AstraZeneca

STUDY REPORT SUMMARY

ASTRAZENECA PHARMACEUTICALS

FINISHED PRODUCT: -
ACTIVE INGREDIENT: -

Study No: NIS-CFR-BRI-2012/1 - D5137L00001
AReMIS

Developmental Phase:
Study Completion Date: March 2016
Date of Report: December 2016

OBJECTIVES:

To determine if ticagrelor was associated with a lower risk of reMI (new non-fatal MI or cardiac death) compared with clopidogrel after acute coronary syndrome (ACS).

METHODS:

We designed a case-cohort study using the PGRx-ACS registry. Cases were reMI patients with an index ACS selected from a cohort of patients with an index ACS or external to the cohort but in the same cardiology sites. Controls with an index ACS but no reMI were selected from the same cohort through matching performed on age, sex, date, type of index ACS, and source of information on exposure, using a sample stratified by age (≤69 and >69 years old). Multivariate conditional logistic regression assessed the OR for reMI associated with ticagrelor vs. clopidogrel adjusted for ASA use, and other cardiovascular risk factors.

RESULTS:

From October 2013 to March 2016, a definitive sample of 1,047 cases and 2,234 controls was obtained from 409 cardiology and 67 general practice centres, after matching by type of index ACS (first unstable angina, first MI, recurrent ACS) on top of age, sex, and index date. Compared with clopidogrel, ticagrelor and prasugrel were associated with OR of 0.66 (95% CI: 0.53 - 0.83) and 0.74 (95% CI: 0.55 - 1.00), respectively, for the occurrence of reMI. In the subpopulation where the index ACS was a first MI, the OR for ticagrelor vs. clopidogrel was 0.50 (95% CI: 0.38 - 0.67). For ticagrelor, OR of 0.71 (95% CI: 0.51 - 0.99) and 0.63 (95% CI: 0.45 - 0.87) were found in the ≤69 and >70 year-old stratas.