DEVOTE STUDY RESULTS

WHAT KIND OF STUDY WAS DEVOTE?

DEVOTE was a long-term, multinational study that looked at safety related to the heart and blood vessels during treatment with insulin degludec (Market name Tresiba) compared with insulin glargine (Market name Lantus), in people with type 2 diabetes who are at high risk for diseases of the heart and blood vessels

WHO TOOK PART AND FOR HOW LONG?

7637 people from 20 countries participated in the study. Participants were aged 50 years or above, had type 2 diabetes, and either heart disease or a high risk of heart disease. The study lasted for just under 3 years. 63% of participants were male and 37% of participants were female with an average age of 65 years old.

WHY IS THIS STUDY AND STUDIES LIKE IT SO IMPORTANT?

Type 2 diabetes can lead to several health problems, including increasing the risk of heart disease. This means that it is important that medicines used by people with type 2 diabetes do not increase this risk.

The goal of the DEVOTE study was to evaluate the safety of insulin degludec on the heart and blood vessels compared to insulin glargine. Participants were monitored closely throughout the study.

WHICH MEDICATIONS WERE STUDIED?

Participants were randomly divided into two groups and received either insulin degludec or insulin glargine (in addition to their usual diabetes care).

Insulin is an important treatment option for people with type 2 diabetes. Insulin is a hormone naturally made in the human body which helps the body to use blood sugar, but in type 2 diabetes the body cannot use insulin properly. Insulin degludec and insulin glargine work in a similar way to human insulin but work for a longer period of time and are therefore known as long-acting insulins. Insulin degludec and insulin glargine are both taken as once-daily injections to improve and maintain stable blood sugar levels.

HEADLINE RESULTS

Below please find an edited version of the official company announcement released by Novo Nordisk 29 November 2016 regarding the DEVOTE study results:

"The trial demonstrated that Tresiba® was no worse than insulin glargine U100 with regards to major adverse cardiovascular events (Primary endpoint).

The primary endpoint of the DEVOTE study was defined as the outcome of the first occurrence of heart-related death, non-fatal heart attack or non-fatal stroke, with no statistically significant difference between the two treatments.

From an average HbA1c baseline of 8.4%, the trial showed a similar reduction with Tresiba® compared to insulin glargine U100 and fulfilled the requirements for fairly comparing low blood sugar rates between the two treatments.

In the trial, 27% fewer patients in the Tresiba® treated group experienced an episode of severe low blood sugar, resulting in a 40% overall reduction of total episodes of severe low blood sugar (Secondary endpoint). Furthermore, patients in the Tresiba® treated group experienced a 54% relative reduction in the rate of severe low blood sugar at night. These differences were all statistically significant.

Thus, Tresiba® appeared to be safe and well-tolerated, consistent with previous clinical studies conducted with Tresiba®."

You can find the full statement at https://www.novonordisk.com/bin/getPDF.2060124.pdf