

## STUDY REPORT SUMMARY

### ASTRAZENECA PHARMACEUTICALS

**FINISHED PRODUCT:** No specific product

**ACTIVE INGREDIENT:**

<b>Study No:</b> NIS-CDK-DUM-2008/1    NCT00713960
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CARE - Quality Development in Cardiovascular Disease in General Practice
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**Developmental Phase:** IV

**Study Completion Date:** December 31<sup>th</sup> 2010

**Date of Report:** October 12<sup>th</sup> 2011

### OBJECTIVES:

The overall objective was to improve the management of patients in secondary prevention of cardiopathy in general practice by implementing regular standardized procedures. The standard procedures consisted of scheduled consultations monitoring the disease. A guideline was developed based on the principles of guidelines from DSAM (Danish College of General Practitioners)<sup>6</sup> to secure standardized procedures.

### METHODS:

Basically all GP clinics having a nurse employed could attend the study. Successful execution required however that the nurse was updated within the cardiovascular area with focus at secondary prevention.

Inclusion criteria were patients age 18 years or older in secondary prevention of cardiopathy (Ischemic Cardiovascular Disease, Claudio Intermittent, Thrombotic Apoplexia Cerebri and Diabetes) who were not followed in an outpatient department. Written and oral consent was obtained.

Before the study started the GP's and the nurses had to participate in an educational start-up meeting to receive training in guidelines, information about the study and background for registering parameters.

The consultation could be handled by the GP or by the consultation nurse. In close to all clinics the consultation was handled by the nurse.

During the consultation the nurse filled in a questionnaire based on the principles of the guidelines from DSAM. The main parameters to register at visits included patient characteristics, physical exercise, Total Cholesterol, HDL Cholesterol, LDL Cholesterol,

smoking habits, plasma glucose, weight – Body Mass Index, waistline, blood pressure and changes in the medical treatment (no change, titration or new medication).

The clinics committed themselves to include at least 12 patients in the study; subsequently they could stop by request. When 12 patients had been implemented in the study it was expected that the nurse had developed skills and routines enabling her to handle these chronic patients. The clinic could decide whether they wanted to keep on including patients in the study or just use the developed skills in their daily practice. Based on the results from the first 12 patients the clinic received a written feedback report, and could, based on that, plan how to precede in or out of the study. The feedback report was presenting data from the specific clinic compared to mean data from all participating clinics.

## **RESULTS:**

In total 2193 patients had been included in the study. Of the 2193 patients, 1080 patients (49%) attended a follow up visit.

In the entire baseline group 40% of the patients were female. The majority of the patients had the diagnoses Ischemic Cardiovascular Disease (39%) and Diabetes (33%).

The risk factors that affect the medical treatment, i.e. total cholesterol, LDL cholesterol, blood pressure and plasma glucose and the correlation between numbers of risk factors and change in medical treatment showed that 49% of the patients had 2-3 risk factors, 19% of these patients had changes in their medication. 32% of the patients with 5 risk factors had changes in medication. In general the clinics changed the medical treatment in 340 patients but 564 patients had no registration about medication in the database.

At baseline 49% of all the patients had too high systolic blood pressure and 31% had too high diastolic blood pressure. 70% of the patients with diabetes had too high systolic blood pressure and 59% had too high diastolic blood pressure.

The fasting plasma glucose was too high in 86% of the patients with diabetes and in 36% of the patients without diabetes.

Looking at cholesterol, 57% of the patients had a LDL cholesterol < 2.5, 51% of the patients had total cholesterol < 4.5 and 80% of the patients had HDL cholesterol >1.0 as recommended.

23% of the patients had a BMI<25 and only 16% of the male patients, 13% of the female patients had a waistline as recommended. 69% of the patients did exercise > 3 hours per week.

Looking at improvement of risk factors, all the factors improved over time. The study showed a trend that the patients' average value of total cholesterol, LDL cholesterol and blood pressure improved from visit to visit, which could be an indication that close controls of the patients has a beneficial effect on these values and thus enables more patients to reach the treatment targets.