Title: A pharmacoepidemiological study of Rivaroxaban use and potential adverse outcomes in routine clinical practice in the Netherlands

Progress Report - EUPAS11141

This PASS category 1 study is being conducted in collaboration with The PHARMO Institute for Drug Outcomes Research, a member of the ENCePP, in the population-based PHARMO Database Network in The Netherlands, which contains patient-level healthcare records. The study is currently ongoing. The primary objective of this prospective cohort study is to characterize the drug utilization, safety and effectiveness of rivaroxaban in approved indications under clinical practice conditions.

A Progress Report for this reporting period is provided below and includes descriptive statistics of the study cohort accrued from 01 Jan 2012 to 31 Dec 2017 in the PHARMO Database Network. This report describes some baseline characteristics of new users of rivaroxaban and acenocoumarol including age, gender and dose distributions.

In summary, users of rivaroxaban and acenocoumarol were identified from the overall population, captured in the PHARMO outpatient pharmacy dispensing database. This overall cohort has diagnostic information from hospital admissions and, for comorbidity, treatment of chronic conditions. A subcohort has additional diagnostic information available from GP records. However, for the present progress report, linkages between outpatient pharmacy dispensing data to data from general practices and hospital admissions have not been conducted yet, only limited baseline characteristics are included.
A total of 31 728 rivaroxaban users and 193 581 acenocoumarol users were identified in the PHARMO outpatient pharmacy database. Of those, 24 431 individuals had a first-time rivaroxaban dispensing record in the PHARMO outpatient pharmacy database and 101 595 individuals had a first acenocoumarol dispensing in 2012-2017. Among the first-time rivaroxaban users, 0.09% (n=23), 32.7% (n=7 991), 17.89% (n=4 355) and 49.45% (n=12 062) were prescribed rivaroxaban 2.5 mg, 10 mg, 15 mg and 20 mg tablets, respectively.

Of the study cohorts of 24 431 first-time users of rivaroxaban and 101 595 first-time users of acenocoumarol, the corresponding estimated numbers of patients with general practitioner (GP) data were 5 445 and 22 643, respectively. This estimation was based on the number of patients linked in 2016 (22%) since the linkage for 2017 had not been done yet. The proportion of patients with linkage to GP data tend to increase marginally over time, from 20% from previous report to 22% in the current report.

The mean age of study drug users was similar between the cohorts, though acenocoumarol users slightly older: 69±12 years among rivaroxaban users and 71±15 years among acenocoumarol users. There was a somewhat higher proportion of women in the in rivaroxaban cohort compared to the acenocoumarol cohort (51% vs 48%, respectively).

Study finalization is estimated for 2020.