

Observational/Non-Interventional Registration Information

Unique Protocol ID: 13120

Brief Title: A study of the treatment pattern and bleeding risks in patients treated with prasugrel and clopidogrel

Official Title: Treatment Patterns and Bleeding Risks Comparison in Patients Treated with Clopidogrel and Prasugrel During the Index Hospitalisation in Germany

Secondary IDs: H7T-MC-B008

Study Type: Observational

Sponsor: Eli Lilly and Company

Collaborator(s): Arbeitsgemeinschaft Leitende Kardiologische Krankenhausärzte-Percutaneous Coronary Intervention (ALKK-PCI) registry in Germany

Brief Summary: The main purpose of this study is to describe the treatment patterns in prasugrel treated patients and to compare bleeding risks between prasugrel- and clopidogrel-treated patients during the index hospitalization in Germany.

Detailed Description: This is a prospective, non-interventional cohort study aimed to assess the bleeding risks in prasugrel-treated patients as compared to clopidogrel-treated patients and the treatment patterns of prasugrel during the index hospitalisation in the ALKK-PCI registry in Germany. Consecutive patients will be prospectively enrolled into the registry over a three-year recruitment period and observed only during the index hospitalisation following enrolment.

Overall Status: Recruiting

Study Start Date: Oct 15th, 2009

Study Completion Date: Oct 14th, 2012

Study Design:

Observational Study Model: Cohort

Time Perspective: Prospective

Biospecimen Retention: None Retained

Biospecimen Description: N/A

Enrollment: >13,000 (anticipated)

Outcome Measures:

Primary Outcome Measure: incidence rates of non-CABG-related bleeding and any bleeding in prasugrel- and clopidogrel-treated patients

Secondary Outcome Measures:

Counts and percentages of the treatment patterns (eg. indication, contraindications) in prasugrel-treated patients

Conditions or Focus of Study: acute coronary syndrome

Sample Population Description: Patients who undergo an invasive cardiac diagnostic procedure in hospitals participating in the ALKK-PCI registry will be considered for the study.

Sampling Method: Non-Probability Sample

Eligibility Criteria:

Inclusion Criteria:

- At least 18 years of age at study entry,
- Prescribed clopidogrel or prasugrel during the index hospitalisation.

Exclusion Criteria:

- Simultaneously participating in another study which includes an investigational drug or procedure at study entry.

Gender: Both

Minimum Age: 18 years

Maximum Age: N/A

Central Contact: 1-800-LillyRx

Countries of Recruitment: Germany