The XAMOS Study

What is the XAMOS Study?

XAMOS (**XA**relto® in the prophylaxis of post-surgical venous thromboembolism after elective **M**ajor **O**rthopaedic **S**urgery of hip or knee) was a large real-world study in clot prevention following elective total hip or knee replacement surgery in over 17,000 patients.

- XAMOS was an international, non-interventional, open-label, controlled cohort study comparing outcomes observed in daily clinical practice in patients receiving oral 'Xarelto' or conventional pharmacological thromboprophylaxis regimens (standard of care)

- XAMOS was designed to represent a broad patient population as treated in routine clinical practice and was intended to supplement experience from RECORD clinical studies by providing information on the use of rivaroxaban in the orthopaedic setting

- Approximately 250 centres across 37 countries enrolled adult patients (aged 18 or over) undergoing elective hip or knee replacement surgery. The attending physician determined the type, duration and dose of thromboprophylaxis

- Main outcomes from the study included symptomatic thromboembolic events and bleeding events reported as adverse events. Other adverse events as well as all-cause mortality were also analysed. All adverse events, including symptomatic thromboembolic and bleeding events, were documented by the investigators[1]

XAMOS Results: Summary

- Findings from the XAMOS study reaffirm the safety and efficacy of 'Xarelto' for the prevention of VTE after elective total hip or knee replacement surgery. The incidence of symptomatic thromboembolic events was lower in patients treated with 'Xarelto' compared with standard of care (0.89% vs. 1.35%, respectively)[1]. Importantly, low and similar rates of major bleeding were observed in both study groups (major bleeding RECORD definition: 0.40% vs. 0.34%, respectively)[2]

- Results from XAMOS support the excellent clinical findings from RECORD (the world's largest clinical trial programme assessing novel oral anticoagulation in people requiring hip or knee replacement) which showed oral, once-daily 'Xarelto' to have consistently superior efficacy as well as a comparable and good safety profile in comparison to injectable LMWH enoxaparin

- Findings from XAMOS were presented at the Annual Scientific Meeting of the British Society for Haematology in Glasgow, Scotland in April 2012

XAMOS[1,2,3]	
Study design	♦ International, non-interventional, open-label cohort study ♦ Primary hip/knee replacement accounted for >90% of all procedures
Interventions	♦ Attending physician determined the type, duration and dose of 'Xarelto' or standard of care regimen
Number of patients	♦ 17,413 patients in 37 countries ♦ 8,778 patients received 'Xarelto' and 8,635 received standard of care [low molecular weight heparins (LMWHs), 81.7%]
Primary outcome measures	Outcomes were reported as serious or non-serious adverse events, and all events were analysed in the safety population ♦ Symptomatic thromboembolic events (e.g. arterial and venous thromboembolic events, including symptomatic deep vein thrombosis, pulmonary embolism) ♦ Bleeding events ♦ Other adverse events ♦ All-cause mortality
RESULTS	
Symptomatic thromboembolic events	♦ The incidence of symptomatic thromboembolic events was lower in patients treated with 'Xarelto' compared with standard of care ♦ 0.89% (78 of 8,778) 'Xarelto' patients versus 1.35% (117 of 8,635) standard of care patients
Major bleeding	♦ Comparable and low rates of major bleeding (RECORD definition) ♦ 0.40% (35 of 8,778) 'Xarelto' patients versus 0.34% (29 of 8,635) standard of care patients
Other outcomes	♦ Overall all-cause mortality was low in both groups at approximately 0.10% ♦ There was a low and comparable incidence of serious adverse events in 'Xarelto' and standard of care groups (4.0% vs 3.9%)

References

1) Turpie AG, A Schmidt A, Kreutz R, et al. Rationale and design of XAMOS: noninterventional study of rivaroxaban for prophylaxis of venous thromboembolism after major hip and knee surgery. *Vasc Health Risk Manag*. 2012; 8 363-370
2) Turpie AG, Jamal W, A Schmidt A, et al. XAMOS: A non-interventional study comparing oral rivaroxaban with conventional regimens for thromboprophylaxis after major orthopaedic surgery of the hip and knee. *Br. J. Haematol.* 2012; 157,(Suppl. 1)9-10, Abstract only
3) Clinicaltrials.gov. Available at http://www.clinicaltrials.gov/ct2/show/NCT00831714?term=XAMOS&rank=1. Last accessed April 2012

About Xarelto® (Rivaroxaban)

Rivaroxaban is the most broadly indicated novel oral anticoagulant and is marketed under the brand name Xarelto®. To date, Xarelto has been approved for use in the following venous arterial thromboembolic (VAT) indications:

- The prevention of stroke and systemic embolism in adult patients with non-valvular atrial fibrillation (AF) with one or more risk factors in more than 70 countries worldwide
- The treatment of deep vein thrombosis (DVT) and prevention of recurrent DVT and pulmonary embolism (PE) in adults in more than 70 countries worldwide
- The prevention of venous thromboembolism (VTE) in adult patients undergoing elective hip or knee replacement surgery in more than 120 countries worldwide

Since the first approval of Xarelto in 2008 in the orthopaedic setting, more than two and a half million patients worldwide have received Xarelto in daily clinical practice in this indication alone.

Rivaroxaban was discovered by Bayer HealthCare, and is being jointly developed with Janssen Research & Development, LLC. Xarelto is marketed outside the U.S. by Bayer HealthCare and in the U.S. by Janssen Pharmaceuticals, Inc. (a Johnson & Johnson Company).

Anticoagulant medicines are potent therapies used to prevent or treat serious illnesses and potentially life threatening conditions. Before initiating therapy with anticoagulant medicines, physicians should carefully assess the benefit and risk for the individual patient.

Responsible use of Xarelto is a high priority for Bayer, and the company has developed a Prescribers Guide for physicians and a Xarelto Patient Card for patients to support best practices. To learn more, please visit: https://prescribe.xarelto.com.

To learn more about thrombosis, please visit www.thrombosisadviser.com
To learn more about VAT, please visit www.VATspace.com
To learn more about Xarelto, please visit www.xarelto.com