AstraZeneca

STUDY REPORT SUMMARY

ASTRAZENECA PHARMACEUTICALS

FINISHED PRODUCT: NA
ACTIVE INGREDIENT: NA

Study No: NIS-CIT-DUM 2007/1

Developmental Phase: NA
Study Completion Date: February 10th 2010
Date of Report: May 3rd 2010

OBJECTIVES:

The ORSA (Regional Observatory of Metabolic Syndrome) study was an observational study based on the identification of subjects with a documented diagnosis of Metabolic Syndrome (MS) within a population of individuals attending general practitioner clinics in a single geographical area of Italy (Piedmont).

The primary aims of the study were:

1. to estimate the prevalence of MS in real-life clinical practice of general practitioners;
2. to determine, among the patients with MS, the presence of other cardiovascular risk factors that can modify the patients' global cardiovascular risk.

The secondary aim was:

1. To increase the awareness of MS among general practitioners and improve their practice of identifying subjects with this syndrome, in order to deliver more effective primary prevention of cardiovascular diseases and the development of diabetes mellitus.

METHODS:

Each of the investigators recruited patients according the following steps:

Phase I inclusion criteria

- Male and females patients aged between 18 and 75 years old
- Laboratory results [lipid profile (total cholesterol, HDL-cholesterol, LDL-cholesterol, triglycerides) and fasting glycaemia] from the most recent blood-chemistry tests carried out within the preceding year
- Written informed consent to participation in the study

Phase I exclusion criteria

- Pregnancy or lactation
- Clinical or relational conditions that, in the judgement of the investigator, are contraindications to recruitment in the study
- Patients already enrolled in other clinical studies aimed at evaluating the efficacy and/or tolerability of antihypertensive and/or lipid lowering agents

All patients who fulfilled the inclusion criteria and did not have exclusion criteria were included in the study.

The population included in the study was characterized by the presence of MS according to the finding of three or more of the following five risk factors, in accordance with the ATPIII criteria:

- abdominal obesity (waist circumference > 102 cm in men and > 88 cm in women);
- systolic blood pressure ≥ 130 mmHg and/or diastolic blood pressure ≥ 85 mmHg or taking antihypertensive drugs;
- fasting triglycerides ≥ 150 mg/dl;
- HDL cholesterol < 40 mg/dl in men and < 50 mg/dl in women;
- fasting blood glucose ≥ 110 mg/dl.

In order to complete the definition of the global cardiovascular risk profile of each patient, the following information was recorded in the CRF:

- Age (years)
- Sex
- Body weight (Kg)
- Height (cm)
- Smoking habits
- Family history of cardiovascular diseases or diabetes

Phase II inclusion criteria

- completion of Phase I
- a diagnosis of MS according to the NCEP ATP III criteria (presence of at least three of the five risk factors for MS evaluated in Phase I).

In addition the following information was recorded by the investigators:

- antihypertensive therapy, if being taken
- lipid-lowering therapy, if being taken
- antidiabetic therapy, if being taken
- renal profile [plasma creatinine (mg/dl), urea (mg/dl), uric acid
- (mg/dl), sodium (mEq/l), potassium (mEq/l)], if availables
- previous major cardiovascular events (angina pectoris, chronic ischaemic cardiomyopathy, myocardial infarction, transient ischaemic attacks, stroke, heart failure, renal failure)
- previous diagnosis of diabetes mellitus (fasting glycaemia >126 mg/dl or use of oral hypoglycaemic agents or insulin).

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RESULTS:

At the end of the study 1498 individuals were recruited.

53% were women and 47% were men.

449 out of 1498 individuals had a Metabolic Syndrome diagnosis according to the ATPIII criteria. This means that the prevalence of MS was 29.97%.

207 (46.1%) out of 449 individuals with MS were women and 242 (53.9%) were men.

In terms of age 221 (49.2%) individuals were < 65 years old and 228 (50.8) were ≥ 65 years old.

Blood pressure (systolic ≥ 130 mmHg and/or diastolic ≥ 85 mmHg) and abdominal obesity (waist circumference >102 cm in men and > 88 cm in women) were the most frequent risk factors of MS (93.1% and 83.1% respectively).

The others were fasting triglycerides (≥ 150 mg/dl) (70.8%), fasting blood glucose (≥ 110 mg/dl) (51.9) and HDL cholesterol (< 40 mg/dl in men and < 50 mg/dl in women) (52.3%).

The frequency of smokers, ex-smokers and non-smokers was 24.5%, 26.5% and 49% respectively.

A family history of hypertension, diabetes and cardiovascular diseases was present in 51.4%, 32.7% and 26.7% out of the individuals with MS respectively.

Finally, previous cardiovascular events or cardiovascular risk equivalents were recorded in the individuals with MS. The frequencies of these conditions were as follows: angina pectoris (8.0%), cerebral ischaemia (1.6%), renal failure (5.5%), chronic ischaemic heart disease (11,6%), diabetes mellitus (40.2%), peripheral arterial disease (6.1%), myocardial infarction (8.0%), heart failure (4.5%), previous revascularisation procedures (8.7%) and transient ischaemic attack (5.8%).

AZ Synopsis Template 2010 June 4