

Supplemental Digital Content 2: Primary and secondary outcomes for rotavirus-vaccinated population.¹

Outcome	n	<i>L reuteri</i> DSM 17938	n	Placebo	p	MD/RR (95% CI) ²
Duration of diarrhea, h	11	65.2 (29.9; 100.5)	13	79.8 (33.7; 125.9)	0.6	14.6 (-40.3; 69.5)
Need for intravenous rehydration, n (%)	11	11 (100.0)	13	13 (100.0)	>0.99	1.000 (1.000; 1.000)
Duration of intravenous rehydration, h ⁵	11	26.0 (14.0; 52.0)	13	30.0 (18.0; 51.0)	0.9	4.0 (-24.0; 18.0)
Duration of hospitalization, h ³	11	64.6 (45.7; 79.0)	13	60.3 (51.0; 77.3)	0.9	-4.3 (-17.4; 19.4)
Number of watery stools per day ^{3,4}						
Day 1	11	3.0 (2.0; 5.0)	13	3.0 (2.0; 6.0)	0.8	0.0 (-2.0; 3.0)
Day 2	11	3.0 (1.5; 5.5)	13	2.0 (0.0; 7.0)	0.6	-1.0 (-3.0; 3.0)
Day 3	11	1.0 (0.0; 3.0)	13	0.0 (0.0; 5.0)	>0.99	-1.0 (-1.0; 3.0)
Day 4	11	0.0 (0.0; 1.5)	13	0.0 (0.0; 1.0)	0.9	0.0 (-1.0; 1.0)
Day 5	11	0.0 (0.0; 0.5)	13	0.0 (0.0; 2.0)	0.8	0.0 (-0.00005; 1.0)
Day 6	11	0.0 (0.0; 1.0)	13	0.0 (0.0; 0.0)	0.8	0.0 (-1.0; 0.00005)
Day 7	11	0.0 (0.0; 0.0)	13	0.0 (0.0; 0.0)	0.3	0.0 (-0.00002; 0.00001)
Day 8	11	0.0 (0.0; 0.0)	13	0.0 (0.0; 0.0)	0.4	0.0 (-0.00002; 0.00005)
Vomiting, n (%)	11	10 (90.9)	13	10 (76.9)	0.6	0.846 (0.595; 1.203)
Vesikari scale, score						
Day 1	11	7.6 (6.8; 8.5)	13	7.1 (5.5; 8.7)	0.5	-0.5 (-2.3; 1.2)
Day 2 ^{3,4}	11	6.0 (5.0; 8.5)	13	4.0 (3.0; 6.0)	0.1	-2.0 (-4.0; 0.00006)
Day 3 ^{3,4}	11	4.0 (1.0; 6.5)	13	3.0 (2.0; 4.0)	0.7	-1.0 (-4.0; 2.0)
Day 4 ^{3,4}	11	1.0 (0.0; 2.5)	13	2.0 (0.0; 4.0)	0.5	1.0 (-1.0; 3.0)
Day 5 ^{3,4}	11	0.0 (0.0; 2.0)	13	0.0 (0.0; 4.0)	0.9	0.0 (-1.0; 1.0)
Day 6 ^{3,4}	11	0.0 (0.0; 1.0)	13	0.0 (0.0; 0.0)	0.8	0.0 (-1.0; 0.00005)
Day 7 ^{3,4}	11	0.0 (0.0; 0.0)	13	0.0 (0.0; 0.0)	0.6	0.0 (-0.00002; 0.00002)
Day 8 ^{3,4}	11	0.0 (0.0; 0.0)	13	0.0 (0.0; 0.0)	0.4	0.0 (-0.00004; 0.00009)
Max score (Day 1 - Day 8)	11	9.4 (7.6; 11.1)	13	8.6 (6.8; 10.4)	0.5	-0.8 (-3.1; 1.6)
Vesikari scale, ≥ 9 points, n (%)						
Day 1	11	3 (27.3)	13	3 (23.1)	>0.99	0.846 (0.212; 3.378)
Day 2	11	3 (27.3)	13	1 (7.7)	0.3	0.282 (0.034; 2.340)
Day 3	11	0 (0.0)	13	1 (7.7)	>0.99	n/a
Day 4	11	1 (9.1)	13	1 (7.7)	>0.99	0.846 (0.059; 12.012)
Day 5	11	0 (0.0)	13	0 (0.0)	>0.99	n/a
Day 6	11	0 (0.0)	13	0 (0.0)	>0.99	n/a
Day 7	11	0 (0.0)	13	0 (0.0)	>0.99	n/a
Day 8	11	0 (0.0)	13	0 (0.0)	>0.99	n/a
Max score (Day 1 - Day 8), ≥ 9 points, n (%)	11	6 (54.5)	13	7 (53.8)	>0.99	0.987 (0.472; 2.064)
Recurrence of diarrhea (48 hours after intervention), n (%)	11	1 (9.1)	13	0 (0.0)	0.5	n/a
Needs for hospitalization in outpatients, n (%)	11	0 (0.0)	13	0 (0.0)	>0.99	n/a
Adverse events, n (%)	11	0 (0.0)	13	0 (0.0)	>0.99	n/a
Other medicines, n (%)	11	1 (9.1)	13	1 (7.7)	>0.99	0.846 (0.060; 12.012)

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 log-transformed before testing.