ClinicalTrials.gov Protocol Registration and Results System (PRS) Receipt
Release Date: 02/18/2016

ClinicalTrials.gov ID: NCT00443053

Study Identification

Unique Protocol ID:	ART108053
Brief Title:	Evaluation Of Fondaparinux (Also Called ARIXTRA) 2.5 mg Subcutaneously Once Daily For The Treatment Of Superficial Thrombophlebitis (Also Known As Superficial Vein Thrombosis)
Official Title:	See Detailed Description
Secondary IDs:	

Study Status

Record Verification:	February 2013
Overall Status:	Completed
Study Start:	March 2007
Primary Completion:	July 2009 [Actual]
Study Completion:	July 2009 [Actual]

Sponsor/Collaborators

Sponsor:	GlaxoSmithKline
Responsible Party:	Sponsor
Collaborators:	GlaxoSmithKline

Oversight

FDA Regulated?:	
IND/IDE Protocol?:	No

Review Board:	Approval Status: Approved Approval Number: 46/06 Board Name: Comite Etico de Investigacion Clinica del Consorci Sanitari del Maresme Board Affiliation: Hospital de Mataro Phone: +34 93 741 77 00 Email: cmas@csdm.es
Data Monitoring?:	
Plan to Share Data?:	
Oversight Authorities:	Netherlands: Medicines Evaluation Board (MEB)

Study Description

Brief Summary:	To evaluate fondaparinux 2.5mg subcutaneously once daily for 45 days in the treatment of acute (recent) superficial thrombophlebitis.
Detailed Description:	Comparison of ARIXTRA™ in lower LImb Superficial Thrombophlebitis with placebo (CALISTO). An International, Multicentre, Randomised, Double-blind, Placebo-controlled, Two-parallel Group, Phase III Study to Evaluate the Efficacy and Safety of ARIXTRA (2.5 mg subcutaneously) for the Treatment of Patients with Acute Symptomatic Isolated Superficial Thrombophlebitis of the Lower Limbs to prevent Thromboembolic Complications

Conditions

Conditions:	Thrombosis, Venous
Keywords:	superficial vein thrombosis superficial thrombophlebitis fondaparinux deep vein thrombosis venous thromboembolism treatment thrombosis

Study Design

Study Type:	Interventional
Primary Purpose:	Treatment
Study Phase:	Phase 3
Intervention Model:	Parallel Assignment
Number of Arms:	2

Masking: Double Blind (Subject, Investigator, Outcomes Assessor)

Allocation: Randomized

Endpoint Classification: Safety/Efficacy Study

Enrollment: 3002 [Actual]

Arms and Interventions

Arms	Assigned Interventions
Active Comparator: Fondaparinux 2.5mg	Drug: Fondaparinux 2.5mg or placebo Fondaparinux 2.5mg or matching placebo subcutaneously once daily up to day 45 day
Placebo Comparator: Placebo	Drug: Fondaparinux 2.5mg or placebo Fondaparinux 2.5mg or matching placebo subcutaneously once daily up to day 45 day

Outcome Measures

[See Results Section.]

Eligibility

Minimum Age: 18 Years

Maximum Age:

Gender: Both

Accepts Healthy Volunteers?: No

Criteria: Inclusion criteria:

- Acute symptomatic superficial thrombophlebitis of the lower limbs at least 5 cm long diagnosed by compression ultrasound.

Exclusion criteria:

- Superficial thrombophlebitis that is within 3 cm from the sapheno-femoral junction,
- deep vein thrombosis on ultrasound exam, deep vein thrombosis or pulmonary embolism within last 6 months, treatment for cancer during last 6 months,
- anticoagulant medication for more than 48 hours prior to inclusion,
- need for oral non-steroidal anti-inflammatory drugs during the study, significant bleeding event during past month,
- major surgery within last 3 months, low platelet count (below 100×109/L),
- kidney disease (Calculated creatinine clearance < 30 mL/min), woman of child-bearing potential not using reliable contraceptive method

Contacts/Locations

Study Officials: GSK Clinical Trials
Study Director
GlaxoSmithKline

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References

Citations:

Links:

Study Data/Documents:

Participant Flow

Reporting Groups

	Description
Fondaparinux 2.5 mg	Fondaparinux 2.5 milligrams (mg) administered subcutaneously (SC) once daily for 45 days
Placebo	Matching placebo

