▶ **Conclusion:**
The results of the double-blind, randomized controlled trial showed that the Apple ORS is as safe and effective as the standard ESPGHAN ORS in the outpatient treatment of young children with acute gastroenteritis and mild-to-moderate dehydration.

HiPP ORS 200 Apple

- ✔ **ready to drink:**
  - no mixing necessary – as for regular ORS products in powder form
  - therefore, potential mistakes during preparation at home can be ruled out
- ✔ **as safe and effective as the established standard ESPGHAN ORS**
- ✔ **tendency to consume higher amounts of Apple ORS than of regular ORS in control group**

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Efficacy and safety of a new apple-flavoured oral rehydration solution in children with acute gastroenteritis: a double-blind randomized controlled trial

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ABSTRACT

Objective:
To assess the efficacy and safety of a new oral rehydration solution (ORS) with improved flavour in the management of children with acute gastroenteritis (AGE).

Subjects and methods:
Children aged 4 to 48 months with AGE (≥3 loose or watery stools per day for >1 but <5 days) and mild-to-moderate dehydration (3% to 9% loss of body weight) according to the World Health Organization criteria were randomized to received either regular hypotonic ORS (Na 60 mmol/L, glucose 78 mmol/L) or the same hypotonic ORS with apple taste.

Results:
Of the 147 children randomized, 130 (88.4%) were available for intention-to-treat analysis. The proportion of children with resolution of signs of dehydration in the experimental group compared with the control group was similar at 24 h (49/63 vs. 57/67, respectively, p = 0.28). There were also no significant differences in adequate weight gain (p = 0.48) and urine production at 24 h (p = 0.95) between groups. There were no differences between groups in any of the secondary outcome measures, including ORS intake. No adverse events were observed in the study groups.

Conclusions:
In an outpatient setting, there was no difference in efficacy between the study products. Both ORSs were equally effective and may be used interchangeably.

Pieścik-Lech, M., Szymański, H. and Szajewska, H. (2012), Efficacy and safety of a new apple-flavoured oral rehydration solution in children with acute gastroenteritis: a double-blind randomized controlled trial. Acta Paediatrica, 101: e458–e464. doi: 10.1111/j.1651-2227.2012.02782.x

Summary of the original

Objective:

To assess the efficacy and safety of a new oral rehydration solution (ORS) with improved flavour in the treatment of children with acute gastroenteritis (AGE).

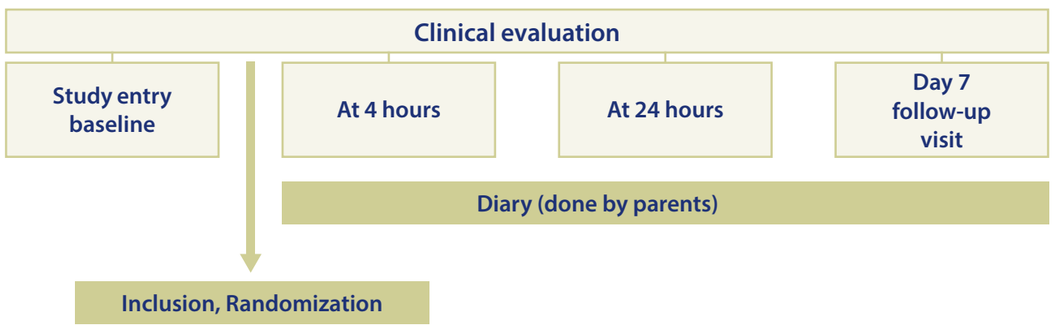
Subjects and methods:

- Double-blind, randomized, controlled study
- Carried out at 2 paediatric hospitals in Poland (emergency department)
- **Patients:** children aged 4 to 48 months with acute gastroenteritis (AGE)
  - AGE defined as ≥3 loose or watery stools per day for > 1 but < 5 days with mild-to-moderate dehydration (3 to 9 % loss of body weight) according to World Health Organization (WHO) criteria
- **Study products:**
  - Control group: regular hypotonic ESPGHAN ORS
  - Experimental group: hypotonic ORS with apple flavour

Table 1: Composition of the study products

	Experimental group	Control group
Glucose (mmol/l)	78	78
Sodium (mmol/l)	60	60
Potassium (mmol/l)	20	20
Citrate (mmol/l)	9	10
Chloride (mmol/l)	61	60
Osmolarity (mOsm/l)	240	240

- **Study procedure:**
  - Enrollment of patients in the emergency room of the study centres
  - Children's treatment according to current recommendations, e. g. fast oral rehydration in 3-4 hours, 75 ml per kg for the first 4 hours, 5-10 ml/kg for ongoing losses
  - Diary: Parents received a diary with recommended fluid intake of ORS for their child. The diary was used by parents to record parameters like frequency of bowel movements, vomiting, urine production, ORS intake, etc.



