Bifidobacterium breve M16V - List of Human Clinical Studies

(1) Effects on the intestinal microflora and intestinal environment (Infant study)

	Title	Author	Publication	Country
1	Effects of oral administration of Bifidobacterium breve on development of intestinal microflora in extremely premature infants.	Akiyama K, et al.	Acta Neonatologica Japonica. 30, 130-137 (1994)	Japan
2	Effects of administration of Bifidobacterium in extremely premature infants development of intestinal microflora by orally administered Bifidobacterium longum (in comparison with Bifidobacterium breve).	Akiyama K, et al.	(Tanslation from) Acta Neonatologica Japonica. 30, 257-263 (1994)	Japan
3	Effects of Bifidobacterium breve supplementation on intestinal flora of low birth weight infants.	Li Y, et al.	Pediatrics International. 46, 509-515 (2004)	Japan
4	Effects of oral administration of Bifidobacterium breve on fecal lactic acid and short-chain fatty acids in low birth weight infants.	Wang C, et al.	J Pediatr Gastroenterol Nutr. 44, 252-257 (2007)	Japan
5	Transient colonization of the gut of newborn infants by orally administered bifidobacteria and lactobacilli.	Bennet R, et al.	Acta Paediatr. 81, 784- 787 (1992)	Sweden
6	Effect of administration of bifidobacteria on intestinal microbiota in low-birth-weight infants and transition of administered bifidobacteria: A comparison between onespecies and three-species administration.	Ishizeki S, et al.	Anaerobe. 23, 38-44 (2013)	Japan
7	Effect of Bifidobacterium breve M-16V Supplementation on Fecal Bifidobacteria in Preterm Neonates - A Randomised Double Blind Placebo Controlled Trial.	Sanjay Patole, et al.	PLoS One. 9, e89511 (2014)	Australia
8	Effect of Bifidobacterium breve M-16V supplementation on faecal bifidobacteria in growth restricted very preterm infants - analysis from a randomised trial.	Patole SK, et al.	J Matern Fetal Neonatal Med. 29, 3751-3755 (2016)	Australia
9	Efficacy of a mixture of probiotic agents as complementary therapy for chronic functional constipation in childhood.	Russo M, et al.	Ital J Pediatr. 43, 24 (2017)	Italy
10	Digestion of human milk oligosaccharides by Bifidobacterium breve in the premature infant.	Underwood MA, et al.	J Pediatr Gastroenterol Nutr. 65, 449-455 (2017)	Australia
11	Effect of synbiotic on the gut microbiota of caesarean delivered infants: a randomized, double- blind, multicenter study.	Chua MC, et al.	J Pediatr Gastroenterol Nutr. 65, 102-106 (2017)	Singapore & Thailand
12	Infant formula containing galacto-and fructo- oligosaccharides and Bifidobacterium breve M-16V supports adequate growth and tolerance in healthy infants in a randomised, controlled, double-blind, prospective, multicentre study.	Abrahamse -Berkeveld M, et al.	J Nutr Sci. 5, e42 (2016)	Germany

13	A synbiotic mixture of scGOS/IcFOS and Bifidobacterium breve M-16V increases faecal Bifidobacterium in healthy young children.	Kosuwon P,	Benef Microbes. 9, 541-552 (2018)	Thailand
14	A specific synbiotic-containing amino acid-based formula in dietary management of cow's milk allergy: a randomized controlled trial.	Fox AT, et al.	Clin Transl Allergy. 9, 5 (2019)	Netherlands
15	A specific synbiotic-containing amino acid-based formula restores gut microbiota in non-IgE mediated cow's milk allergic infants: a randomized controlled trial.	Wopereis H, et al.	Clin Transl Allergy. 9, 27 (2019)	Netherlands

(2) Effects on the prevention of allergy (Infant & child study)

