

Supplemental Digital Content 1: Primary and secondary outcomes for rotavirus non-vaccinated population.¹

Outcome	n	<i>L reuteri</i> DSM 17938	n	Placebo	p	MD/RR (95% CI) ²
Duration of diarrhea, h ³	33	58.8 (47.5; 79.5)	34	64.0 (50.3; 84.8)	0.6	5.2 (-20.3; 26.4)
Need for intravenous rehydration, n (%)	33	33 (100.0)	34	31 (91.2)	0.2	0.912 (0.821; 1.012)
Duration of intravenous rehydration, h ⁵	33	38.0 (30.5; 45.0)	31	47.0 (35.0; 54.0)	0.2	9.0 (-4.0; 20.0)
Duration of hospitalization, h ³	33	60.9 (52.7; 66.9)	31	70.5 (63.1; 84.3)	0.025	9.6 (1.3; 22.3)
Number of watery stools per day ^{3,4}						
Day 1	33	5.0 (2.0; 7.0)	34	3.5 (1.3; 7.0)	0.5	-1.5 (-3.0; 1.0)
Day 2	33	3.0 (0.0; 4.0)	34	2.0 (0.0; 5.0)	>0.99	-1.0 (-1.0; 1.0)
Day 3	33	1.0 (0.0; 2.0)	34	1.0 (0.0; 2.0)	0.8	0.0 (-1.0; 1.0)
Day 4	33	0.0 (0.0; 0.0)	34	0.0 (0.0; 1.8)	0.1	0.0 (-0.00005; 1.0)
Day 5	33	0.0 (0.0; 0.0)	34	0.0 (0.0; 1.0)	0.1	0.0 (-0.00003; 0.00001)
Day 6	33	0.0 (0.0; 0.0)	34	0.0 (0.0; 0.0)	0.3	0.0 (-0.00004; 0.00004)
Day 7	33	0.0 (0.0; 0.0)	34	0.0 (0.0; 0.0)	0.3	0.0 (-0.00003; 0.00005)
Day 8	33	0.0 (0.0; 0.0)	34	0.0 (0.0; 0.0)	n/a	n/a
Vomiting, n (%)	33	30 (90.9)	34	27 (79.4)	0.3	0.874 (0.714; 1.069)
Vesikari scale, score						
Day 1	33	7.8 (7.1; 8.5)	34	7.5 (6.5; 8.4)	0.6	-0.3 (-1.5; 0.9)
Day 2	33	5.9 (4.9; 6.8)	34	5.2 (4.1; 6.2)	0.3	-0.7 (-2.1; 0.6)
Day 3	33	4.1 (3.1; 5.1)	34	3.7 (2.9; 4.5)	0.5	-0.4 (-1.7; 0.8)
Day 4 ^{3,4}	33	0.0 (0.0; 3.0)	34	2.0 (0.0; 3.8)	0.2	2.0 (-0.00006; 2.0)
Day 5 ^{3,4}	33	0.0 (0.0; 0.0)	34	0.0 (0.0; 1.0)	0.2	0.0 (-0.00001; 0.00007)
Day 6 ^{3,4}	33	0.0 (0.0; 0.0)	34	0.0 (0.0; 0.0)	0.3	0.0 (-0.00006; 0.00002)
Day 7 ^{3,4}	33	0.0 (0.0; 0.0)	34	0.0 (0.0; 0.0)	0.3	0.0 (-0.00004; 0.00009)
Day 8 ^{3,4}	33	0.0 (0.0; 0.0)	34	0.0 (0.0; 0.0)	0.2	0.0 (-0.00004; 0.00008)
Max score (Day 1 - Day 8)	33	9.5 (8.4; 10.5)	34	8.6 (7.4; 9.9)	0.3	-0.9 (-2.5; 0.7)
Vesikari scale, ≥ 9 points, n (%)						
Day 1	33	12 (36.4)	34	14 (41.2)	0.9	1.132 (0.619; 2.072)
Day 2	33	6 (18.2)	34	5 (14.7)	0.9	0.809 (0.273; 2.396)
Day 3	33	2 (6.1)	34	1 (2.9)	0.6	0.485 (0.046; 5.099)
Day 4	33	0 (0.0)	34	1 (2.9)	>0.99	n/a
Day 5	33	1 (3.0)	34	1 (2.9)	>0.99	0.971 (0.063; 14.884)
Day 6	33	2 (6.1)	34	1 (2.9)	0.6	0.485 (0.046; 5.099)
Day 7	33	2 (6.1)	34	1 (2.9)	0.6	0.485 (0.046; 5.099)
Day 8	33	0 (0.0)	34	0 (0.0)	>0.99	n/a
Max score (Day 1 - Day 8), ≥ 9 points, n (%)	33	19 (57.6)	34	18 (52.9)	0.9	0.920 (0.597; 1.416)
Recurrence of diarrhea (48 hours after	33	3 (9.1)	34	2 (5.9)	0.7	0.647 (0.115; 3.628)

Outcome	n	<i>L reuteri</i> DSM 17938	n	Placebo	p	MD/ RR (95% CI)²
intervention), n (%)						
Needs for hospitalization in outpatients, n (%)	33	0 (0.0)	34	1 (2.9)	>0.99	n/a
Adverse events, n (%)	33	3 (9.1)	34	1 (2.9)	0.4	0.324 (0.035; 2.955)
Other medicines, n (%)	33	8 (24.2)	34	7 (20.6)	0.9	0.849 (0.347; 2.077)

1 Values are means (95% CI) or medians (95% CI) unless otherwise indicated. Groups were compared with the use of chi-square test or Fisher exact test (for nominal data) and independent-samples t-test or Mann-Whitney U test (for continuous variables).

2 Mean difference or median difference, representing placebo group minus *L reuteri* group (95% CI), for continuous variables, or relative risk (95% CI), representing placebo group vs. *L reuteri* group, for nominal variables. n/a – not applicable.

3 Groups compared with Mann-Whitney U test, as data did not conform to a normal distribution after transformation.

4 Values are medians (IQR: 25th-75th percentile).

5 Data square-root-transformed before testing.