Outcomes:

- **Primary:**
  - Percentage of successfully rehydrated children after 4 h and after 24 h
  - Resolution of signs of dehydration determined clinically (yes/no)
  - Adequate weight gain (yes/no)
  - Production of urine (yes/no)
- **Secondary:**
  ORS intake, weight gain, vomiting, unscheduled intravenous therapy, return to the emergency department within a week, hospitalization within a week, duration of diarrhoea, adverse events

Results:

- Of the 147 children randomly selected, 130 (88.4 %) were available for intention-to-treat analysis.
- The baseline data did not differ between the two study groups

Table 2: Study population baseline characteristics

	Experimental group n = 63	Control group n = 67
Male/female (n)	38/25	46/21
Age, months (mean ± SD)	20 ± 10.7	22.2 ± 6.3
Weight, kg (mean ± SD)	11.6 ± 3.0	11.7 ± 1.2
Duration of diarrhoea, days (mean ± SD)	1.9 ± 0.9	2.0 ± 0.9
Vomiting, n (%)	40 (63.5)	48 (71.6)

- No data were available for the assessment of the rate of successful rehydration at 4 hours (except for urine production). Despite initial consent, the majority of parents refused to stay in the emergency room once it became clear that the child was drinking the prescribed ORS.
- The results of all outcomes were similar in the experimental group and in the control group. For primary and secondary outcomes at 4 and 24 hours there were no significant differences in both groups; for the "per-protocol analysis" as well as for the "intention-to-treat analysis" (see table 3).
- No adverse events were observed in either study groups.

Table 3: Primary and secondary outcome measures (intention-to-treat analysis)

Outcomes	Experimental group n = 63	Control group n = 67	p value	Effect size (95% CI)
Primary				
Resolution of signs of dehydration 24h, n (%)	49 (77.8)	57 (85)	0.28	RD -0.07 (-0.2 to 0.06)
Adequate weight gain at 24h, n (%)	6 (10.5)	9 (13.4)	0.48	RD -0.04 (-0.15 to 0.07)
Urine production at 24h, n (%)	61 (96.8)	65 (97)	0.95	RD -0.00 (-0.06 to 0.06)
Secondary				
ORS intake at 4h, % prescribed (mean ± SD)	33.2 ± 24.1	33.6 ± 21	0.91	MD -0.4 (-8.2 to 7.4)
ORS intake at 24h, % prescribed (mean ± SD)	48.6 ± 26.7	51.5 ± 37.9	0.62	MD -2.9 (-14.2 to 8.4)
ORS intake in the first 24h, ml/kg (mean ± SD)	52.4 ± (36.6)	50.2 ± (34.6)	0.74	MD 2.2 (-10.6 to 14.5)
ORS intake total, ml/kg (mean ± SD)	87.4 ± 62.5	77.2 ± 58.5	0.33	MD 10.2 (-10.6 to 31.0)
ORS intake total, % prescribed (mean ± SD)	56.9 ± 27.6	55.9 ± 36.9	0.85	MD 1.0 (-10.2 to 12.2)
Weight gain at 24h, % of adequate weight (mean ± SD)	96.2 ± 3.5	96.7 ± 3.6	0.43	MD -0.5 (-1.7 to 0.7)
Weight gain within 24h, g (mean ± SD)	97 ± 198	123 ± 167	0.41	MD -26.0 (-89.2 to 37.2)
Unscheduled intravenous therapy in the first 24h, n (%)	3 (4.7)	5 (7.4)	0.52	RD -0.03 (-0.1 to 0.05)
Vomiting starting or progressing in the first 24h, n (%)	0	0	-	RD N/A
Duration of diarrhoea after randomization, h (mean ± SD)	69.1 ± 42.6	61.9 ± 38.6	0.31	MD 7 (-7.1 to 21.1)
Return to the emergency department within a week, n (%)	0	0	-	RD N/A
Hospitalization with a week, n (%)	3 (4.7)	5 (7.4)	0.52	RD -0.03 (-0.1 to 0.05)

MD: mean difference, RD: risk difference, ORS: oral rehydration solution, CI: confidence intervall, SD: standard deviation