	Title	Author	Publication	Country
1	Effects of administration of bifidobacteria on fecal microflora and clinical symptoms in infants with atopic dermatitis.	Hattori K, et al.	Japanese Journal of Allergology. 52, 20-30 (2003)	Japan
2	Bifidobacterium breve enhances transforming growth factor $\beta 1$ signaling by regulating Smad7 expression in preterm infants.	Fujii T, et al.	J Pediatr Gastroenterol Nutr. 43, 83-88 (2006)	Japan
3	Administration of Bifidobacterium to infants with atopic dermatitis: Changes in fecal microflora and clinical symptoms.	Taniuchi S, et al.	The Journal of Applied Research. 5, 387-396 (2005)	Japan
4	Effect of a new synbiotic mixture on atopic dermatitis in infants: a randomized-controlled trial.	van der Aa LB, et al.	Clinical & Experimental Allergy. 40, 795-804 (2010)	Netherlands
5	Synbiotics prevent asthma-like symptoms in infants with atopic dermatitis.	van der Aa LB, et al.	Allergy. 66, 170-177 (2011)	Netherlands
6	Prophylactic probiotics reduce cow's milk protein intolerance in neonates after small intestine surgery and antibiotic treatment presenting symptoms that mimics postoperative infection.	Ezaki S, et al.	Allergology International. 61, 107- 113 (2012)	Japan
7	Galectin-9 induced by dietary synbiotics is involved in suppression of allergic symptoms in mice and humans.	de Kivit S, et al.	Allergy. 67, 343-352 (2012)	Netherlands
8	No detectable beneficial systemic immunomodulatory effects of a specific synbiotic mixture in infants with atopic dermatitis.	van der Aa LB, et al.	Clin Exp Allergy. 42, 531- 539 (2012)	Netherlands
9	Effects of bifidobacterial supplementation to pregnant women and infants in the prevention of allergy development in infants and on fecal microbiota.	Enomoto T, et al.	Allergology International. 63, 575- 585 (2014)	Japan
10	Effects on growth and tolerance and hypoallergenicity of an amino acid-based formula with synbiotics.	Harvey BM, et al.	Pediatr Research. 75, 343-51 (2014)	USA

11	Effects of a fermented soy product and Bifidobacterium on atopic dermatitis in children: a pilot study.	Kanto N, et al.	Allergology & Immunology. 22, 96-102 (2015)	Japan
12	Bifidobacterium mixture (B longum BB536, B infantis M-63, B breve M-16V) treatment in children with seasonal allergic rhinitis and intermittent asthma.	Miraglia Del Giudice M, et al.	Ital J Pediatr. 43, 25 (2017)	Italy
13	Probiotics and antimicrobial protein and peptide levels in preterm infants.	Strunk T, et al.	Acta Paediatr. 106, 1747-1753 (2017)	Australia
14	Synbiotics-supplemented amino acid-based formula supports adequate growth in cow's milk allergic infants.	Burks AW, et al.	Pediatr Allergy Immunol. 26, 316-322 (2015)	USA
15	A synbiotic-containing amino-acid-based formula improves gut microbiota in non-IgE-mediated allergic infants.	Candy DCA, et al.	Pediatr Res. 83, 677- 686 (2018)	UK, Italy, Belgium, and Sweden
16	Exploring Immune Development in Infants With Moderate to Severe Atopic Dermatitis.	Hulshof L, et al.	Front Immunol. 9, 630 (2018)	Netherlands

(3) E	3) Effects on the prevention of infection (Infant study)				
	Title	Author	Publication	Country	
1	Effect of administration of Bifidobacterium in low birth weight infants.	Ishibashi N, et al.	The CELL 37, 30-33 (2005)	Japan	
2	Bifidobacteria prevents preterm infants from developing infection and sepsis.	Umezaki H, et al.	Int J Probiotics Prebiotics. 5, 33 (2010)	Japan	

(4) E	4) Effects on pre-term infants of NEC (Infant study)				
	Title	Author	Publication	Country	
1	Bifidobacteria prevents necrotizing enterocolitis and infection in preterm infants.	Satoh Y, et al.	Int J Probiotics Prebiotics. 2, 149-154 (2007)	Japan	
2	Benefits of Bifidobacterium breve M-16V Supplementation in Preterm Neonates - A Retrospective Cohort Study.	•	PLoS One. 11, e0150775 (2016)	Australia	
3	Outcomes in preterm small versus appropriate for gestation infants after Bifidobacterium breve M-16 V supplementation.	G, et al.	J Matern Fetal Neonatal Med. 1-7. (2018)	Australia	

(5) E1	(5) Effects on Irritable Bowel Syndrome for children			
	Title	Author	Publication	Country

		A Mixture of 3 Bifidobacteria Decreases Abdominal Pain and	Giannetti E,	J Clin Gastroenterol. 51, e5-	
ı		Improves the Quality of Life in Children With Irritable Bowel	et al.	e10 (2017)	ta - l
ı	1	Syndrome: A Multicenter, Randomized, Double-Blind, Placebo-			Italy
ı		Controlled, Crossover Trial.			

(6) Effects on atopic dermatitis and asthma for adults

Title	Author	Publication	Country
Clinical effects of probiotic Bifidobacterium breve supplementation in adult patients with atopic dermatitis.	•	Yonago Acta medica. 53, 37-45 (2010)	Japan
Synbiotics reduce allergen-induced T-helper 2 response and improve peak expiratory flow in allergic asthmatics.	van de Pol MA, et al.	Allergy. 66, 39-47 (2011)	Netherlands