AstraZeneca

**STUDY REPORT SUMMARY**

**ASTRAZENECA PHARMACEUTICALS**

**FINISHED PRODUCT: -**
**ACTIVE INGREDIENT: -**

| **Study No: NIS-CFR-CRE-2007/1** |
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| PGRx-MI |

**Developmental Phase:**
**Study Completion Date: January 2011**
**Date of Report:** September 2011

## OBJECTIVES:

The objective of the study was to assess the impact of statins usage on the risk of having a first myocardial infarction (MI) in a real life situation in France.

## METHODS:

This study was conducted using data collected by the pharmaco-epidemiologic information system "PGRx".
PGRx is an information system employing the case-control methodology developed in response to the lack of databases or information systems available for the study of rare diseases and/or delayed adverse events associated with the use of medicines.
Cases of first recent (≤ 1 month) myocardial infarction (MI) were recruited prospectively by cardiologists participating in the PGRx network throughout France.
Controls were identified in the PGRx pool of referents recruited by general practitioners.
Referents were defined as patients who reside in the same regions as cases and seen by a participating general practitioner (GP) with no restriction as to the reasons for consultation.
For controls, eligibility criteria and matching rules have been applied during the draw of study controls from the pool of referents.

## RESULTS:

Out of 63 cardiology centres and 387 GP settings who had recruited at least one patient for the PGRx system, 60 cardiology centres and 371 GP settings were employed to be part of the PGRx Statins– MI study, after considering inclusion/exclusion criteria.

Overall, 3,110 cases were recruited, and after considering inclusion/exclusion criteria, 2,555 were interviewed; 12,313 referents were recruited, and after considering inclusion/exclusion criteria, 8,381 were interviewed. Among these, 2,238 controls were matched to 2238 cases for the case-control analysis.

Seventy-six per cent of MI cases were male, and only 24% were female. Majority of cases were more than 50 years old. Mean age of all patients was 59 years old.

All patients with recorded information had positive enzymatic criterion (either Troponin Ic > 2ULN or Troponin T > 2 ULN or CPKMB > 2 ULN), and 99% of patients were admitted with characteristic pain.

Having Body Mass Index (BMI) 25 kg/m² or more was associated with increase in the risk of the first MI by 17% to 22%, depending on the range of BMI.

Physical activity for more than 30 minutes a day was associated with decrease in the risk of the first MI by 35% (adjusted OR 0.65 ; 95% CI 0.56-0.75).

Among variables considered in the model, smoking was the factor that seemed to be associated with the most substantial increase in the risk of the first MI. Particularly, being a smoker was associated with around four times increase in the risk of the first MI compared to never smoked patients (adjusted OR 3.97 ; 95% CI 3.30-4.78).

Existence of cardiovascular related comorbidities, such as hypertension and diabetes, increased the risk of the first MI by around 54% (adjusted OR 1.54; 95% CI 1.32-1.80) or 22% (adjusted OR 1.22; 95% CI 1.00-1.50), respectively.

After adjusting for the various risk factors, current use of any statin (use in the 2 months before the index date, whatever the use in the 3 to 24 months period) was associated with significant reduction in the risk of the first MI by 33% (adjusted OR 0.67;95% CI 0.56 - 0.79).

In addition, those taking statins regularly (‘compliant’ patients) had substantially higher protective effect of statins compared to non-compliant patients -31% (adjusted OR 0.69; 95% CI 0.58-0.81) vs +36% (adjusted OR 1.36; 95% CI 0.87-2.13).

Among individual statin molecules, after similar adjustments, use of rosuvastatin within 24 months preceding the index date was associated with significant reduction in the risk of the first MI by around 37% compared to the use of simvastatin (adjusted OR 0.63 ; 95% CI 0.43-0.91). There were no significant differences when using any other statin molecules.

We also repeated the main model, changing reference from simvastatin to atorvastatin. No substantial differences in associations were observed as a result of such change. After adjusting for the same risk factors, use of rosuvastatin within 24 months preceding the index date was associated with significant reduction in the risk of the first MI by 49% compared to the use of atorvastatin (adjusted OR 0.51 ; 95% CI 0.36-0.73).