

Effects of a Novel Infant Formula on Weight Gain, Body Composition, Safety and Tolerability of Infants: The INNOVA 2020 Study

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Equally contributed

Table S1. Body mass index, weight, and height percentiles.

Body mass index percentiles				P-value		
Visits	BFD (N=58)	STD (N=65)	INN (N=62)	Formula	Visit	Formula x visit
Visit 1	0.45 ± 0.26	0.42 ± 0.24	0.47 ± 0.25	0.504	0.009	0.006
Visit 2	0.45 ± 0.25	0.43 ± 0.25	0.41 ± 0.26			
Visit 3	0.40 ± 0.24	0.44 ± 0.29	0.50 ± 0.29			
Visit 4	0.43 ± 0.26	0.47 ± 0.31	0.55 ± 0.31			
Visit 5	0.51 ± 0.28	0.57 ± 0.31	0.55 ± 0.31			
Height percentiles				P-value		
Visits	BFD (N=58)	STD (N=65)	INN (N=62)	Formula	Visit	Formula x visit
Visit 1	0.54 ± 0.30	0.43 ± 0.30	0.48 ± 0.26	0.433	0.011	<0.001
Visit 2	0.58 ± 0.33	0.52 ± 0.30	0.60 ± 0.27			
Visit 3	0.52 ± 0.31	0.55 ± 0.30	0.59 ± 0.27			
Visit 4	0.47 ± 0.30	0.52 ± 0.31	0.56 ± 0.26			
Visit 5	0.53 ± 0.31	0.58 ± 0.30	0.63 ± 0.27			
Weight percentiles				P-value		
Visits	BFD (N=58)	STD (N=65)	INN (N=62)	Formula	Visit	Formula x visit
Visit 1	0.49 ± 0.27	0.40 ± 0.27	0.47 ± 0.25	0.368	<0.001	<0.001
Visit 2	0.51 ± 0.26	0.45 ± 0.27	0.49 ± 0.25			
Visit 3	0.43 ± 0.26	0.47 ± 0.30	0.54 ± 0.26			
Visit 4	0.42 ± 0.25	0.48 ± 0.32	0.56 ± 0.28			
Visit 5	0.53 ± 0.26	0.59 ± 0.32	0.61 ± 0.29			

Data are expressed as mean and standard deviation

Table S2. Stool Characteristics.

Stool consistency	Visit 1			Visit 2			Visit 3			Visit 4			Visit 5		
	BFD	STD	INN	BFD	STD	INN	BFD	STD	INN	BFD	STD	INN	BFD	STD	INN
Soft	3 (4.3%)	22 (31.4%)	12 (17.1%)	5 (7.7%)	17 (25.8%)	12 (18.8%)	8 (13.1%)	16 (24.2%)	13 (20.6%)	3 (5.2%)	16 (24.2%)	12 (19.0%)	11 (19.0%)	13 (20.0%)	10 (16.1%)
Hard	5 (7.1%)	6 (8.6%)	11 (15.7%)	0 (0.0%)	1 (1.5%)	3 (4.7%)	0 (0.0%)	0 (0.0%)	1 (1.6%)	1 (1.7%)	4 (6.1%)	0 (0.0%)	4 (6.9%)	7 (10.8%)	5 (8.1%)
Liquid	27 (38.6%)	4 (5.7%)	7 (10.0%)	24 (36.9%)	0 (0.0%)	0 (0.0%)	13 (21.3%)	0 (0.0%)	1 (1.6%)	9 (15.5%)	1 (1.5%)	4 (6.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Normal	0 (0.0%)	3 (4.3%)	2 (2.9%)	0 (0.0%)	4 (6.1%)	1 (1.6%)	2 (3.3%)	7 (10.6%)	3 (4.8%)	2 (3.4%)	8 (12.1%)	2 (3.2%)	7 (12.1%)	9 (13.8%)	16 (25.8%)
Pasty	8 (11.4%)	31 (44.3%)	34 (48.6%)	13 (20.0%)	40 (60.6%)	45 (70.3%)	13 (21.3%)	38 (57.6%)	38 (60.3%)	23 (39.7%)	33 (50.0%)	42 (66.7%)	36 (62.1%)	36 (55.4%)	31 (50.0%)
Semiliquid	27 (38.6%)	4 (5.7%)	4 (5.7%)	23 (35.4%)	4 (6.1%)	3 (4.7%)	25 (41.0%)	5 (7.6%)	7 (11.1%)	20 (34.5%)	4 (6.1%)	3 (4.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)

