AstraZeneca

STUDY REPORT SUMMARY

ASTRAZENECA PHARMACEUTICALS

FINISHED PRODUCT: Not applicable
ACTIVE INGREDIENT: Not applicable

Study No: NIS-CSE-DUM 2010/1,   NCT number NCT01121315

A Retrospective Epidemiological Study to Investigate Outcome and Mortality with Glucose Lowering Drug Treatment in Primary Care - ROSE

Developmental Phase: Data Base Audit
Study Completion Date: 15 August 2011
Date of Report: 27 June 2012
OBJECTIVES:

In a retrospective, epidemiological setting, we have described the type II diabetes population in primary care with special reference to treatment, and co-morbidity, including risk factor profile and mortality during the last decade.

The aim was to explore the association of HbA1c with risk of cardiovascular events (CVD) in patients with type 2 diabetes.

METHODS:

Primary care data was extracted in 2010 from electronic patient records from 84 primary care centres in Sweden. No formal stratification of the centers was performed, but effort was made to ensure a selection covering a representative sample of the Swedish population. Patient data between the years 1999 to 2009 was extracted for all 58,326 patients with a diagnosis of type-2 diabetes (ICD-9 code 250, ICD-10 codes E10-E14) and/or prescription of drug within Anatomic Therapeutic Chemical classification system class A10. The primary care data was linked to data from Swedish national cause of death and in-patient registries. Data on educational level was generated from the Swedish censuses and categorized into two groups; compulsory (9-year comprehensive) school or upper school (including all kind of secondary education as upper secondary education or tertiary education).
Patients who were not subjected to pharmacological treatment for diabetes (n=16,973), under the age of 35 years (n=876) and patients with incomplete data on HbA1c at baseline (n=7,606) were excluded. , rendering a final sample of 32,871 patients. HbA1c

levels and educational level with risks of cardiovascular events and all-cause mortality were analyzed.

The primary endpoint was a composite endpoint of the first non-fatal or fatal event of hospitalization for acute myocardial infarction, heart failure, stroke or cardiovascular mortality.

RESULTS:

The associations of HbA1c with risk of all-cause and cardiovascular mortality were J-shaped. The lowest risk for cardiovascular mortality was seen at an HbA1c level of 51 mmol/mol (6.8 %), and 56 mmol/mol (7,3%) for subjects on oral agents (OA) and for insulin-treated patients, respectively; while the lowest risk observed for all-cause mortality was at an HbA1c level of 51 mmol/mol (6.8 %) and 56 mmol/mol (7.3%).

There was an increased risk for cardiovascular death at the lowest HbA1c decile for subjects in the low education category. For subjects with higher education there was no evident J curve for cardiovascular death.