Overall Study

	Fondaparinux 2.5 mg	Placebo
Started	1502	1500
Completed	1481	1467
Not Completed	21	33
Adverse Event	2	1
Withdrawal by Subject	9	18
Lost to Follow-up	4	5
Did Not Meet Eligibility Criteria	1	0
Noncompliance	2	1
Unknown	3	4
Physician Decision	0	4

Baseline Characteristics

Reporting Groups

	Description
Fondaparinux 2.5 mg	Fondaparinux 2.5 milligrams (mg) administered subcutaneously (SC) once daily for 45 days
Placebo	Matching placebo

Baseline Measures

	Fondaparinux 2.5 mg	Placebo	Total
Number of Participants	1502	1500	3002

	Fondaparinux 2.5 mg	Placebo	Total
Age, Continuous [units: years] Mean (Standard Deviation)	57.1 (13.29)	56.9 (13.56)	57.0 (13.43)
Gender, Male/Female [units: participants]			
Female	974	944	1918
Male	528	556	1084
Race/Ethnicity, Customized [units: participants]			
White, European Heritage	1485	1492	2977
Arabic/North African Heritage	15	4	19
African American Heritage	0	2	2
Asian/South Asian Heritage	0	1	1
Mixed Race	1	0	1
Missing	1	1	2

Outcome Measures

1. Primary Outcome Measure:

Measure Title	Number of Participants With at Least on Event of Venous Thromboembolism (VTE) and/or Death From Any Cause Recorded up to Day 47
Measure Description	VTE was defined as a composite of symptomatic deep-vein thrombosis (DVT), symptomatic pulmonary embolism (PE), symptomatic extension of superficial vein thrombosis (SVT), or symptomatic recurrence of SVT. All VTEs were confirmed by objective tests and then adjudicated by an independent central adjudication committee (CAC), whose members were blinded to treatment assignment.
Time Frame	Baseline to Day 47
Safety Issue?	No

Analysis Population Description

Intent-to-Treat (ITT) Population: all randomized participants

Reporting Groups

	Description
Fondaparinux 2.5 mg	Fondaparinux 2.5 milligrams (mg) administered subcutaneously (SC) once daily for 45 days
Placebo	Matching placebo

Measured Values

	Fondaparinux 2.5 mg	Placebo
Number of Participants Analyzed	1502	1500
Number of Participants With at Least on Event of Venous Thromboembolism (VTE) and/or Death From Any Cause Recorded up to Day 47 [units: participants]	13	88

Statistical Analysis 1 for Number of Participants With at Least on Event of Venous Thromboembolism (VTE) and/or Death From Any Cause Recorded up to Day 47

Statistical Analysis Overview	Comparison Groups	Fondaparinux 2.5 mg, Placebo
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	<0.001
	Comments	[Not specified]
	Method	Fisher Exact
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Risk Ratio (RR)
	Estimated Value	0.15
	Confidence Interval	(2-Sided) 95% 0.08 to 0.26
	Estimation Comments	[Not specified]

2. Secondary Outcome Measure:

Measure Title	Number of Participants With at Least One Event of Venous Thromboembolism (VTE) and/or Death From Any Cause Recorded up to Day 77
Measure Description	VTE was defined as a composite of symptomatic deep-vein thrombosis (DVT), symptomatic pulmonary embolism (PE), symptomatic extension of superficial vein thrombosis (SVT), or symptomatic recurrence of SVT. All VTEs were confirmed by objective tests and then adjudicated by an independent central adjudication committee (CAC), whose members were blinded to treatment assignment.
Time Frame	Baseline to Day 77
Safety Issue?	No

Analysis Population Description

ITT Population

Reporting Groups

	Description
Fondaparinux 2.5 mg	Fondaparinux 2.5 milligrams (mg) administered subcutaneously (SC) once daily for 45 days
Placebo	Matching placebo

Measured Values

	Fondaparinux 2.5 mg	Placebo
Number of Participants Analyzed	1502	1500
Number of Participants With at Least One Event of Venous Thromboembolism (VTE) and/or Death From Any Cause Recorded up to Day 77 [units: participants]	18	94

Statistical Analysis 1 for Number of Participants With at Least One Event of Venous Thromboembolism (VTE) and/or Death From Any Cause Recorded up to Day 77

