



Redefining Hypoglycemia Rescue in Type 1 Diabetes: Clinical Results from a MESH Formulation

Summary

People living with type 1 diabetes (T1D) still face a significant burden from hypoglycemia. Glucose-only treatments often result in a cycle of glucose overshoot and recurrent lows, alongside a prolonged cognitive and physical "hangover" that impacts daily functioning.

Klario® is a first-in-class Multi-Energy Substrate for Hypoglycemia (MESH) formulation that supports both blood glucose correction and brain energy recovery. Its proprietary formulation combines fast-acting carbohydrates with adaptive energy sources (β -hydroxybutyrate (BHB) and Lactate).

This white paper summarizes clinical study results demonstrating effectiveness of Klario®'s MESH formulation. Evolving hypoglycemia management from simple glucose replacement to active metabolic rescue with MESH formulations can help to improve outcomes for people with diabetes.

1. Methods

The efficacy of Klario® was validated through two clinical studies:

- 1) A randomized, crossover study in healthy adults comparing the pharmacokinetic profile of Klario® against standard of care (SoC) 15g fast-acting glucose-only gel.
- 2) A 12-week randomized, open-label, crossover study in adults with T1D comparing Klario® to SoC. The study evaluated glycemic control using continuous glucose monitoring (CGM) and assessed patient experience through structured questionnaires.

Interviews led by trained facilitators were conducted with each participant at the final Week 12 study visit.



2. Pharmacokinetic Results

Glucose Bioequivalence

Klario[®] demonstrated bioequivalent glucose absorption to SoC, with comparable peak concentrations and similar total glucose exposure. Klario[®] demonstrated a more gradual return to baseline at approximately 150 minutes compared to <120 minutes for SoC, consistent with a more stable post-treatment glycemic profile.

Sustained BHB Delivery

In contrast to SoC, Klario[®] produced a rapid elevation of plasma BHB levels, reaching peak concentration at 30 minutes. Crucially, these levels remained significantly elevated above baseline for the entire 180-minute observation period confirming the effective elevation of circulating BHB to physiologically relevant levels.

3. Clinical Effectiveness Results

1032 hypoglycemic episodes identified from CGM data were analyzed over the 12-week study duration. Results showed significant improvements in glycemic stability following hypoglycemia treatment with Klario[®] compared to standard glucose, alongside significant improvements in patient-reported outcomes.

Glycemic Control

Klario[®] significantly improved post-hypoglycemia time in range (82%) compared to standard glucose and reduced risk of recurrent hypoglycemic events by 27% (Table 1).

Patient-reported outcomes

Patient experience assessments across 14 validated domains demonstrated consistent superiority of Klario[®]. Ten of 14 patient experience assessment domains showed statistically significant improvement (Figure 1).

Parameter	Klario [®]	SoC	p-value
Post-Hypoglycemia TIR (2h)	82.5±10.1%	77.0 ±12.3%	0.019
Recurrent Hypoglycemia (2h)	6.3 ± 4.1%	8.6 ± 5.2%	0.031

Table 1: Analysis of 1032 episodes of hypoglycemia assessed: Time in range (TIR) (2 hour period post event) significantly improved & relative risk of recurrent episodes reduced with Klario[®] v SoC.

Patient experience highlights

75%

reported faster return to daily activities with Klario[®]

73%

reported Klario[®] worked faster than standard glucose

75%

found Klario[®] easier to use during a hypo

82%

felt more in control when managing hypos using Klario[®]

Figure 2. Participant-reported differences in recovery, displaying the percentage of participants who indicated preference for Klario[®] over SoC glucose gel across key measures.

