Clinical trial results:
A Three Month Prospective Open Label Study of Therapy With Fragmin (Dalteparin Sodium Injection) in Children With Venous Thromboembolism With or Without Malignancies

Summary

EudraCT number	2016-000394-21
Trial protocol	ES SI PL GB DE HR
Global end of trial date	20 March 2018

Results information

Result version number	v2 (current)
This version publication date	16 June 2019
First version publication date	03 October 2018
Version creation reason	

Trial information

Trial identification

Sponsor protocol code	A6301094

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT00952380
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Pfizer, Inc.
Sponsor organisation address	235 E 42nd Street, New York, United States, NY 10017
Public contact	Pfizer ClinicalTrials.gov Call Center, Pfizer, Inc., 001 18007181021, ClinicalTrials.gov_Inquiries@pfizer.com
Scientific contact	Pfizer ClinicalTrials.gov Call Center, Pfizer, Inc., 001 18007181021, ClinicalTrials.gov_Inquiries@pfizer.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	30 May 2018
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	20 March 2018
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

1. To determine the pharmacodynamic (PD) profiles for treatment doses of dalteparin in pediatric subjects of different ages with venous thromboembolism (VTE), and with or without cancer, using anti-factor Xa levels and a population PD analysis methodology;
2. To determine the median dose (IU/kg) required to achieve therapeutic anti-Xa levels (0.5 to 1.0 International Units [IU]/mL) based on subject age and weight.

Protection of trial subjects:

The study was in compliance with the ethical principles derived from the Declaration of Helsinki and in compliance with all International Council for Harmonization (ICH) Good Clinical Practice (GCP) Guidelines. All the local regulatory requirements pertinent to safety of trial subjects were followed.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	20 August 2009
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Norway: 1
Country: Number of subjects enrolled	Russian Federation: 8
Country: Number of subjects enrolled	Slovenia: 1
Country: Number of subjects enrolled	Spain: 1
Country: Number of subjects enrolled	United States: 27
Worldwide total number of subjects	38
EEA total number of subjects	3

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	1
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	2
Children (2-11 years)	15

Adolescents (12-17 years)	20
Adults (18-64 years)	0
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

The study was conducted in the 5 countries from 20 August 2009 to 20 March 2018. A total of 38 subjects were enrolled. This study had dose adjustment (DA) phase (Day 1-7), pharmacodynamic (PD) phase (Day 8-14) and follow up (FU) phase (Day 15-104).

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Dalteparin Sodium: Group 1 (>=0 to <8 week)

Arm description:

Subjects aged greater than or equal to (>=) 0 to less than (<) 8 weeks were administered 125 international unit per kilogram (IU/kg) of dalteparin sodium injection subcutaneously twice daily from Day 1 to 7 in DA phase, Day 8 to 14 in PD phase and from Day 15 in FU phase (up to 104 days). Subjects were to participate in the study for up to 104 days of study drug treatment to monitor the status of the qualifying venous thromboembolism (VTE). Subjects were followed up for safety for up to 28 days after last dose of study drug (up to 132 days).

Arm type	Experimental
Investigational medicinal product name	Dalteparin sodium
Investigational medicinal product code	
Other name	Fragmin
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Subjects received 125 IU/kg of dalteparin sodium injection subcutaneously twice daily.

Arm title	Dalteparin Sodium: Group 2 (>=8 week to <2 year)

Arm description:

Subjects aged >=8 weeks to <2 years were administered 150 IU/kg of dalteparin sodium injection subcutaneously twice daily from Day 1 to 7 in DA phase, Day 8 to 14 in PD phase and from Day 15 in FU phase (up to 104 days). Subjects were to participate in the study for up to 104 days of study drug treatment to monitor the status of the qualifying VTE. Subjects were followed up for safety for up to 28 days after last dose of study drug (up to 132 days).

Arm type	Experimental
Investigational medicinal product name	Dalteparin sodium
Investigational medicinal product code	
Other name	Fragmin
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Subjects received 150 IU/kg of dalteparin sodium injection subcutaneously twice daily.

