

GSK Medicine: Fondaparinux Sodium	
Study No.: 108034	
Title: An open label, multi-centre, non-interventional post-marketing surveillance to monitor the safety and/or efficacy of fondaparinux sodium administered in Korean patients according to the prescribing information	
Rationale: The present study collected clinical data, mainly focused on safety as per the requirement of KFDA for market authorization.	
Objectives: Primary objective was to assess the occurrence of adverse events reported after administration of fondaparinux in Korean patients undergoing hip fracture surgery, hip replacement surgery and knee replacement surgery.	
Indication: Prevention of Venous Thromboembolic Events (VTE) in patients undergoing major orthopaedic surgery of the lower limbs such as: hip fracture, including extended prophylaxis, knee replacement surgery, hip replacement surgery	
Study Investigators/Centers: 25 Investigators/ 21 Centers	
Data Source: Standardized hard copy Case Report Form (CRF)	
Study Design: Open label, multi-center, post-marketing surveillance.	
Study Population: Male and female subjects who were considered appropriate to take fondaparinux according to the prescribing information were eligible for this study. Subjects who had previously been treated with fondaparinux were not eligible for this surveillance.	
Number of Subjects:	
Planned, N	3,000
Entered, N	1,599
Completed, N (%)	1,562(97.69)
Total Number Subjects Withdrawn, N (%)	37(2.31)
Withdrawn due to Adverse Events N (%)	0(0)
Withdrawn due to Lack of Efficacy N (%)	0(0)
Withdrawn for other reasons N (%)	31(2.31)
Study Exposures, Outcomes:	
Primary endpoint was the occurrence of adverse events after fondaparinux administration.	
Secondary outcomes were occurrence of unexpected adverse events after fondaparinux administration, occurrence of serious adverse events after fondaparinux administration, and Efficacy assessment.	
Data Analysis Methods:	
The percentage of individual adverse event during the follow-up period after administration of the study drug was tabulated with 95% confidence interval; to identify the risk factors related to the incidence of any adverse events, Chi-square test or Fisher's exact test were used.	
Limitations: As being a PMS, there was no comparison group.	
Demographics/Baseline Characteristics:	
N (ITT Safety population)	1,562
Female: Male(%)	78.80 : 21.20
Mean age, years ±SD	64.30±12.23
Type of surgery, N (%)	
Hip fracture surgery	166(10.63)
Knee replacement surgery	1,121(71.77)
Hip replacement surgery	156(9.99)
Others	119(7.62)
Concomitant disease, N(%)	
Yes	573(36.68)
No	989(63.32)
Concomitant medication, N(%)	
Yes	816(52.24)
No	746(47.76)

Primary Outcome			
Overall incidence of adverse events, N (% , 95% CI)	160(10.24, 8.74~11.75)		
Summary of incidence of adverse events	Adverse events, n(%)		
Covariates	Yes (N=160)	No(N=1,402)	p-value
Gender, n(%)			
Male	40(12.08)	291(87.92)	0.2150
Female	120(9.76)	1,110(90.24)	
Type of surgery, n(%)			
Hip fracture surgery	19(11.45)	147(88.55)	<0.0001
Knee replacement surgery	74(6.60)	1,047(93.40)	
Hip replacement surgery	53(33.97)	103(66.03)	
Others	14(11.76)	105(88.24)	
Concomitant disease, n(%)			
Yes	83(14.49)	490(85.51)	<0.0001
No	77(7.79)	912(92.21)	
Concomitant medication			
Yes	86(10.54)	730(89.46)	0.6866
No	74(9.92)	672(90.08)	
Secondary Outcome			
Efficacy (PP population), N	1,401		
Efficacy judged by investigators, N(%)			
Yes	1,399(99.9)		
No	2(0.1)		
Safety Results (ITT population), case (n)			
Unexpected adverse events, n	7		
Subjects with unexpected adverse events, N(%)	7(0.5)		
Most Frequent Adverse Events – On-Therapy			
Subjects with any AE(s), n(%)	N=160		
Anemia	107(6.9)		
Post-operative haemorrhage	32(2.1)		
Oedema	28(1.8)		
Hepatic enzymes increased	17(1.1)		
Surgical site reaction	10(0.6)		
Post-operative haematoma	4(0.3)		
Prothrombin time prolonged	3(0.2)		
Rash ecchymotic	3(0.2)		
Localised Oedema	2(0.1)		
Toxic hepatitis	2(0.1)		
Purpura	2(0.1)		
Serious Adverse Event	0(0.0)		
Conclusion			
The incidence of adverse events was 10.2%(160/1,562subjects, 218events) The serious adverse event was not occurred. The most frequent adverse event was anaemia.(6.9%, 107/1,562) The overall efficacy rate was 99.9 %(1,399/1,401).			
Note: The purpose of this study was to meet the requirement of KFDD which mandates PMS in case of new drug. So the result of this study was included in Arixtra re-examination report for KFDD along with Arixtra observational study (111271).			