AstraZeneca

STUDY REPORT SUMMARY

ASTRAZENECA PHARMACEUTICALS

FINISHED PRODUCT: Anti-Hypertensive Medications
ACTIVE INGREDIENT: Anti-Hypertensive Medications

Study No: NIS-CME-ATA-2010/1
An Observational Study of Treatment Compliance and Quality of Life in Patients on Antihypertensive Medications: COMPLIANCE

Developmental Phase: Phase IV

Study Completion Date: Last Patient Last Visit was in September 2012

Date of Report: 25 March 2014

OBJECTIVES:

The Primary Objective was to assess anti-hypertensive treatment compliance in a cohort of hypertensive Jordanian and Lebanese patients newly diagnosed with hypertension, or patients diagnosed with uncontrolled essential hypertension according to the JNC VII 1 criteria, and treated with anti-hypertensive medication for more than 6 months

Secondary Objectives were to assess the quality of life in this cohort of patients and subjectively to identify whether patients believe they are compliant to their prescribed treatments.

To identify associated factors that may alter adherence to anti-hypertensive treatment.

To identify pharmacological interventions used during treatment.

To compare treatment compliance levels to the different therapeutic regimens used**.**

METHODS:

This is a multi-site survey of patients in two Levant countries (Jordan and Lebanon) pharmacologically treated for hypertension.

Data collection took place during 3 mandatory visits.

Before each patient assessment by the investigator, patients recorded on a patient questionnaire an assessment of their current treatment compliance (if being treated) and quality of life

During the initial visit, the investigator completed a case record form (CRF) with the patient's personal information, the physical examine measurements, known cardiovascular

risk factors and the cardiovascular medical history. During one-mandatory intermediate visit and a final 6-month visit the investigator completed a CRF with physical examination measurements. During the final visit patients also recorded on a patient questionnaire an assessment of their current treatment compliance and quality of life.

The target survey population was comprised of subjects of either gender, aged above 21 years, newly diagnosed with hypertension or patients with uncontrolled hypertension that have been undergoing treatment for 6 months or more. Subjects provide informed consent and complied with the survey procedures. Subjects who were unwilling or unable to provide informed consent were excluded.

The planned sample size was 750 subjects from Jordan; 750 subjects from Lebanon (Total = 1500 subjects)

The follow up duration was 6 months and the planned trial period was one year.

RESULTS:

A total of 142 investigators recruited 1506 patients. About 36 patients were initially excluded leaving an initial cohort of 1470 (745 patients from Jordan and 725 patients from Lebanon) patients to be followed for six months.

About 1401 patients followed up for visit 2, 708 patients from Jordan and 693 patients from Lebanon.

A total of 1406 followed up for the final visit with 703 patients from Jordan and 703 patients from Lebanon.

Among the patients initially enrolled, about 622 patients (42%) were newly diagnosed with hypertension (371 from Jordan and 251 from Lebanon) compared with a total of 484 patients who had uncontrolled hypertension on medications for at least six months (58%), of which 374 patients were from Jordan and 474 patients were from Lebanon.

The newly diagnosed patients were younger in age. The mean age for the newly diagnosed patients was 51.67 years + _(11.86) in Jordan and 55.81 years +_(11.52) in Lebanon whereas the uncontrolled hypertension group had a mean age of 57.01 years +_(12.16) in Jordan and 61.67 years +_(11.02) in Lebanon.

The percentage of male patients was higher among newly diagnosed patients where about 224(60.54%) in Jordan and 155 (61.75%) in Lebanon compared to about 194 (52.86%) among the uncontrolled hypertension group in Jordan and 268 (56.66%) in Lebanon.

As expected the newly diagnosed group had fewer co morbidities and less end organ damage as compared to the uncontrolled hypertension group.
The percentage of cardiovascular disease, diabetes and dyslipidemia was 11 (2.96%), 75 (20.27%), and 73 (19.68%) respectively for the newly diagnosed patients in Jordan and about 10 (3.98%), 35 (13.94%), and 65 (25.90%) respectively in the newly diagnosed group in Lebanon. This is compared with 62 (16.85%) , 131 (35.50%) and 153 (41.35%) among the uncontrolled patient group in Jordan and 81 (17.09%), 182 (38.40%) and 249 (52.53%) among those in Lebanon.

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