Arm title	Dalteparin Sodium: Group 3 (>=2 year to <8 year)

Arm description:

Subjects aged >=2 years to <8 years were administered 125 IU/kg of dalteparin sodium injection subcutaneously twice daily from Day 1 to 7 in DA phase, Day 8 to 14 in PD phase and from Day 15 in FU phase (up to 104 days). Subjects were to participate in the study for up to 104 days of study drug

treatment to monitor the status of the qualifying VTE. Subjects were followed up for safety for up to 28 days after last dose of study drug (up to 132 days).

Arm type	Experimental
Investigational medicinal product name	Dalteparin sodium
Investigational medicinal product code	
Other name	Fragmin
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Subjects received 125 IU/kg of dalteparin sodium injection subcutaneously twice daily.

Arm title	Dalteparin Sodium: Group 4 (>=8 year to <12 year)

Arm description:

Subjects aged >=8 years to <12 years were administered 125 IU/kg of dalteparin sodium injection subcutaneously twice daily from Day 1 to 7 in DA phase, Day 8 to 14 in PD phase and from Day 15 in FU phase (up to 104 days). Subjects were to participate in the study for up to 104 days of study drug treatment to monitor the status of the qualifying VTE. Subjects were followed up for safety for up to 28 days after last dose of study drug (up to 132 days).

Arm type	Experimental
Investigational medicinal product name	Dalteparin sodium
Investigational medicinal product code	
Other name	Fragmin
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Subjects received 125 IU/kg of dalteparin sodium injection subcutaneously twice daily.

Arm title	Dalteparin Sodium: Group 5 (>=12 year to <19 year)

Arm description:

Subjects aged >=12 years to <19 years were administered 100 IU/kg of dalteparin sodium injection subcutaneously twice daily from Day 1 to 7 in DA phase, Day 8 to 14 in PD phase and from Day 15 in FU phase (up to 104 days). Subjects were to participate in the study for up to 104 days of study drug treatment to monitor the status of the qualifying VTE. Subjects were followed up for safety for up to 28 days after last dose of study drug (up to 132 days).

Arm type	Experimental
Investigational medicinal product name	Dalteparin sodium
Investigational medicinal product code	
Other name	Fragmin
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Subjects received 100 IU/kg of dalteparin sodium injection subcutaneously twice daily.

Number of subjects in period 1	Dalteparin Sodium: Group 1 (>=0 to <8 week)	Dalteparin Sodium: Group 2 (>=8 week to <2 year)	Dalteparin Sodium: Group 3 (>=2 year to <8 year)
Started	1	2	8
Completed	1	1	6
Not completed	0	1	2
Physician decision	-	-	1
Adverse Event	-	1	-
Non-compliant to protocol	-	-	-

Unspecified	-	-	-
Withdrawal by subject	-	-	1

Number of subjects in period 1	Dalteparin Sodium: Group 4 (>=8 year to <12 year)	Dalteparin Sodium: Group 5 (>=12 year to <19 year)
Started	7	20
Completed	4	14
Not completed	3	6
Physician decision	2	-
Adverse Event	-	3
Non-compliant to protocol	1	-
Unspecified	-	1
Withdrawal by subject	-	2

