

EFFECT OF A NEW SYNBIOTIC MIXTURE ON ATOPIC DERMATITIS IN INFANTS: A RANDOMISED-CONTROLLED TRIAL

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BACKGROUND

Atopic dermatitis (AD) is a chronic itching skin disease, it often presents in infancy and can affect the quality of life of children and their families. There is increasing evidence that the intestinal microbiota plays an important role in the development of allergic diseases. This double blind, placebo-controlled multi-centre trial investigated the effect of an infant formula with synbiotics, (Bifidobacterium breve M-16V 1.3X10⁹ CFU/100ml and 90% short chain galacto-oligosaccharide and 10% long chain fructo-oligosaccharide mixture 0.8g/100ml) on the severity of AD in infants. Additionally, the effect of this synbiotic formula on the composition and the metabolic activity of the intestinal microbiota.

METHODS

90 infants with AD, aged <7 months and exclusively formula fed, were randomly assigned to receive either an extensively hydrolysed formula with the synbiotic, or the same formula without the synbiotic for 12 weeks. The primary outcome was a change in severity of AD after intervention compared with baseline, severity was assessed using the SCORAD index. A secondary outcome measure was intestinal microbiota composition. Other secondary outcome measures included change in (1) topical corticosteroid usage, (2) total serum IgE, specific IgE against food and inhalant allergens and serum eosinophilic granulocytes, (3) faecal short-chain fatty acids (SCFAs), lactate and pH and stool frequency and (4) consistency and occurrence of gastrointestinal symptoms, diaper dermatitis and adverse events.

RESULTS

Atopic dermatitis: There was no significant difference in SCORAD change between the two groups and no change in use of topical corticosteroids.

Table 1: Effect of synbiotic on the severity of IgE associated AD

	Synbiotics (n = 24)	Placebo (n = 24)	Difference Syn vs. plac (95% CI)	P-value
SCORAD change week 4 – baseline, EMM±SE	-5.2±2.1	-3.5±2.2	-1.7 (-7.9 to 4.4)	0.57
SCORAD change week 8 – baseline, EMM±SE	-13.7±2.2	-9.3±2.3	-4.4 (-10.6 to 2.0)	0.17
SCORAD change week 12 – baseline, EMM±SE	-18.1±1.6	-13.5±1.6	-4.6 (-9.1 to -0.1)	0.04

Univariate analysis of variance with cofactors treatment, topical steroid use at baseline and previous use of hydrolysed formula and covariate SCORAD score at baseline.

EMM, estimated marginal mean; AD, atopic dermatitis; SCORAD, SCORing Atopic Dermatitis; Syn, synbiotics; Plac, placebo.

SCORAD score improvement were significantly greater in the synbiotic group for infants with IgE associated AD

Gut Modulation: The synbiotic group showed significantly higher percentages of bifidobacteria (54.7 vs 30.1, P<0.001) and significantly lower percentages of Clostridium litusebureuse/Clostridium histolyticum (0.5 vs. 1.8, P= 0.02) and E.rectale/C. coccoides (7.5 vs. 38.1, P<0.001) than children in the placebo group. Faecal pH was significantly lower, and L-Lactate and D-Lactate concentrations were significantly higher in the synbiotic group than in the placebo group after 1 and 12 weeks of intervention. After 12 weeks, the synbiotic group had significantly lower percentages of butyric, isobutyric and isovaleric acid.

CONCLUSION

This synbiotic mixture does not have a beneficial effect on the severity of atopic dermatitis in infants but does positively modulate the intestinal microbiota of infants with atopic dermatitis. There was promising effects in a subgroup of infants with IgE associated AD, this requires further investigation.