Statistical Analysis Overview	Comparison Groups	Fondaparinux 2.5 mg, Placebo
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	<0.001
	Comments	[Not specified]
	Method	Fisher Exact
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Risk Ratio (RR)
	Estimated Value	0.19
	Confidence Interval	(2-Sided) 95% 0.12 to 0.32
	Estimation Comments	[Not specified]

3. Secondary Outcome Measure:

Measure Title	Number of Participants With at Least One Occurrence of Each Adjudicated Component of the Primary Efficacy Endpoint at Days (D) 47 and 77
Measure Description	VTE was defined as a composite of symptomatic DVT; symptomatic PE; symptomatic extension of SVT, defined as downstream progression of the initial SVT by at least 2 cm and to within <=3 cm from the sapheno-femoral junction; or symptomatic recurrence of SVT, defined as a new episode in any other superficial venous location, meeting the following criteria: the new SVT was in a different superficial vein and not directly contiguous upstream with the index SVT, or it was in the same superficial vein but clearly distinct from the index SVT with an open venous segment of at least 10 cm in length.
Time Frame	Days 47 and 77
Safety Issue?	No

Analysis Population Description

ITT Population

Reporting Groups

	Description
Fondaparinux 2.5 mg	Fondaparinux 2.5 milligrams (mg) administered subcutaneously (SC) once daily for 45 days
Placebo	Matching placebo

Measured Values

	Fondaparinux 2.5 mg	Placebo
Number of Participants Analyzed	1502	1500

	Fondaparinux 2.5 mg	Placebo
Number of Participants With at Least One Occurrence of Each Adjudicated Component of the Primary Efficacy Endpoint at Days (D) 47 and 77 [units: participants]		
Participants with at least one event, D 47	13	88
Death, D 47	2	1
Symptomatic PE, D 47	0	5
Symptomatic DVT, D 47	3	18
Symptomatic recurrence of SVT, D 47	5	24
Symptomatic extension of SVT, D 47	4	51
Participants with at least one event, D 77	18	94
Death, D 77	2	1
Symptomatic PE, D 77	0	6
Symptomatic DVT, D 77	4	19
Symptomatic recurrence of SVT, D 77	8	26
Symptomatic extension of SVT, D 77	5	54

4. Secondary Outcome Measure:

Measure Title	Number of Participants Who Required Surgery to Treat Superficial Vein Thrombosis Recurrence at Days 47 and 77
Measure Description	The number of participants requiring surgery was measured.
Time Frame	Days 47 and 77
Safety Issue?	No

Analysis Population Description
ITT Population

Reporting Groups

	Description
Fondaparinux 2.5 mg	Fondaparinux 2.5 milligrams (mg) administered subcutaneously (SC) once daily for 45 days

	Description
Placebo	Matching placebo

Measured Values

	Fondaparinux 2.5 mg	Placebo
Number of Participants Analyzed	1502	1500
Number of Participants Who Required Surgery to Treat Superficial Vein Thrombosis Recurrence at Days 47 and 77 [units: participants]		
Day 47	11	57
Day 77	15	61

5. Secondary Outcome Measure:

Measure Title	Number of Adjudicated Major Bleeding Events and Deaths at Days 47 and 77
Measure Description	Major bleeding was defined as bleeding that was fatal and/or (1) in a critical area/organ (e.g., intracranial, intraspinal, intraocular, retroperitoneal, intra-articular or pericardial, or intramuscular with compartment syndrome); (2) associated with a fall in hemoglobin >=20 g/L (1.24 mmol/L); (3) led to a transfusion of >=2 units of packed red blood cells/whole blood. The revision of the Day 47 time point was to account for participants with treatment duration longer than 45 days. Adverse events were evaluated “On-Treatment,” defined as from randomization up to the last injection +4 days.
Time Frame	Days 47 (or last dose plus 4 days) and 77
Safety Issue?	No

Analysis Population Description

As-Treated Population: randomized participants who received at least one dose of study treatment, as actually received

Reporting Groups

	Description
Fondaparinux 2.5 mg	Fondaparinux 2.5 milligrams (mg) administered subcutaneously (SC) once daily for 45 days
Placebo	Matching placebo