Baseline characteristics

Reporting groups	
Reporting group title	Dalteparin Sodium: Group 1 (>=0 to <8 week)
Reporting group description:	
Subjects aged greater than or equal to (>=) 0 to less than (<) 8 weeks were administered 125 international unit per kilogram (IU/kg) of dalteparin sodium injection subcutaneously twice daily from Day 1 to 7 in DA phase, Day 8 to 14 in PD phase and from Day 15 in FU phase (up to 104 days). Subjects were to participate in the study for up to 104 days of study drug treatment to monitor the status of the qualifying venous thromboembolism (VTE). Subjects were followed up for safety for up to 28 days after last dose of study drug (up to 132 days).	
Reporting group title	Dalteparin Sodium: Group 2 (>=8 week to <2 year)
Reporting group description:	
Subjects aged >=8 weeks to <2 years were administered 150 IU/kg of dalteparin sodium injection subcutaneously twice daily from Day 1 to 7 in DA phase, Day 8 to 14 in PD phase and from Day 15 in FU phase (up to 104 days). Subjects were to participate in the study for up to 104 days of study drug treatment to monitor the status of the qualifying VTE. Subjects were followed up for safety for up to 28 days after last dose of study drug (up to 132 days).	
Reporting group title	Dalteparin Sodium: Group 3 (>=2 year to <8 year)
Reporting group description:	
Subjects aged >=2 years to <8 years were administered 125 IU/kg of dalteparin sodium injection subcutaneously twice daily from Day 1 to 7 in DA phase, Day 8 to 14 in PD phase and from Day 15 in FU phase (up to 104 days). Subjects were to participate in the study for up to 104 days of study drug treatment to monitor the status of the qualifying VTE. Subjects were followed up for safety for up to 28 days after last dose of study drug (up to 132 days).	
Reporting group title	Dalteparin Sodium: Group 4 (>=8 year to <12 year)
Reporting group description:	
Subjects aged >=8 years to <12 years were administered 125 IU/kg of dalteparin sodium injection subcutaneously twice daily from Day 1 to 7 in DA phase, Day 8 to 14 in PD phase and from Day 15 in FU phase (up to 104 days). Subjects were to participate in the study for up to 104 days of study drug treatment to monitor the status of the qualifying VTE. Subjects were followed up for safety for up to 28 days after last dose of study drug (up to 132 days).	
Reporting group title	Dalteparin Sodium: Group 5 (>=12 year to <19 year)
Reporting group description:	
Subjects aged >=12 years to <19 years were administered 100 IU/kg of dalteparin sodium injection subcutaneously twice daily from Day 1 to 7 in DA phase, Day 8 to 14 in PD phase and from Day 15 in FU phase (up to 104 days). Subjects were to participate in the study for up to 104 days of study drug treatment to monitor the status of the qualifying VTE. Subjects were followed up for safety for up to 28 days after last dose of study drug (up to 132 days).	

Reporting group values	Dalteparin Sodium: Group 1 (>=0 to <8 week)	Dalteparin Sodium: Group 2 (>=8 week to <2 year)	Dalteparin Sodium: Group 3 (>=2 year to <8 year)
Number of subjects	1	2	8
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	1	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	2	0
Children (2-11 years)	0	0	8
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	0	0	0
From 65-84 years	0	0	0

85 years and over	0	0	0

Age Continuous			
Units: years			
median	0.0684	1.0569	5.3676
full range (min-max)	0.0684 to 0.0684	0.1999 to 1.9138	2.3409 to 7.3949
Sex: Female, Male			
Units: Subjects			
Female	0	1	2
Male	1	1	6
Race (NIH/OMB)			
Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	0	0
White	1	2	7
More than one race	0	0	0
Unknown or Not Reported	0	0	1
Ethnicity (NIH/OMB)			
Units: Subjects			
Hispanic or Latino	0	0	2
Not Hispanic or Latino	1	2	6
Unknown or Not Reported	0	0	0

Reporting group values	Dalteparin Sodium: Group 4 (>=8 year to <12 year)	Dalteparin Sodium: Group 5 (>=12 year to <19 year)	Total
Number of subjects	7	20	38
Age categorical			
Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	1
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	2
Children (2-11 years)	7	0	15
Adolescents (12-17 years)	0	20	20
Adults (18-64 years)	0	0	0
From 65-84 years	0	0	0
85 years and over	0	0	0
Age Continuous			
Units: years			
median	10.0287	15.7208	
full range (min-max)	8.3833 to 11.8741	12.4682 to 18.7187	-
Sex: Female, Male			
Units: Subjects			
Female	5	6	14
Male	2	14	24

Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	0	1	1
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	3	4	7
White	4	15	29
More than one race	0	0	0
Unknown or Not Reported	0	0	1
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	2	4	8
Not Hispanic or Latino	5	16	30
Unknown or Not Reported	0	0	0

