QWINT-2

CLINICAL TRIAL SUMMARY

Presenters	Eli Lilly and Company
Objectives	To determine the effect and safety of insulin efsitora alfa compared to degludec in adult participants with type 2 diabetes who are starting basal insulin for the first time.

Source: https://clinicaltrials.gov/study/NCT05362058

TRIAL DESIGN

52-week, Phase 3, Parallel-Design, Open-Label, Treat-to-Target, Randomized Controlled trial

SAMPLE SIZE

928 Participants with Type 2 Diabetes

INCLUSION CRITERIA

- 18 Years and older
- Have diagnosis of Type 2 diabetes (T2D)
- Have an Hemoglobin A1c (HbA1c) of 7.0 percent (%) - 10.5% inclusive, at screening
- Are on a stable treatment with 1 to 3 antihyperglycemic medication for at least 3 months
- Are insulin naïve

METHODOLOGY

- A total of 928 participants underwent randomization (466 to the efsitora group and 462 to the degludec group).
- The primary end point was the change in the glycated hemoglobin level from baseline to week 52; we hypothesized that efsitora would be non-inferior to degludec.
- Secondary and safety end points included the change in the glycated hemoglobin level in subgroups of participants using and not using glucagon-like peptide-1 (GLP-1) receptor agonists, the percentage of time that the glucose level was in the target range of 70 to 180 mg per deciliter in weeks 48 through 52, and hypoglycemic episodes.

RESULTS

The mean glycated hemoglobin level decreased from 8.21% at baseline to 6.97% at week 52 with efsitora and from 8.24% to 7.05% with degludec, findings that showed noninferiority.

Efsitora was noninferior to degludec with respect to the change in the glycated hemoglobin level in participants using and not using GLP-1 receptor agonists. The percentage of time that the glucose level was within the target range was 64.3% with efsitora and 61.2% with degludec.

The rate of combined clinically significant or severe hypoglycemia was 0.58 events per participant-year of exposure with efsitora and 0.45 events per participant-year of exposure with degludec. No severe hypoglycemia was reported with efsitora; six episodes were reported with degludec. The incidence of adverse events was similar in the two groups.

CONCLUSION

In adults with type 2 diabetes who had not previously received insulin, once-weekly efsitora was non-inferior to once-daily degludec in reducing glycated hemoglobin levels.

Wysham C, Bajaj HS, Del Prato S, et al. Insulin Efsitora versus Degludec in Type 2 Diabetes without Previous Insulin Treatment. *N Engl J Med*. 2024;391(23):2201-2211. doi:10.1056/NEJMoa2403953