

MERCURIUS CLINICAL STUDY: SHORT TERM OUTCOMES AND LONG-TERM BENEFITS

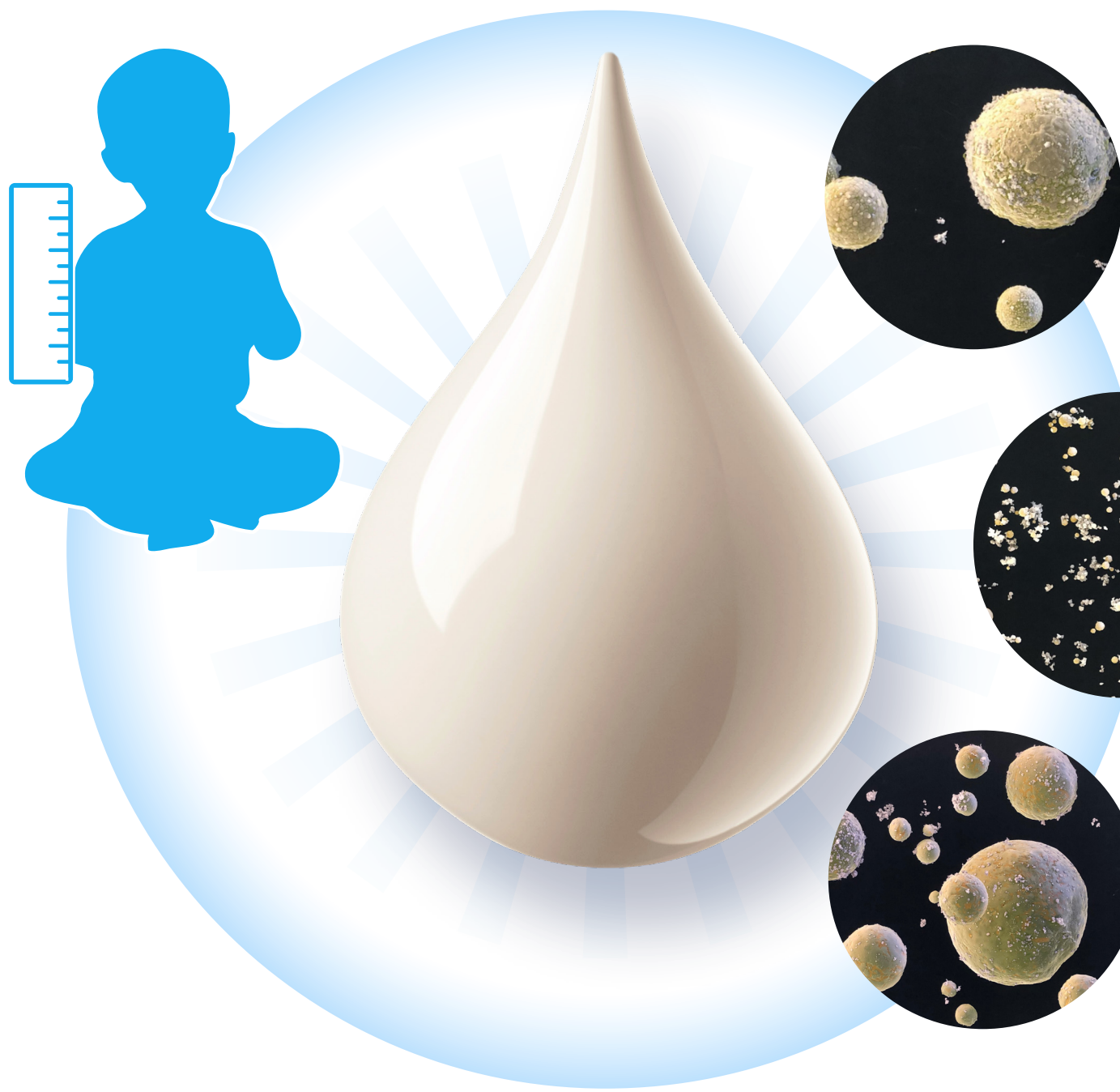
Introduction

Exclusive breast milk is the preferred feeding for infants and provides a complete supply of nutrients to support growth and development in early life.

Breast milk is rich in lipids, important for growth, brain and cognitive development, as well as gastrointestinal and immune function¹⁻³.

Compared to breast milk, the lipid droplets in standard infant formula are smaller, lack a milkfat globule membrane and may differ in overall lipid composition and triglyceride structure⁴.

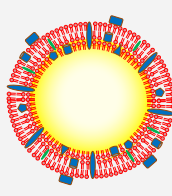
Danone Nutricia Research has developed a unique concept infant formula with large, milk phospholipid coated lipid droplets (mode diameter 3-5 µm; NUTURIS®) which brings the structural and functional properties of infant formula closer to those of breastmilk⁴.



BREAST MILK LIPID DROPLETS have a volume-based mode diameter of 4 µm⁵.

STANDARD INFANT FORMULA LIPID DROPLETS have a volume-based mode diameter of ~0.5 µm⁴.

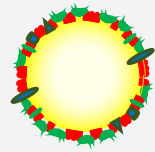
CONCEPT INFANT FORMULA LIPID DROPLETS have a mode diameter of 3-5 µm; NUTURIS®⁴.



