AstraZeneca

STUDY REPORT SUMMARY

ASTRAZENECA PHARMACEUTICALS

FINISHED PRODUCT: no drug study
ACTIVE INGREDIENT: none

Study No: NIS-CNL-DUM-2010/1
Perceived hypoglycemia- and weight-related Quality of Life of patients with sulfonylurea derivate-treated Diabetes Mellitus Type 2, a non-interventional study. **Acronym: HYPODIM study.**

Developmental Phase: Non-Interventional Study
Study Completion Date: August 2012
Date of Report: December 2012

OBJECTIVES: The primary objective of the study is to investigate the impact on Quality of Life of symptoms of hypoglycemia, hypoglycemic events and weight changes in patients with DM2 after approximately 6 months of treatment with a sulfonylurea derivative (SU) on top of existing metformin treatment.
The secondary objective of the study is to evaluate the frequency of hypoglycemic symptoms, the incidence of hypoglycemic events, treatment adherence and body weight changes in relation to the outcomes of the Quality of Life questionnaires after approximately 3 and 6 months of treatment with an added SU derivative.

METHODS: HYPODIM was initiated as a Non Interventional Study (NIS) conducted in an usual primary care setting. Consecutive patients with type 2 diabetes who had a clinical need to initiate therapy with a sulphonylureum (SU) derivative as add-on therapy to metformin were contacted and included by their physician and consequently followed for 6 months. . Medical data were collected routinely at baseline, after 3 and after 6 months by the treating physicians, including: type of diabetes, time since diagnosis, HbA1c, Fasting Blood Glucose (FBG), complication status, height, weight, and diabetes medications. Demographics and hypoglycaemic episodes (mild and severe nocturnal and during daytime) were measured by self-report. In addition, Patient-Reported Outcomes (PRO) were collected, for which purpose the following short, validated questionnaires (total of 70 items) were administered at baseline and at 6 months follow-up:
The Worry subscale of the Hypoglycemia Fear Survey (**HFS-W.**), the Impact of Weight on Quality Of Life questionnaire (**IWQOL-Lite**), the Diabetes Symptom Checklist-Revised (**DSC-R**), the Problem Areas In Diabetes scale-1 (PAID-1), the EuroQol EQ-5D questionnaire (**EQ-5D**), the Medication Adherence Rating Scale (**MARS-5**).

Both physicians and patients received a log-in code to a website (www.hypodim.nl) after they concented to participate. All data was entered on the website.

RESULTS: The study was terminated due to recruitment problems, as a result of which no firm conclusions can be drawn from the obtained data. After early termination the total study sample consisted of 51 patients (in stead of originally planned 125), of whom 1 withdrew informed consent. Analyses were performed over the remaining 50 patients. At baseline, complete medical data was available for all patients. Complete data on patient-reported outcomes was available for 44 patients (88%). At three months, medical data were available for 36 (72%) patients and data on patient-reported outcomes was available for 34 (68%) of the patients. After 6 months, these proportions were 26 (52%) and 27 (54%) respectively. At baseline, all patients used metformin and continued to do so during the study. SU treatment was discontinued for 1 patient at 3 month follow-up. This patient remained in the study for analysis, based on the intention-to-treat principle.