Summary Interim Report - EUPAS9977

Title
An Observational Post-authorization Safety Specialist Cohort Event Monitoring Study (SCEM) to monitor the Safety and Utilization of rivaroxaban (XARELTO®) initiated in secondary care for the prevention of atherothrombotic events in patients who have had acute coronary syndrome (ACS) in England and Wales (The ROSE-ACS study): Interim analysis.

Keywords
Rivaroxaban – Post-marketing – Safety – SCEM – ROSE-ACS

Rationale and background
Rivaroxaban, co-administered with acetylsalicylic acid (ASA) alone or with ASA plus clopidogrel or ticlopidine, is indicated for the prevention of atherothrombotic events in adult patients after an ACS with elevated cardiac biomarkers in the EU.

Research question and objectives
To monitor the short-term (up to 12 weeks) safety and drug utilisation of rivaroxaban in combination with standard oral antiplatelet therapy for the prevention of atherothrombotic events after an ACS episode in the secondary care hospital setting in England and Wales.
The interim report includes the following:

a) **for both rivaroxaban and contextual cohorts**:
   Cohort accrual
   Demographics (age, sex) and reported indication
   Setting and reasons for prescribing

b) **for rivaroxaban cohort only**:
   Baseline health characteristics
   Therapy plan and treatment initiation including acute management
   Crude event frequencies for targeted and general events occurring in the 12 weeks observation period

Study design
An observational, population-based cohort design of two cohorts (rivaroxaban and a contextual cohort of patients receiving the current standard treatment of care) with data collection at start of treatment (index date) and 12 weeks post-index date.

Setting
Secondary care hospital setting in England and Wales.

Subjects and study size, including dropouts
Five hundred and twenty-six patients have provided consent to participate in the study. Baseline and Outcome Data case report forms (CRFs) were provided for 466 (88.6%) patients of which 400 (85.8%) were prescribed standard oral antiplatelet combination therapy alone i.e. the contextual

cohort, and 66 (14.2%) were prescribed rivaroxaban in combination with standard oral antiplatelet therapy.

Variables and data sources
Patient data were derived by healthcare professionals from medical charts at index date and 12 weeks post-index date. Information on specialist characteristics was derived from self-reported information, supplemented from publically available professional body registration data.

Results
A total of 466 evaluable patients (66 rivaroxaban and 400 contextual cohort) were available for the interim analysis. There were no bleeds which fulfilled the TIMI definition of non-CABG related major bleeding in the rivaroxaban group.

Discussion
This interim analysis of the ROSE-ACS Study data shows that rivaroxaban is largely being prescribed to populations in accordance with prescribing recommendations and national clinical guidelines. At interim datalock there were no bleeds in the rivaroxaban cohort which fulfilled the TIMI definition of non-CABG related major bleeding, although the cohort is small. The study is ongoing and continuing to recruit patients. The next final analysis will have greater power to detect bleeding events and estimate the incidence risk and rate. This report provides information on raw data, has undergone minimal data cleaning and will become obsolete when validation and follow-up are complete.

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