GEMINI-ACS-1: A Randomized Trial Evaluating Clinically Significant Bleeding With Low-Dose Rivaroxaban Versus Aspirin, in Addition to P2Y12 Inhibition, for Patients After Acute Coronary Syndromes

Purpose: To compare rivaroxaban to aspirin for bleeding risk (safety) in patients with ACS who are also taking a P2Y12 inhibitor, either clopidogrel or ticagrelor.

Trial Design: Randomized, phase 2, parallel-controlled, double-dummy, multi-center – 21 countries; N= 3037. Aspirin 100 mg daily + clopidogrel 75 mg daily; rivaroxaban 2.5 mg bid +clopidogrel 75 mg daily; aspirin 100 mg daily + ticagrelor 90 mg bid; rivaroxaban 2.5 mg bid + ticagrelor 90 mg bid. F/U up to 390 days.

Primary Endpoint: Number of patients with thrombolysis in myocardial infarction (TIMI) clinically significant bleeding events.

Trial Results	Aspirin	Rivaroxaban
Clinically significant bleeding	4.9%	5.3%
Mortality	4.7%	5%

Conclusions: Post ACS bleeding was not increased with the addition of rivaroxaban compared to aspirin. Patients were also taking either clopidogrel or ticagrelor.

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