HEALTHCARE PROFESSIONALS ONLY

omnipod 5 automated insulin delivery system

Safety and Glycemic Outcomes With a Tubeless Automated Insulin Delivery System in Very Young Children With Type 1 Diabetes: A Single-Arm, Multicentre 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 customizable glycemic targets, in very young children with type 1 diabetes.
- **Primary endpoints:**
  - 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 standard therapy (ST) phase
  - Incidence rates of severe hypoglycemia or diabetic ketoacidosis (DKA)
- **Secondary endpoints** included percent time with glucose levels <3.9 mmol/L and >10.0 mmol/L during the AID phase compared with the ST phase.

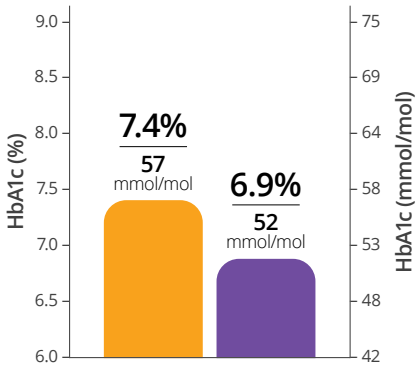
Study Design

- Single-arm, multicentre, outpatient study:
  - 14-day ST phase
  - 3-month AID phase with Omnipod 5 system
- No requirement for minimum body weight or total daily dose of insulin

Study Participants

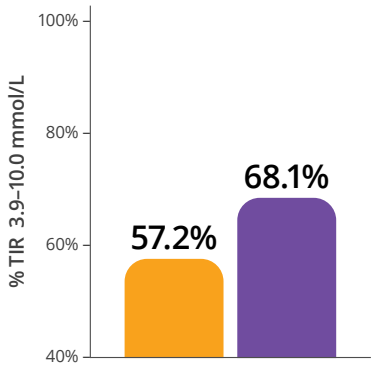
- 80 Children with type 1 diabetes: Age 2.0–5.9 years, with caregiver informed consent
- HbA1c <10% (86 mmol/mol) at screening
- Prior pump or CGM use not required
- Exclusion criteria: history of DKA or severe hypoglycemia in the past 6 months

Reduction in HbA1c



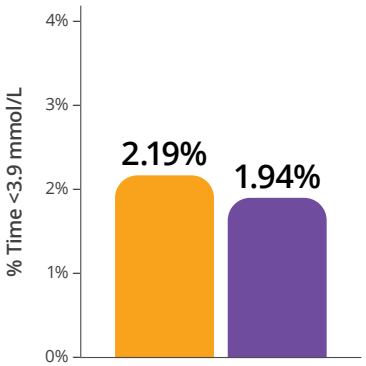
-0.55 % (6 mmol/mol) reduction in HbA1c*

Improved Time in Range (TIR)



+2.6 h/day increase in Time in Range*

Minimal Hypoglycemia



-4 min/day reduction in hypoglycemia**

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 hypoglycemia or DKA in the AID phase.

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Study Highlights:

- Compared to the ST phase, the Omnipod 5 System lowered HbA1c, increased TIR, and reduced hypoglycemia 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 hypoglycemia or DKA in the AID phase
- The proportion of children meeting consensus targets for HbA1c, <7.0% (53 mmol/mol), 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%
- The 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.

References 1. Adapted from; Sherr JL, et al. Safety and Glycemic Outcomes With a Tubeless Automated Insulin Delivery System in Very Young Children With Type 1 Diabetes: A Single-Arm Multicenter Clinical Trial. *Diabetes Care* 2022; 45:1907-1910.

In a 3-month clinical study, 0 cases of severe hypoglycemia and 0 cases of diabetic ketoacidosis (DKA) were reported in children during Omnipod 5 System use.

The Omnipod 5 Automated Insulin Delivery System is a single hormone insulin delivery system intended to deliver U-100 insulin subcutaneously for the management of type 1 diabetes in persons aged 2 and older requiring insulin. The Omnipod 5 System is intended for single patient use.

The Omnipod 5 System is intended to operate as an automated insulin delivery system when used with compatible Continuous Glucose Monitors (CGM). When in automated mode, the Omnipod 5 system is designed to assist people with type 1 diabetes in achieving glycemic targets set by their healthcare providers. It is intended to modulate (increase, decrease, or pause) insulin delivery to operate within predefined threshold values using current and predicted CGM values to maintain blood glucose at variable target glucose levels, thereby reducing glucose variability. This reduction in variability is intended to lead to a reduction in the frequency, severity, and duration of both hyperglycemia and hypoglycemia.

The Omnipod 5 System can also operate in a manual mode that delivers insulin at set or manually adjusted rates.

The Omnipod 5 System is indicated for use with NovoLog®/NovoRapid®, Humalog®/Liprolog®, Trurapi®/Truvelog®/Insulin aspart Sanofi®, Kirsty®, and Admelog®/Insulin lispro Sanofi U-100 insulin.

Warnings:

- SmartAdjust™ technology **should NOT be used** by anyone under the age of 2 years old.
- SmartAdjust™ technology **should NOT be used** by people who require less than 5 units of insulin per day as the safety of the technology has not been evaluated in this population.
- The Omnipod 5 System is **NOT recommended** for people who are unable to monitor glucose as recommended by their healthcare provider, are unable to maintain contact with their healthcare provider, are unable to use the Omnipod 5 System according to instructions, are taking hydroxyurea as it could lead to falsely elevated CGM values and result in over-delivery of insulin that can lead to severe hypoglycemia, and do NOT have adequate hearing and/or vision to allow recognition of all functions of the Omnipod 5 System, including alerts, alarms, and reminders. Device components including the Pod, CGM transmitter, and CGM sensor must be removed before Magnetic Resonance Imaging (MRI), Computed Tomography (CT) scan, or diathermy treatment. In addition, the Controller and smartphone should be placed outside of the procedure room. Exposure to MRI, CT, or diathermy treatment can damage the components.

Refer to the Omnipod 5 Automated Insulin Delivery System User Guide for a complete list of indications, contraindications, warnings, cautions, and instructions. The Guides are available by calling us at 1-855-POD-INFO (1-855-763-4636) or by visiting our website at omnipod.com

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