End points

End points reporting groups

Reporting group title	Dalteparin Sodium: Group 1 (>=0 to <8 week)

Reporting group description:

Subjects aged greater than or equal to (>=) 0 to less than (<) 8 weeks were administered 125 international unit per kilogram (IU/kg) of dalteparin sodium injection subcutaneously twice daily from Day 1 to 7 in DA phase, Day 8 to 14 in PD phase and from Day 15 in FU phase (up to 104 days). Subjects were to participate in the study for up to 104 days of study drug treatment to monitor the status of the qualifying venous thromboembolism (VTE). Subjects were followed up for safety for up to 28 days after last dose of study drug (up to 132 days).

Reporting group title	Dalteparin Sodium: Group 2 (>=8 week to <2 year)

Reporting group description:

Subjects aged >=8 weeks to <2 years were administered 150 IU/kg of dalteparin sodium injection subcutaneously twice daily from Day 1 to 7 in DA phase, Day 8 to 14 in PD phase and from Day 15 in FU phase (up to 104 days). Subjects were to participate in the study for up to 104 days of study drug treatment to monitor the status of the qualifying VTE. Subjects were followed up for safety for up to 28 days after last dose of study drug (up to 132 days).

Reporting group title	Dalteparin Sodium: Group 3 (>=2 year to <8 year)

Reporting group description:

Subjects aged >=2 years to <8 years were administered 125 IU/kg of dalteparin sodium injection subcutaneously twice daily from Day 1 to 7 in DA phase, Day 8 to 14 in PD phase and from Day 15 in FU phase (up to 104 days). Subjects were to participate in the study for up to 104 days of study drug treatment to monitor the status of the qualifying VTE. Subjects were followed up for safety for up to 28 days after last dose of study drug (up to 132 days).

Reporting group title	Dalteparin Sodium: Group 4 (>=8 year to <12 year)

Reporting group description:

Subjects aged >=8 years to <12 years were administered 125 IU/kg of dalteparin sodium injection subcutaneously twice daily from Day 1 to 7 in DA phase, Day 8 to 14 in PD phase and from Day 15 in FU phase (up to 104 days). Subjects were to participate in the study for up to 104 days of study drug treatment to monitor the status of the qualifying VTE. Subjects were followed up for safety for up to 28 days after last dose of study drug (up to 132 days).

Reporting group title	Dalteparin Sodium: Group 5 (>=12 year to <19 year)

Reporting group description:

Subjects aged >=12 years to <19 years were administered 100 IU/kg of dalteparin sodium injection subcutaneously twice daily from Day 1 to 7 in DA phase, Day 8 to 14 in PD phase and from Day 15 in FU phase (up to 104 days). Subjects were to participate in the study for up to 104 days of study drug treatment to monitor the status of the qualifying VTE. Subjects were followed up for safety for up to 28 days after last dose of study drug (up to 132 days).

Subject analysis set title	Dalteparin Sodium: All Subjects (>= 0 to < 19 years)
Subject analysis set type	Safety analysis

Subject analysis set description:

All subjects who received dalteparin sodium injection, subcutaneously at a dose of 100 to 150 IU/kg twice daily from Day 1 to 7 in dose adjustment phase, Day 8-14 in PD phase and from Day 15 in follow up phase until bleeding necessitating or unexpected permanent discontinuation of anticoagulation therapy, unexpected thrombocytopenia and other adverse event necessitating discontinuation of study drug (up to a maximum of 132 days).

Primary: Median Dose of Dalteparin Required to Achieve Prespecified Therapeutic Anti- Factor Xa Level

End point title	Median Dose of Dalteparin Required to Achieve Prespecified Therapeutic Anti- Factor Xa Level[1]

End point description:

Prespecified therapeutic anti-factor Xa level was 0.5-1.0 international unit per milliliter (IU/mL). Cumulative data of Day 1 to 7 has been reported. The PD analysis set included all subjects who received at least 1 dose of study drug and achieved therapeutic range of anti-factor Xa during dose adjustment phase.

