



Fact Sheet

First results of the EU Childhood Obesity Programme

The clinical trial

- The EU Childhood Obesity Programme is funded by the EU framework Five Quality of Life Programme (QLK1-2001-00389). The study continues under the Framework 6 EC funded project EARNEST (FOOD-CT-2005-007036).
- The clinical trial started on October 1st 2002 and ended in July 2006 when the last study infants reached the age of two years.
- About 990 infants were included in the study and have been followed-up until the age of two years. About 335 children were randomised to a formula with low protein (1.8g/100kcal and then 2.25g/100kcal in follow on formulas) and 350 children to formulas with a high protein (3g/100kcal and then 4.5g/100kcal in follow-on formulas) were followed. In parallel, some 305 breastfed children were followed.
- The intervention phase with infant formulae took 12 months and the children were followed up until they were two years old.
- It is important to note that the protein contents of infant formulae used within the Programme were in accordance with the composition for infant formulae as authorised by the EU.

Randomisation of the infants

- This was successful, as the lower and higher protein groups did not differ in the evaluated descriptors of socioeconomic status (percentages of foreigners and single mothers, persons in household, educational level, number of siblings), smoking habits and parental anthropometry.
- Also, there were no differences in gestational age, birth weight, birth length and head circumference at birth between the two formula groups. Compared to the formula fed groups, parents in the reference group of breastfed children were found to be of higher education and with lower smoking frequency.

- The evaluation of the infantile diet confirmed that it is possible to feed two groups of infants isocaloric diets during the first two years of life; at the same time establishing a significantly different contribution of dietary protein and fat to the total energy intake.

Diet results show compliance with study protocol

- The protein intake of infants fed high protein formula was significantly higher than protein intake in the low protein group at time points up to 12 months while fat intake was significant lower. There were no significant differences in carbohydrate and total energy intake at all investigated time points. Between the age of 12 and 24 months , the study formulas were no longer fed, thus no significant differences between the two formula groups were seen for energy, protein, fat and carbohydrate intake.

Anthropometrical results support the primary hypothesis

- The primary hypothesis was that one possible causal factor for the difference in long-term obesity risk between breast and formula fed infants is the much lower protein content of breast milk compared to infant formula.
- Anthropometrical results were expressed as Z scores which are based on the international growth standards of the World Health Organisation for length, weight, weight-for-length and body mass index (at ages 6, 12 and 24 months).

i) Comparison of low and high protein groups

The two measures relating weight to length, i.e. weight -for- length and body mass index (BMI) showed significant differences between the groups with the infants fed the high protein diet having significantly greater values at 12 and 24 months.

ii) Comparison with the breast feeding reference group

The infants fed the low protein formula showed growth patterns over the 24 months which were more similar to the breast fed infants. Expressed as BMI, there was no significant difference between the averages of the low protein formula group and the breast fed group at 24 months.

Possible mechanisms to explain these first results

- A further hypothesis to be tested in the European Childhood Obesity Programme was that a protein intake in excess of metabolic needs would increase the secretion of insulin and insulin like growth factor 1 (IGF1), possibly leading to enhanced growth during the first two years of life which might predispose to a higher obesity risk in later life.¹

¹ It is important to note that IGF-1 favours the development of adipocytes.

- High protein formula fed infants showed significantly higher plasma concentrations of IGF-1, as well as lower plasma concentrations of insulin like growth factor binding protein 2 (IGF-BP2). The urinary excretion of C-peptide related to urinary creatinine concentration to correct for differences in fluid excretion, tended to be higher in infants with higher protein intakes at 3 months of age and was significantly higher at 6 months, which also indicates a greater degree of insulin secretion.
- At 3 months, high protein formula fed infants had a significantly higher urinary osmolarity, reflecting the higher renal molar load associated with the higher protein intake while the ability of concentrating urine is still limited in young infants.
- At 6 months, there was a similar trend but no significant difference, potentially because infants at this age already had started to diversify their diet and hence the difference in renal molar load was smaller, and also because of maturation of renal function and the ability to concentrate urine.

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