Measured Values

	Fondaparinux 2.5 mg	Placebo
Number of Participants Analyzed	1499	1488
Number of Adjudicated Major Bleeding Events and Deaths at Days 47 and 77 [units: events]		
Major bleeding events, Day 47	1	1
Deaths, Day 47	2	1
Major bleeding events, Day 77	1	1
Deaths, Day 77	2	1

6. Secondary Outcome Measure:

Measure Title	Number of Adjudicated Non-Major Bleeding Events at Days 47 and 77
Measure Description	Clinically relevant non-major bleeding was defined as clinically relevant bleeding that did not qualify as major but satisfied a priori criteria, and/or any bleeding that resulted in clinical consequences for a participant. The revision of the Day 47 time point was to account for participants with treatment duration longer than 45 days. Adverse events were evaluated “On-Treatment,” defined as from randomization up to the last injection +4 days.
Time Frame	Days 47 (or last dose plus 4 days) and 77
Safety Issue?	No

Analysis Population Description
As-Treated Population

Reporting Groups

	Description
Fondaparinux 2.5 mg	Fondaparinux 2.5 milligrams (mg) administered subcutaneously (SC) once daily for 45 days
Placebo	Matching placebo

Measured Values

	Fondaparinux 2.5 mg	Placebo
Number of Participants Analyzed	1499	1488
Number of Adjudicated Non-Major Bleeding Events at Days 47 and 77		

	Fondaparinux 2.5 mg	Placebo
[units: events]		
Day 47	5	8
Day 77	6	9

7. Secondary Outcome Measure:

Measure Title	Number of Any Adjudicated Bleeding Events at Days 47 and 77
Measure Description	The sum of adjudicated major bleeds, non-major clinically relevant bleeds, and minor bleeds was calculated. Minor bleeding was defined as other clinically overt bleeding events that did not meet the criteria for major or clinically relevant non-major bleeding. The revision of the Day 47 time point was to account for participants with treatment duration longer than 45 days. Adverse events were evaluated “On-Treatment,” defined as from randomization up to the last injection +4 days.
Time Frame	Days 47 (or last dose plus 4 days) and 77
Safety Issue?	No

Analysis Population Description

As-Treated Population

Reporting Groups

	Description
Fondaparinux 2.5 mg	Fondaparinux 2.5 milligrams (mg) administered subcutaneously (SC) once daily for 45 days
Placebo	Matching placebo

Measured Values

	Fondaparinux 2.5 mg	Placebo
Number of Participants Analyzed	1499	1488
Number of Any Adjudicated Bleeding Events at Days 47 and 77 [units: events]		
Day 47	15	14
Day 77	16	15

Reported Adverse Events

Time Frame	[Not specified]
Additional Description	Serious adverse events (SAEs) and adverse events (AEs) were collected in the As-Treated Population, defined as randomized participants who received at least one dose of study treatment, as actually received.

Reporting Groups

	Description
Fondaparinux 2.5 mg	Fondaparinux 2.5 milligrams (mg) administered subcutaneously (SC) once daily for 45 days
Placebo	Matching placebo

Serious Adverse Events

	Fondaparinux 2.5 mg	Placebo
	Affected/At Risk (%)	Affected/At Risk (%)
Total	10/1499 (0.67%)	16/1488 (1.08%)
Cardiac disorders		
Angina pectoris [A] †	0/1499 (0%)	1/1488 (0.07%)
Atrial fibrillation [A] †	0/1499 (0%)	1/1488 (0.07%)
Cardiac failure acute [A] †	0/1499 (0%)	1/1488 (0.07%)
Coronary artery disease [A] †	0/1499 (0%)	2/1488 (0.13%)
Myocardial infarction [A] †	0/1499 (0%)	1/1488 (0.07%)
Right ventricular failure [A] †	1/1499 (0.07%)	0/1488 (0%)
Gastrointestinal disorders		
Gastrointestinal haemorrhage [A] †	0/1499 (0%)	1/1488 (0.07%)
Intestinal obstruction [A] †	0/1499 (0%)	1/1488 (0.07%)
Hepatobiliary disorders		
Billiary colic [A] †	0/1499 (0%)	1/1488 (0.07%)