End point type	Primary

End point timeframe:

4 hours post-dose at each Day 1 to 7 in dose adjustment phase

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Justification: Descriptive analysis was planned to be reported for arms Dalteparin Sodium: Group 2 (>=8 week to <2 year), Group 3 (>=2 year to <8 year), Group 4 (>=8 year to <12 year) and Group 5 (>=12 year to <19 year

End point values	Dalteparin Sodium: All Subjects (>= 0 to < 19 years)			
Subject group type	Subject analysis set			
Number of subjects analysed	34			
Units: IU/mL				
median (full range (min-max))	125 (99.1 to 213.5)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Who Achieved Prespecified Therapeutic Anti-Factor Xa Levels

End point title	Percentage of Subjects Who Achieved Prespecified Therapeutic Anti- Factor Xa Levels

End point description:

Prespecified therapeutic anti-factor Xa level was 0.5-1.0 IU/mL. Percentage of subjects who achieved the prespecified level during the dose adjustment phase were reported in this endpoint. Analysis population included all the subjects who received at least 1 dose of study drug.

End point type	Secondary

End point timeframe:

Day 1 to 7 in dose adjustment phase

End point values	Dalteparin Sodium: Group 1 (>=0 to <8 week)	Dalteparin Sodium: Group 2 (>=8 week to <2 year)	Dalteparin Sodium: Group 3 (>=2 year to <8 year)	Dalteparin Sodium: Group 4 (>=8 year to <12 year)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	2	8	7
Units: percentage of subjects				
number (confidence interval 95%)	0 (0.00 to 97.50)	100.0 (15.81 to 100.0)	100.0 (63.06 to 100.0)	100.0 (59.04 to 100.0)

End point values	Dalteparin Sodium: Group 5 (>=12 year to <19 year)			

Subject group type	Reporting group			
Number of subjects analysed	20			
Units: percentage of subjects				
number (confidence interval 95%)	85.0 (62.11 to 96.79)			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With New or Progressive Symptomatic Venous Thromboembolism (VTE)

End point title	Number of Subjects With New or Progressive Symptomatic Venous Thromboembolism (VTE)[2]

End point description:

Symptomatic VTE defined as new or progressive signs and symptoms as judged by the investigator including but not limited to: objective swelling, pain or tenderness, pitting edema, erythema or cyanosis. Progression of VTE: Progression of clot burden in terms of severity of occlusion, or involvement of new venous segments at any time after the initial diagnosis. The PD analysis set included all subjects who received at least 1 dose of study drug and achieved therapeutic range of anti-factor Xa during dose adjustment phase. Data for this endpoint was not planned to be collected and analysed for age group of >=0 to <8 weeks.

End point type	Secondary

End point timeframe:

Baseline up to 28 days after the last dose of study drug (up to Day 132)

Notes:

[2] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Justification: Descriptive analysis was planned to be reported for arms Dalteparin Sodium: Group 2 (>=8 week to <2 year), Group 3 (>=2 year to <8 year), Group 4 (>=8 year to <12 year) and Group 5 (>=12 year to <19 year

End point values	Dalteparin Sodium: Group 2 (>=8 week to <2 year)	Dalteparin Sodium: Group 3 (>=2 year to <8 year)	Dalteparin Sodium: Group 4 (>=8 year to <12 year)	Dalteparin Sodium: Group 5 (>=12 year to <19 year)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	8	7	17
Units: subjects	0	0	1	0

Statistical analyses

No statistical analyses for this end point

Secondary: Time to First Occurrence of Symptomatic Recurrent Venous Thromboembolism (VTE)

End point title	Time to First Occurrence of Symptomatic Recurrent Venous Thromboembolism (VTE)

End point description:

It was defined as the time interval (in days) between date of first study treatment and date of documentation of first VTE. VTEs included both Deep Vein Thrombosis (DVT) and Pulmonary Embolism (PE). DVT is a blood clot in the deep veins of the leg. If a DVT clot breaks off from a vein wall and flows

towards the lungs and blocks some or all of the blood supply, it becomes PE. When a blood clot breaks, loose and travels in the blood, this is called VTE. VTE was confirmed by at least one radiographic test and was defined as any new or progressive VTE whose signs and symptoms (identified by the investigator) included: objective swelling or tenderness, pitting edema, erythema or cyanosis. The PD analysis set included all subjects who received at least 1 dose of study drug and achieved therapeutic range of anti-factor Xa during dose adjustment phase.

