ONWARDS-9

CLINICAL TRIAL SUMMARY

Presenters	Novo Nordisk A/S
Objectives	To examine the effect of continuous glucose monitoring (CGM)-based titration of once-weekly insulin icodec (icodec) on glycemic control and safety outcomes in individuals with type 2 diabetes (T2D)

https://clinicaltrials.gov/study/NCT05823948

TRIAL DESIGN

Multicenter, Single-arm, Treat-to-Target, Phase 3b Trial

SAMPLE SIZE

Of 58 participants screened, 51 received icodec treatment

INCLUSION CRITERIA

- Adults (≥18 years) with type 2 diabetes for ≥180 days
- HbA1c 7.0%–11.0%
- Insulin-naïve (except limited short-term use)
- BMI ≤40 kg/m²
- On stable doses of anti-diabetic medications for ≥90 days.
- Eligible for basal insulin initiation to reach fasting glucose targets (80–130 mg/dL).

METHODOLOGY

- In this 26-week, multicenter, single-arm phase 3b trial, insulin-naive adults with type 2 diabetes (HbA1c 7.0%–11.0%) started once-weekly insulin icodec at 70 U/week.
- Doses were adjusted weekly using pre-breakfast CGM readings (target: 80–130 mg/d).
- The primary outcome was change in HbA1c from baseline to week 26.
- Exploratory outcomes included time in range (70–180 mg/dL), time above (>180 mg/dL), and time below range (<54 mg/dL) between weeks 22–26.
- Safety, including hypoglycemia episodes, was also monitored.

RESULTS

HbA1c dropped from a mean of 8.18% at baseline to an estimated 7.00% at week 26, showing a significant reduction of -1.17 percentage points (95% CI: -1.36 to -0.99; $P < 0.0001$).

Time in range increased from 54.4% to 76.4%, while time above range decreased from 45.2% to 22.9%.

Time below range remained very low (0.03% to 0.04%). No severe hypoglycemia or new safety issues with icodec were reported.

CONCLUSION

After 26 weeks of CGM-guided icodec treatment, HbA1c significantly decreased from baseline, and recommended CGM targets for TIR, TAR >180 mg/dL, and TBR <54 mg/dL were met. These results support CGM-based icodec titration as a practical approach for starting insulin in type 2 diabetes.

Bergenstal RM, Ásbjörnsdóttir B, Johanning Bari T, et al. Continuous Glucose Monitoring-Based Titration of Once-Weekly Insulin Icodec in Insulin-Naive Individuals with Type 2 Diabetes (ONWARDS 9): A Phase 3b, Multicenter, Single-Arm, Treat-to-Target Clinical Trial. Diabetes Technol Ther. 2025 Jul;27(7):527-536. doi: 10.1089/dia.2025.0050. Epub 2025 Mar 5. PMID: 40040516.