AstraZeneca

STUDY REPORT SUMMARY

ASTRAZENECA PHARMACEUTICALS

FINISHED PRODUCT: Atacand
ACTIVE INGREDIENT: Candesartan

Study No: NIS-CKR-DUM-2009/2
Effect of PATient education related to CV Risk factOrs in type 2 diabetes meLlitus_(PATROL study)

Developmental phase: Marketed
Study Completion Date: 2009-11-20
Date of Report: 2010-01-22

OBJECTIVES:

Primary objectives

- Proportion of patients achieved in treatment target goal on glycemic control, hypertension and hyperlipidemia according to ADA 2008 guideline.

* The treatment goal of risk factors is based on ADA 2008 guideline. [19)]

Table 11—*Summary of recommendations for glycemic, blood pressure, and lipid control for adults with diabetes*

A1C	<7.0%*
Blood pressure	<130/80 mmHg
Lipids	
LDL cholesterol	<100 mg/dl (<2.6 mmol/l)†

*Referenced to a nondiabetic range of 4.0–6.0% using a DCCT-based assay. †In individuals with overt CVD, a lower LDL cholesterol goal of <70 mg/dl (1.8 mmol/l), using a high dose of a statin, is an option.

Secondary objectives

- Patients satisfaction Questionnaire
- To assess the effect of well-informed patient consultation related to CV risk factors with type II diabetes mellitus

METHODS:

Design

Multi-center, prospective, observational study

Target subject population

Type II diabetes mellitus with hypertension and /or hyperlipidemia.

Inclusion criteria

For inclusion in the study subjects must fulfil all of the following criteria:

1) Patients who had been diagnosed with type II diabetes mellitus.
2) Patients with hypertension and / or hyperlipidemia
3) Patients who had agreed to Informed consents

Exclusion criteria

Any of the following is regarded as a criterion for exclusion from the study:

1) Patients who had been diagnosed with type I diabetes mellitus.
2) Patients with neither hypertension and hyperlipidemia

Result variables

- **Primary variables:** During the period of study, target goal achievement rate of blood pressure and LCL-C according to ADA guideline.
- **Secondary variables:** During the period of study, change of glucose, blood pressure and LCL-C
  Concomitant disease
  Medication
  Risk factors

Statistical Analysis

Since this is an observation study without a control group, statistical analysis results will be presented descriptively. Descriptive analysis will be performed for patient's demographic characteristics, concomitant disease, treatment factors and concomitant medications

Analysis of Assessment Endpoints

Primary assessment

Attainment rate to the target goal achievement rate of blood pressure and LCL-C according to ADA guideline after well-informed patient consultation
Attainment rate to 95% confidence interval will be estimated after well-informed patient consultation.

Secondary assessment

Attainment to the target blood pressure will be investigated according to concomitant diseases and statistical difference among groups will be analyzed using chi-square test.

Additional assessment

Change in pre- and post-study period DBP/SBP and LDL-C value will be addressed and the statistical difference in the pre- and post-study period will be analyzed using paired t-test. Change in the DBP/SBP value will be investigated according to the DM Complication and the statistical difference among groups will be analyzed using t-test.

If additional analysis is necessary after the primary assessment, appropriate statistical analysis will be employed.

TIME SCHEDULE

	First visit (Baseline)	Final visit (Endpoint; after 2months± 2weeks)
Demographics		
Gender	**X**	
Date of Birth	**X**	
Medical history		
Diagnosed date of DM	**X**	
Micro-/Macrovascular Complication	**X**	
Glucose	**X**	**X**
Blood Pressure (SBP/DBP)	**X**	**X**
LDL-C	**X**	**X**
HLD-C	**X**	**X**
TG	**X**	**X**
TC	**X**	**X**
Medication		
Antihypertensive medication	**X**	**X**
Diabetic medication	**X**	**X**
Anti-hyperlipidemia medication	**X**	**X**
Patients Satisfaction		**X**

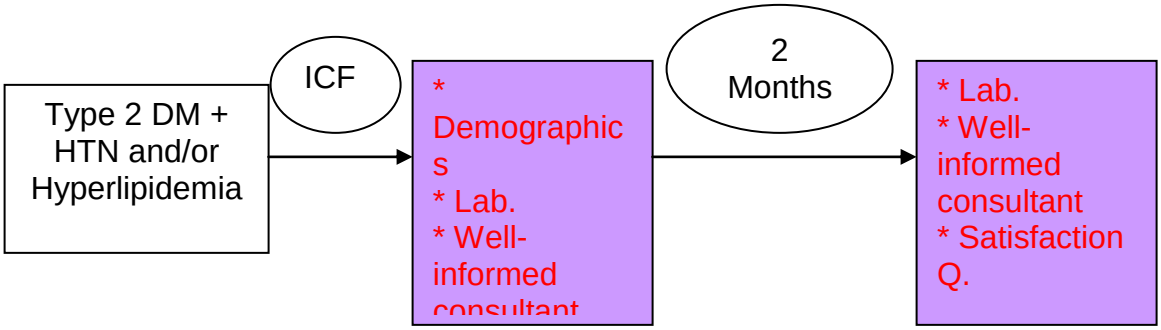
Overall Study Design and Flow Chart

This non-interventional observational study protocol was reviewed in accordance with the standard procedures of AstraZeneca.

This study will be conducted in type II DM patients with hypertension and/or hyperlipidemia. Also this study will be conducted with the patients who agreed to informed consent.

This study will keep a record of the following data on patients selected through medical record review.

They will be informed about general information about the disease and treatment process by explaining them desirable blood pressure (130/85mmHg), blood sugar (HbA1c; 7%) levels as well as treatment goals to fight against CV risk factors in order to help them realize the importance of treatment.



RESULTS:

Primary objectives

- Proportion of patients achieved in treatment target goal on hypertension according to ADA 2008 guideline.

Target Goal	Treatment	N (Except BP missing)	n(%)	99% CI
<130/80mmHg	First visit (Baseline)	3733	340(9.1)	(7.9%, 10.3%)
	Final visit (Endpoint)	3706	723(19.5)	(17.8%, 21.2%)

- Proportion of patients achieved in treatment target goal on hyperlipidemia according to ADA 2008 guideline.

Target Goal	Treatment	N (Except LDL-C missing)	n(%)	99% CI
<100mg/dl	First visit (Baseline)	1990	242(12.2)	(10.3%, 14.1%)
	Final visit (Endpoint)	1945	808(41.5)	(38.7%, 44.4%)

- Proportion of patients achieved in treatment target goal on glycemic control according to ADA 2008 guideline.

Target Goal	Treatment	N (Except HbA1c missing)	n(%)	99% CI
HbA1c < 7.0%	First visit (Baseline)	2269	692(30.5)	(28.0%, 33.0%)
	Final visit (Endpoint)	2105	1062(50.5)	(47.6%, 53.3%)

Secondary objectives

- Patients satisfaction Questionnaire

According to patients satisfaction questionnaire, patients very well satisfied to the this type of consulting method that sharing information of the diabetes and target goal of laboratory results. Also patient though this type of method was very helpful to his/her self managing diabetes and want to continuing the use consulting method to treat his/her diabetes.