	Fondaparinux 2.5 mg	Placebo
	Affected/At Risk (%)	Affected/At Risk (%)
Cholelithiasis [A] †	0/1499 (0%)	1/1488 (0.07%)
Infections and infestations		
Erysipelas [A] †	0/1499 (0%)	1/1488 (0.07%)
Haematoma infection [A] †	0/1499 (0%)	1/1488 (0.07%)
Peritonsillar abscess [A] †	0/1499 (0%)	1/1488 (0.07%)
Prostatic abscess [A] †	0/1499 (0%)	1/1488 (0.07%)
Staphylococcal infection [A] †	0/1499 (0%)	1/1488 (0.07%)
Injury, poisoning and procedural complications		
Fall [A] †	1/1499 (0.07%)	0/1488 (0%)
Road traffic accident [A] †	0/1499 (0%)	1/1488 (0.07%)
Musculoskeletal and connective tissue disorders		
Fasciitis [A] †	0/1499 (0%)	1/1488 (0.07%)
Pain in extremity [A] †	1/1499 (0.07%)	0/1488 (0%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		
Bile duct cancer [A] †	1/1499 (0.07%)	0/1488 (0%)
Pancreatic carcinoma stage IV [A] †	1/1499 (0.07%)	0/1488 (0%)
Nervous system disorders		
Cerebrovascular accident [A] †	0/1499 (0%)	1/1488 (0.07%)
Vertebrobasilar insufficiency [A] †	1/1499 (0.07%)	0/1488 (0%)
Renal and urinary disorders		
Renal colic [A] †	0/1499 (0%)	1/1488 (0.07%)
Renal cyst [A] †	1/1499 (0.07%)	0/1488 (0%)
Urethral obstruction [A] †	0/1499 (0%)	1/1488 (0.07%)

	Fondaparinux 2.5 mg	Placebo
	Affected/At Risk (%)	Affected/At Risk (%)
Reproductive system and breast disorders		
Menometrorrhagia [A] †	0/1499 (0%)	1/1488 (0.07%)
Respiratory, thoracic and mediastinal disorders		
Chronic obstructive pulmonary disease [A] †	1/1499 (0.07%)	0/1488 (0%)
Skin and subcutaneous tissue disorders		
Dermatitis [A] †	1/1499 (0.07%)	0/1488 (0%)
Henoch-Schonlein purpura [A] †	0/1499 (0%)	1/1488 (0.07%)
Petechiae [A] †	0/1499 (0%)	1/1488 (0.07%)
Vascular disorders		
Circulatory collapse [A] †	1/1499 (0.07%)	0/1488 (0%)
Hypertensive crisis [A] †	0/1499 (0%)	1/1488 (0.07%)
Jugular vein thrombosis [A] †	1/1499 (0.07%)	0/1488 (0%)
Subclavian vein thrombosis [A] †	1/1499 (0.07%)	0/1488 (0%)
Vena cave thrombosis [A] †	1/1499 (0.07%)	0/1488 (0%)

† Indicates events were collected by systematic assessment.
A Term from vocabulary, MedDRA (12.0)

Other Adverse Events

Frequency Threshold Above Which Other Adverse Events are Reported: 1%

	Fondaparinux 2.5 mg	Placebo
	Affected/At Risk (%)	Affected/At Risk (%)
Total	95/1499 (6.34%)	79/1488 (5.31%)
General disorders		
Asthenia [A] †	14/1499 (0.93%)	16/1488 (1.08%)
Nervous system disorders		

	Fondaparinux 2.5 mg	Placebo
	Affected/At Risk (%)	Affected/At Risk (%)
Headache [A] †	34/1499 (2.27%)	31/1488 (2.08%)
Skin and subcutaneous tissue disorders		
Injection site hematoma [A] †	27/1499 (1.8%)	17/1488 (1.14%)
Vascular disorders		
Hypertension [A] †	20/1499 (1.33%)	15/1488 (1.01%)

† Indicates events were collected by systematic assessment.
A Term from vocabulary, MedDRA (12.0)

Limitations and Caveats

[Not specified]

More Information

Certain Agreements:

Principal Investigators are NOT employed by the organization sponsoring the study.

There IS an agreement between the Principal Investigator and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.

GSK agreements may vary with individual investigators, but will not prohibit any investigator from publishing. GSK supports the publication of results from all centers of a multi-center trial but requests that reports based on single-site data not precede the primary publication of the entire clinical trial.

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