Data are expressed as counts and percentages

Table S3. Infant's behavior

Visit		BFD	STD	INN
1	N	70	70	70
	Altered mood	27 (38.6%)	29 (41.4%)	22 (31.4%)
	Good mood	43 (61.4%)	41 (58.6%)	48 (68.6%)
2	N	65	66	64
	Altered mood	22 (33.8%)	18 (27.3%)	18 (28.1%)
	Good mood	43 (66.2%)	48 (72.7%)	46 (71.9%)
3	N	61	66	63
	Altered mood	16 (26.2%)	9 (13.6%)	13 (20.6%)
	Good mood	45 (73.8%)	57 (86.4%)	50 (79.4%)
4	N	58	66	63
	Altered mood	13 (22.4%)	13 (19.7%)	7 (11.1%)
	Good mood	45 (77.6%)	53 (80.3%)	56 (88.9%)
5	N	58	65	62
	Altered mood	10 (17.2%)	4 (6.2%)	6 (9.7%)
	Good mood	48 (82.8%)	61 (93.8%)	56 (90.3%)
Total	N	312	333	322
	Altered mood	88 (28.2%)	73 (21.9%)	66 (20.5%)
	Good mood	224 (71.8%)	260 (78.1%)	256 (79.5%)

Data are expressed as counts and percentages

Table S4. Tolerability and overall assessment by parents or guardians across the study

Tolerability	BFD (N=65)	STD (N=66)	INN (N=64)	Overall assessment by parents or guardians	BFD (N=65)	STD (N=66)	INN (N=64)
Visit 2				Visit 2			
Adequate	5 (7.7%)	4 (6.1%)	1 (1.6%)	Acceptable	1 (1.5%) 54	3 (4.6%)	2 (3.1%)
Good	50 (76.9%)	48 (72.7%)	50 (78.1%)	Good	(83.1%)	40 (61.5%)	47 (73.4%)
Very good	7 (10.8%)	13 (19.7%)	13 (20.3%)	Very good	9 (13.8%)	16 (24.6%)	14 (21.9%)
Data not available	2 (3.1%)	0 (0.0%)	0 (0.0%)	Satisfactory	0 (0.0%)	5 (7.7%)	1 (1.6%)
Not satisfactory	1 (1.5%)	1 (1.5%)	0 (0.0%)	Not satisfactory	1 (1.5%)	1 (1.5%)	0 (0.0%)
Visit 3				Visit 3			
Tolerability	BFD (N=65)	STD (N=66)	INN (N=64)	Overall assessment by parents or guardians	BFD (N=65)	STD (N=66)	INN (N=64)
Adequate	3 (4.9%)	5 (7.6%)	2 (3.2%)	Acceptable	6 (9.8%) 37	9 (13.6%)	2 (3.2%)
Good	38 (62.3%)	47 (71.2%)	37 (58.7%)	Good	(60.7%) 15	40 (60.6%)	40 (63.5%)
Very good	14 (23.0%)	13 (19.7%)	23 (36.5%)	Very good	(24.6%)	13 (19.7%)	19 (30.2%)
Data not available	3 (4.9%)	0 (0.0%)	1 (1.6%)	Satisfactory	0 (0.0%)	3 (4.5%)	2 (3.2%)
Not satisfactory	3 (4.9%)	1 (1.5%)	0 (0.0%)	Not satisfactory	3 (4.9%)	1 (1.5%)	0 (0.0%)
Visit 4				Visit 4			
Tolerability	BFD (N=58)	STD (N=66)	INN (N=63)	Overall assessment by parents or guardians	BFD (N=58)	STD (N=66)	INN (N=63)
Adequate	2 (3.4%)	8 (12.1%)	1 (1.6%)	Acceptable	2 (3.4%) 40	9 (13.6%)	1 (1.6%)
Good	39 (67.2%)	44 (66.7%)	38 (60.3%)	Good	(69.0%) 14	44 (66.7%)	41 (65.1%)
Very good	14 (24.1%)	13 (19.7%)	23 (36.5%)	Very good	(24.1%)	9 (13.6%)	17 (27.0%)
Data not available	3 (5.2%)	0 (0.0%)	0 (0.0%)	Satisfactory	2 (3.4%)	4 (6.1%)	3 (4.8%)
Not satisfactory	0 (0.0%)	1 (1.5%)	1 (1.6%)	Not satisfactory	0 (0.0%)	0 (0.0%)	1 (1.6%)
Visit 5				Visit 5			

Tolerability	BFD (N=58)	STD (N=65)	INN (N=62)	Overall assessment by parents or guardians	BFD (N=58)	STD (N=65)	INN (N=62)
Adequate	2 (3.4%)	5 (7.7%)	0 (0.0%)	Acceptable	2 (3.4%)	9 (13.6%)	1 (1.6%)
Good	33 (56.9%)	34 (52.3%)	40 (64.5%)	Good	40 (69.0%)	44 (66.7%)	41 (65.1%)
Very good	18 (31.0%)	24 (36.9%)	21 (33.9%)	Very good	14 (24.1%)	9 (13.6%)	17 (27.0%)
Data not available	4 (6.9%)	0 (0.0%)	0 (0.0%)	Satisfactory	2 (3.4%)	4 (6.1%)	3 (4.8%)
Not satisfactory	1 (1.7%)	0 (0.0%)	1 (1.6%)	Not satisfactory	0 (0.0%)	0 (0.0%)	1 (1.6%)

Data are expressed as counts and percentages