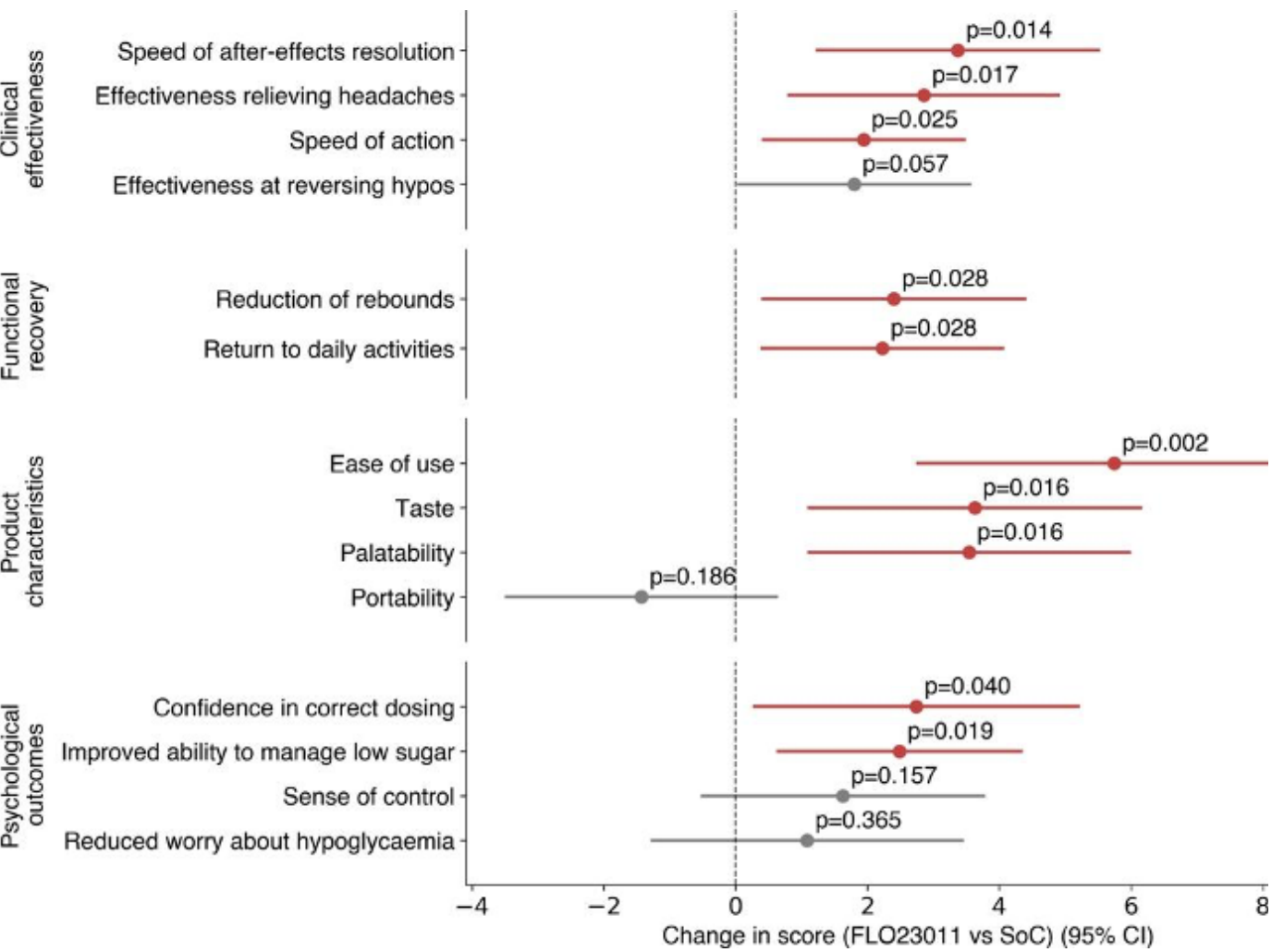


Figure 1. Estimated treatment effects for Klario[®] versus SoC glucose gel. Points represent mean difference between treatments with 95% confidence intervals. Values to the right of zero indicate a preference for Klario[®]. Red-shaded items indicate statistical significance (p<0.05). Klario[®] demonstrated statistical superiority in 10 of 14 domains, including clinical effectiveness, functional recovery, and product characteristics.

4. Exit Interview Analysis

Structured interviews and 5-point Likert scale assessments at the final Week 12 study visit characterized the comparative impact of Klario® versus standard glucose gel on daily life:

- **Overall Effectiveness:** 92% of participants rated Klario® as "Very" or "Extremely" effective, compared to only 50% for standard glucose gel.
- **Eliminating the Hangover:** 92% reported "Never" or "Rarely" experiencing hypo-hangover symptoms (lethargy, headache) with Klario®, versus only 33% with standard glucose gel
- **Speed of Cognitive Recovery:** Participants noted that while standard glucose gel left them in a "foggy" state, Klario® allowed them to "think straight" almost immediately.
- **Reduced Disruption to Daily Routine:** Participants reported that, by minimizing the "hangover," Klario® facilitated a faster return to daily activities without the need for extended rest.
- **Product User Experience:** Participants preferred Klario® over the "sickly sweet" and "difficult to swallow" standard glucose gel, describing it as more palatable.

Conclusions

This is the first clinical study demonstrating superior outcomes using a MESH product compared to glucose-only treatment for hypoglycemia, including improved glycemic control and improved patient experience. Future work with larger numbers could evaluate Klario®'s impact on severe hypoglycemia rates, healthcare utilization, long-term glycemic control and long-term cognitive function.

As the first innovation in hypoglycemia care for 100 years, Klario® represents a paradigm shift: moving beyond simple glucose replacement toward active metabolic rescue. These data establish the foundation for a new standard of care in hypoglycemia management with the potential to improve both clinical outcomes and quality of life of individuals with diabetes worldwide.

References

1. Russell-Jones D, Smout V, Roy S, Myers G, Littlewood R, Shojaee-Moradie F. A novel glucose beta-hydroxybutyrate combination improves hypoglycaemia recovery and patient-reported outcomes in type 1 diabetes. Diabetes Obes Metab. 2025