In breastmilk, lipids are incorporated into large droplets surrounded by a complex triple-layer membrane (Milk Fat Globule Membrane)⁵.



Due to the normal process of infant formula production, the natural fat droplets do not remain intact and the MFGM is disrupted⁴.



Nuturis® brings the structure of the lipid droplets closer to breast milk⁴.

 **Mercurius study: A randomised, controlled, double-blind trial to investigate the effects of a new infant formula on growth, tolerance and safety in healthy term infants⁶**

(registered in the Dutch Trial Register as NTR3683)

4 countries:



Study groups:

- Concept group n=115
Concept infant formula
- Control group n=108
Control infant formula
- Reference group n=88
Breastfed infants

Both Concept and Control formulas were isocaloric (66 kcal/100 ml) and contained:

- ✓ Protein (1.3 g/100 mL)
- ✓ Lipids (3.4 g/100 mL)
- ✓ scGOS/lcFOS prebiotic mixture (9:1, 0.8 g/100 mL)

The differences between formulas were:

- Concept formula contained vegetable (52%) and dairy lipids (48%) & 3-fold increase of sn-2 palmitic acid.
- Control formula contained small lipid droplets with vegetable oils (no dairy lipids).

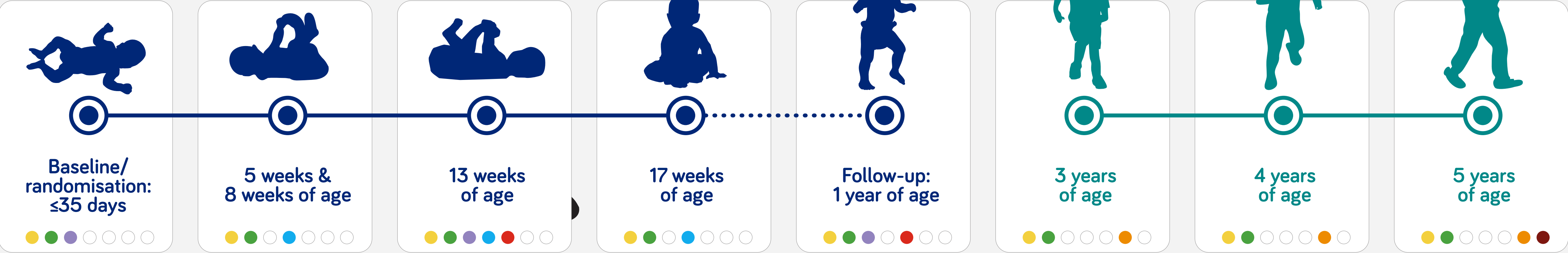
The primary objective:

To investigate equivalence of weight gain from randomisation until the age of 17 weeks.

Secondary objectives:

1. To investigate equivalence of other growth parameters until the age of 17 weeks
2. To assess gastrointestinal tolerance and safety until the age of 17 weeks
3. To investigate efficacy in weight gain at 12 months

INFANTS WERE FULLY FORMULA FED (EITHER CONTROL OR CONCEPT) UNTIL 17 WEEKS OF AGE:



Legend

- Anthropometric parameters
- Adverse Events (AEs)
- Stool samples
- GI symptoms & Stool consistency (7-d period preceding each visit)
- Blood sample
- Cognitive performance
- Blood pressure

FOLLOW-UP STUDY (NTR5538)

Objectives were to evaluate whether early life exposure to the Concept infant formula

1. Impacts BMI trajectory up to 5 years of age
2. Has an impact on blood pressure at 5 years of age*
3. Impacts neurocognitive outcomes at 5 years of age

Conclusions

Formula with NUTURIS® is safe, well tolerated, and supports an adequate growth in healthy infants.

Equivalence in daily weight gain vs. Control formula at 4 months of age.

No relevant differences in number, severity or relatedness of adverse events.

Concept formula group had stool consistency closer to the Breastfed group.



Formula with NUTURIS® may result in a BMI trajectory close to that observed in breastfed infants.

Compared to Control, children in the Concept group had a lower BMI (statistically significant at 1 year of age).

Compared to Breastfed, children in the Control group had a higher BMI up to 5 years of age.

Compared to Breastfed, the BMI trajectory in Concept group was highly similar up to 5 years.



Formula with NUTURIS® might result in reduced childhood blood pressure.

Compared to Control:

- Children in the Concept group had a lower diastolic and arterial blood pressure at 5 years of age (all within healthy ranges).

- A lower percentage of children in the Concept group had elevated blood pressure.
- A lower percentage of children in the Concept group had hypertension, similar to breastfed infants.



Formula with NUTURIS® may improve cognitive outcomes of infants during early childhood, bringing them closer to the performance of breastfed infants.

Compared to Control, children in the Concept group had a higher DCCS score (executive function test, NIH Toolbox Early Childhood Cognition Battery⁸) and closer to the Breastfed group at 5 years of age.

LONG-TERM, FOLLOW-UP PERIOD

References

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6. Breij LM et al. Am J Clin Nutr. 2019;109(3):586-596.
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*Literature indicates that there is a direct relationship between childhood blood pressure and hypertension and the metabolic syndrome in adulthood⁷