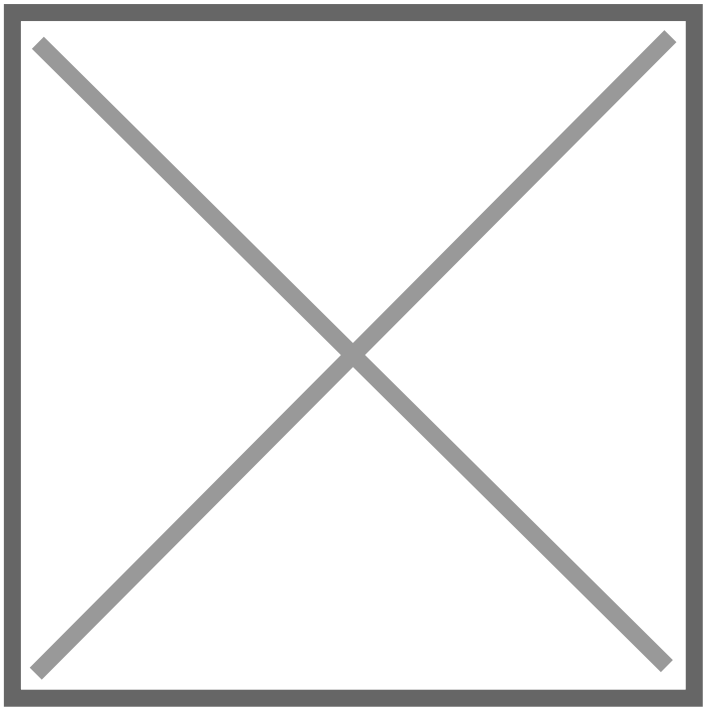
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Novo Nordisk announces results of PIONEER 6 trial on people with high cardiovascular risk

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The main results from PIONEER 6 were presented at the American Diabetes Association (ADA) 79th Scientific Sessions and simultaneously published in The New England Journal of Medicine (NEJM).



Novo Nordisk has announced that the PIONEER 6 trial achieved its primary endpoint by demonstrating non-inferiority of major adverse cardiovascular events (MACE) with oral semaglutide compared with placebo, both in addition to standard of care. The primary endpoint was defined as the MACE composite outcome of the first occurrence of cardiovascular death, non-fatal myocardial infarction or non-fatal stroke and non-inferiority for cardiovascular safety of oral semaglutide versus placebo was confirmed with a hazard ratio (HR) of 0.79 ($p<0.001$) in favour of oral semaglutide compared with placebo. The results are based on an accumulation of 137 first major adverse cardiovascular events and a median follow-up time of 16 months.

The main results from PIONEER 6 were presented at the American Diabetes Association (ADA) 79th Scientific Sessions and simultaneously published in *The New England Journal of Medicine* (*NEJM*). Oral semaglutide is an investigational glucagon-like peptide-1 (GLP-1) analogue in a pill.

The MACE results were driven by the individual components of cardiovascular death [15 (0.9%) events with oral semaglutide vs 30 (1.9%) events with placebo, HR 0.49, p=0.03] and non-fatal strokes [12 (0.8%) events with oral semaglutide vs 16 (1.0%) events with placebo, HR 0.74, non-significant]. The number of non-fatal myocardial infarctions with oral semaglutide was not significantly different than placebo [37 (2.3%) events with oral semaglutide vs 31 (1.9%) events with placebo, HR 1.18, non-significant]. Among the secondary endpoints, the number of all-cause deaths was significantly lower in people treated with oral semaglutide compared with placebo [23 (1.4%) events vs 45 (2.8%) events, HR 0.51, p=0.008].

"Cardiovascular disease is the most common cause of disability and death in people with type 2 diabetes," said DrMansoor Husain, PIONEER 6 investigator and lead author for the *NEJM* publication of PIONEER 6 and director of the Ted Rogers Centre for Heart Research and Toronto General Hospital Research Institute, Canada. "The PIONEER 6 trial demonstrates that oral semaglutide does not increase the risk of major adverse cardiovascular events while providing further evidence for the overall cardiovascular profile of semaglutide."

The safety profile of oral semaglutide was consistent with that of the GLP-1 receptor agonist class and similar to those seen with subcutaneous semaglutide.

"The results of PIONEER 6 further strengthen the overall clinical evidence for oral semaglutide, building upon the strong clinical data reported throughout the PIONEER clinical trial programme," said Mads Krogsgaard Thomsen, executive vice president and chief science officer of Novo Nordisk. "We are excited about the potential of oral semaglutide to become the first and only oral GLP-1 treatment for people with type 2 diabetes."

About PIONEER 6 and the PIONEER clinical trial programme

PIONEER 6 was an event-driven, pre-approval cardiovascular outcomes trial for oral semaglutide. It was a randomised, double-blinded, placebo-controlled trial evaluating the cardiovascular safety of oral semaglutide vs placebo when added to standard of care in 3,183 people with type 2 diabetes at high risk of cardiovascular events.

The PIONEER phase 3a clinical development program for oral semaglutide was a global development programme that enrolled 9,543 people with type 2 diabetes across 10 clinical trials.