

AXIOMATIC-TKR

Milvexian for the Prevention
of Venous Thromboembolism

Parallel-Group, Open-Label Randomized Controlled Trial

OBJECTIVE: To compare the efficacy and safety of milvexian and enoxaparin in patients undergoing elective knee arthroplasty.

1,242
PATIENTS

INCLUSION CRITERIA: Patients undergoing unilateral total knee arthroplasty greater than 50 years of age without contraindication to enoxaparin or history of previous venous thromboembolism (VTE)



ENROLLED IN A 1:1:1:1:1:2 RATIO
MILVEXIAN AT FOUR TWICE DAILY REGIMENS
(25 MG [N=129], 50 MG [N=124], 100 MG [N=134],
200 MG [N=131]) OR TWO ONCE-DAILY REGIMENS
(50 MG [N=127] OR 200 MG [N=123])

OR



ENOXAPARIN AT 40 MG DAILY
(N=252)

PRIMARY ENDPOINT

COMPOSITE OUTCOME OF VTE (ASYMPTOMATIC DEEP VEIN THROMBOSIS BY MANUAL UNILATERAL VENOGRAPHY 10-14 DAYS AFTER SURGERY OR CONFIRMED SYMPTOMATIC VTE), OR DEATH FROM ANY CAUSE:

TWICE DAILY (P<0.001 FOR EFFICACY):
25 MG BID: 21%; 50 MG BID: 11%; 100 MG BID: 9%; 200 MG BID: 8%

ONCE DAILY (P<0.001 FOR EFFICACY):
50 MG DAILY: 24%; 200 MG DAILY: 7%.
TOTAL INCIDENCE ENOXAPARIN: 40 MG DAILY: 21%

SECONDARY OUTCOMES

BLEEDING OF ANY SEVERITY:
MILVEXIAN: 4% vs. ENOXAPARIN: 4%

CLINICALLY RELEVANT BLEEDING (COMPOSITE OF MAJOR BLEEDING AND CLINICALLY RELEVANT NONMAJOR BLEEDING)
MILVEXIAN: 1% vs. ENOXAPARIN: 2%

SERIOUS ADVERSE EVENTS:
MILVEXIAN: 2% vs. ENOXAPARIN: 4%

CONCLUSION

Postoperative factor XIa inhibition with oral milvexian was effective in the prevention of VTE after knee arthroplasty and associated with a low risk of bleeding.