omnipod 5 automated insulin delivery system

Safety and Glycaemic Outcomes With a Tubeless Automated Insulin Delivery System in Very Young Children^ With Type 1 Diabetes: A Single-Arm Multicenter Clinical Trial

- **Clinical objective:** to assess the safety and efficacy of the Omnipod® 5 Automated Insulin Delivery (AID) System, the first tubeless, on-body AID system with customisable glycaemic targets, in very young children with type 1 diabetes.
- **Primary end points** were:
  - HbA1c at the end of the AID phase compared with baseline
  - Time in Range 3.9-10.0 mmol/L during the AID phase compared with the ST phase
  - Incidence rates of severe hypoglycaemia or diabetic ketoacidosis (DKA).
- **Secondary end points** included percent time with glucose levels <3.9 mmol/L and >10.0 mmol/L during the AID phase compared with the ST phase.

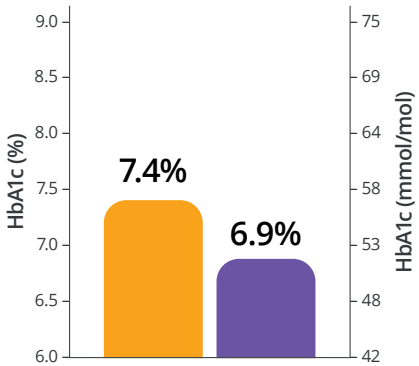
Study Design

- Multicenter, single-arm outpatient study:
  - 14-day standard therapy (ST) phase
  - 3-month AID phase with Omnipod 5 system
- No requirement for minimum body weight or total daily dose of insulin

Study Participants

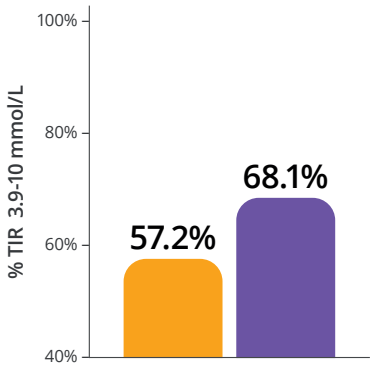
- 80 Children with Type 1 diabetes: Age 2.0–5.9 years, with caregiver informed consent
- HbA1c <10% at screening
- Prior pump or CGM use not required
- Exclusion criteria: history of DKA or severe hypoglycaemia in the past 6 months

Reduction in HbA1c



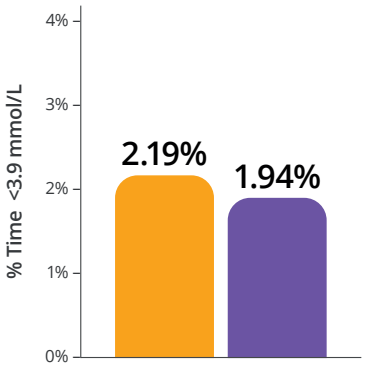
-0.55 % (6 mmol/mol) reduction in HbA1c*

Improved Time in Range (TIR)



+2.6 h/day increase in Time in Range*

Minimal Hypoglycaemia



-4 min/day reduction in hypoglycaemia **

Standard Therapy phase Omnipod 5 System phase

* p<0.0001; ** p=0.02 Baseline and follow-up data were used for the HbA1c primary endpoint. Data shown for Standard Therapy phase and AID phase.

Data Shown as median for time <3.9 mmol/L and mean for all other outcomes.

There were no episodes of Severe Hypoglycaemia or DKA in the AID phase.

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Study Highlights:

- Compared to the ST phase the Omnipod 5 System lowered HbA1c, increased Time in Range and reduced hypoglycaemia in very young children with Type 1 diabetes
- Time in Range overnight (00:00 - 06:00 h) increased from 58.2% (ST phase) to 81.0% (Omnipod 5 phase)
- There were no episodes of Severe Hypoglycaemia or DKA in the AID phase
- The proportion of children meeting consensus targets for HbA1c <7.0% increased from 31% with usual therapy to 54% after using the Omnipod 5 System
- The proportion of children meeting targets for >70% Time in Range increased 2.5-fold from 17% with usual therapy to 44% after using the Omnipod 5 System
- Median time in automated mode during the Omnipod 5 system phase was 97.8%
- Omnipod 5 System can be used safely and effectively in very young children with Type 1 diabetes

Scan code to view published study

This summary has been provided as part of the Omnipod Academy, an educational service provided for Healthcare Professionals by Insulet International.

References 1. Sherr JL et al. Safety and Glycaemic Outcomes with a Tubeless AID System in Very Young Children with T1D: a single-arm, multicenter clinical trial. Diabetes Care. 2022; 45(8):1907-1910 doi: 10.2337/dc21-2359. Study funded by Insulet

^ Omnipod® 5 is indicated for people with type 1 diabetes in persons aged 2 and older requiring insulin. Warning: SmartAdjust technology should not be used by anyone under the age of 2 years old or by people who require less than 5 units of insulin per day. Please see Omnipod.com/safety for important safety information.

Always read the label and follow the directions for use.

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