

REAL WORLD

Real World XAMOS Study Reaffirms the Benefits of Oral, Once-daily 'Xarelto' in Everyday Clinical Practice to Prevent Potentially Deadly Blood Clots Following Major Hip or Knee Joint Replacement Surgery

Real World Study Confirms Clinical Value of 'Xarelto'

>17,000 Orthopaedic Surgery Patients from 37 Countries

Results Reaffirm Robust Findings from RECORD Studies

For patients undergoing hip or knee joint replacement surgery, venous thromboembolism (VTE) is a frequent and potentially fatal complication. Without prophylaxis, patients have a 40-60% risk of deep vein thrombosis (DVT) and up to a 30% risk of developing a pulmonary embolism (PE)¹.

XAMOS was an international, non-interventional, open-label, controlled cohort study comparing outcomes observed in daily clinical practice in both male and female patients aged 18 years or older, receiving oral 'Xarelto' or a standard care treatment for VTE prophylaxis.

Outcomes from the 17,413-patient XAMOS Study show 'Xarelto' provided a favourable benefit-risk profile with patients experiencing fewer thromboembolic events and comparable low major bleeds compared to conventional pharmacological thromboprophylaxis regimens (including low molecular weight heparins [LMWHs], unfractionated heparins, fondaparinux, dabigatran etexilate, acetylsalicylic acid and vitamin K antagonists [VKAs]). The attending physician determined the type, duration and dose of thromboprophylaxis^{1,2}.

XAMOS was published in the *Journal of Thrombosis and Haemostasis* in 2013². Results reaffirm the robust findings from the RECORD clinical development programme that demonstrates superior protection of oral, once-daily 'Xarelto' with similar safety compared to injectable enoxaparin following hip or knee joint replacement surgery³.

Efficacy Results

The incidence of symptomatic thromboembolic events was lower in patients treated with 'Xarelto' compared with conventional pharmacological thromboprophylaxis regimens (0.89% (78 of 8,778) vs. 1.35% (117 of 8,635))².

Safety Results

Importantly, low and similar rates of major bleeding were observed in both study groups (major bleeding RECORD definition: 0.40% (35 of 8,778) 'Xarelto' vs. 0.34% (29 of 8,635) conventional pharmacological thromboprophylaxis regimens)².

The extensive evaluation of rivaroxaban to protect different patient populations at risk of venous and arterial thromboembolism (VAT), makes it the most studied novel OAC in the world. Rivaroxaban (Xarelto®) is already approved for five indications in seven areas of use and its investigation - both completed and ongoing - will include more than 275,000 patients in clinical trials and real world settings.

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, Haas S, Kreutz R, et al. XAMOS. *Thrombosis and Haemostasis* 2014 Jan; 111(1): 94-102. 3) Eriksson BI, Kakkar AK, Turpie AG, et al. Oral rivaroxaban for the prevention of symptomatic venous thromboembolism after elective hip and knee replacement. *J Bone Joint Surg [Br].* 2009; 91-B: 636-44.