

# INFANT FORMULA CONTAINING GALACTO- & FRUCTO-OLIGOSACCHARIDES & BIFIDOBACTERIUM BREVE M-16V SUPPORTS ADEQUATE GROWTH & TOLERANCE IN HEALTHY INFANTS IN A RANDOMISED, CONTROLLED, DOUBLE BLIND, PROSPECTIVE, MULTICENTRE STUDY

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## BACKGROUND

Human milk is the preferred feed for all term newborn infants as it supplies nutrients for growth and development as well as other important components that benefit the gut microbiome and immune system development. A synbiotic mixture (90% short chain galacto-and 10% long chain fructo-oligosaccharide(scGOS/lcFOS) 0.8g/100ml, Bifidobacterium breve M-16V (B. Breve M16V)), has shown potential anti-allergic properties for the management of allergic disease.

This equivalence study was aimed at evaluating the growth and tolerance of healthy infants consuming an extensively hydrolysed formula with this synbiotic mixture.

## METHODS

In a randomised, controlled, double blind, multicentre, intervention study infants were assigned to an extensively hydrolysed formula with the synbiotic or this same formula without this synbiotic for 13 weeks. The primary outcome was daily weight gain and secondary outcomes included other growth parameters, tolerance, safety, faecal microbiota, metabolic faecal profile as well as atopic symptoms.

## RESULTS

Equivalence in daily weight gain was demonstrated for the intention to treat (ITT) population (n=211). In the per protocol (PP) population (n=102), the 90% CI of the difference in daily weight gain slightly crossed the lower equivalence margin. Weight gain (g/d) was not different between groups (Table 1). During the intervention period, the mean for age and length for age values were close to the median of the WHO growth standards in both groups, indicating adequate growth.

Table 1: Weight gain, length gain and head circumference gain during the intervention period\* (mean values and standard deviations)

Intervention group...	ITT population				PP population			
	Synbiotic (n 100)		Control (n 111)		Synbiotic (n 45)		Control (n 57)	
	Mean	SD	Mean	SD	Mean	SD	Mean	SD
Weight gain (g/d)	27.5	0.7	28.5	0.7	28.7	6.4	29.8	6.0
Length gain (cm/week)	0.77 <sup>†</sup>	0.02	0.81	0.02	0.77	0.13	0.82	0.16
Head circumference gain (cm/week)	0.36	0.01	0.38	0.01	0.37	0.01	0.39	0.01

ITT, intention-to-treat; PP, per-protocol.

\* The ANCOVA method was used to evaluate differences taking study centre, risk for allergy, sex, and weight at baseline as covariates.

<sup>†</sup> Tendency for a lower mean length gain compared with control (P=0.093).

**Weight for age development during intervention was in line with age specific WHO growth standard**

There was an increased percentage of faecal bifidobacteria at week 13 in the synbiotic group (60 vs 48%) and a lower percentage of Clostridium lituseburens/C. histolyticum in the synbiotic. (0.2 vs 2.6%).

## CONCLUSION

An extensively hydrolysed formula containing the synbiotic scGOS/lcFOS and B.breve M-16V promotes adequate in growth infants. Benefits to the microbiota composition of this synbiotic previously observed were further confirmed in this study.