688 infants will be selected for the sub-study. Verbal informed consent is obtained from caregivers of infants who choose to participate in this sub-study. The study protocol has been approved by the Institutional Review Boards of the College of Medicine, University of Malawi and the London School of Hygiene and Tropical Medicine.

Sample size: Sample size = 688 infants total, 172 / group (control, 10, 20, 40g LNS). A sample size of 150 is needed to detect a 20% increase in energy intakes from non-breast milk sources (LNS + complementary foods) and a 25% displacement (75-81 kcal) in complementary food intakes compared to the comparison group (inferiority objective) using a predicted standard deviation of 131 kcal, with 80% power and 95% confidence. The sample size was increased by 15% to allow for attrition, resulting in the sample size of 172 per group. The study is not powered to detect a statistically significant difference in energy intakes between the 10g LNS group and the comparison group, as the sample size required to detect this difference was too large and not feasible.

24-hour recall: The mean energy intakes will be assessed using a repeat interactive 24-hour recall. The first recall will be done on a randomly selected day during week 16 or 17 of the study. The repeat recall will be performed exactly one week later. One other interactive 24-hour recall will be done on a randomly selected day during week 40 or 41, when the infants are approximately 15 months old.

Reference:

Kothari, Monica and Nouredine Abderrahim. 2010. *Nutrition Update 2010*. Calverton, Maryland, USA: ICF Macro.