End point type	Secondary

End point timeframe:

Baseline up to 28 days after the last dose of study drug (up to Day 132)

End point values	Dalteparin Sodium: All Subjects (>= 0 to < 19 years)			
Subject group type	Subject analysis set			
Number of subjects analysed	0[3]			
Units: days				
median (confidence interval 95%)	(to)			

Notes:

[3] - Median and 95% CI was not estimable due to the low number of subjects who had VTE.

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With Clinical Response of Progression, Regression, Resolution and No Change in Venous Thromboembolism (VTE)

End point title	Percentage of Subjects With Clinical Response of Progression, Regression, Resolution and No Change in Venous Thromboembolism (VTE)[4]

End point description:

VTEs included both DVT and PE. DVT is a blood clot in the deep veins of the leg. PE is a blood clot in the lungs. Clinical response of progression was defined as progression of clot burden in terms of severity of occlusion, or involvement of new venous segments at any time after the initial diagnosis. Clinical response of regression: Regressed clot burden utilizing the same imaging modality as the screening visit. Clinical response of resolution: Thrombus resolution of the qualifying event measured by repeat imaging at the end of study (EOS) visit. The PD analysis set included all subjects who received at least 1 dose of study drug and achieved therapeutic range of anti-factor Xa during dose adjustment phase. Data for this endpoint was not planned to be collected and analysed for age group of >=0 to <8 weeks.

End point type	Secondary

End point timeframe:

Baseline up to 28 days after the last dose of study drug (up to Day 132)

Notes:

[4] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Justification: Descriptive analysis was planned to be reported for arms Dalteparin Sodium: Group 2 (>=8 week to <2 year), Group 3 (>=2 year to <8 year), Group 4 (>=8 year to <12 year) and Group 5 (>=12 year to <19 year

End point values	Dalteparin Sodium: Group 2 (>=8 week to <2 year)	Dalteparin Sodium: Group 3 (>=2 year to <8 year)	Dalteparin Sodium: Group 4 (>=8 year to <12 year)	Dalteparin Sodium: Group 5 (>=12 year to <19 year)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	8	7	17
Units: percentage of subjects				
number (confidence interval 95%)				
Progression	0 (0.00 to 84.19)	0 (0.00 to 36.94)	0 (0.00 to 40.96)	0 (0.00 to 19.51)
Regression	0 (0.00 to 84.19)	12.5 (0.32 to 52.65)	14.3 (0.36 to 57.87)	29.4 (10.31 to 55.96)
Resolution	100.0 (15.81 to 100.0)	62.5 (24.49 to 91.48)	57.1 (18.41 to 90.10)	58.8 (32.92 to 81.56)
No Change	0 (0.00 to 84.19)	0 (0.00 to 36.94)	14.3 (0.36 to 57.87)	5.9 (0.15 to 28.69)

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With Major and Minor Bleeding Event

End point title	Percentage of Subjects With Major and Minor Bleeding Event

End point description:

A bleeding event was considered as major if it was clinically overt and satisfies 1 or more of the following criteria: fatal bleeding, bleeding accompanied by a decrease in hemoglobin of at least 2 grams per deciliter 24 hours, Overt bleeding deemed by the attending physician to necessitate permanent discontinuation of trial medication, Overt bleeding deemed by the attending physician to be unrelated to the subject's underlying condition and accompanied by blood product administration or bleeding occurred at a critical site (intraocular, intracranial, retroperitoneal). A bleeding event was considered as minor if it was clinically overt but not meeting the criteria for major or clinically relevant no major bleeding (bleeding resulting in any medical or surgical interventions but which did not meet the criteria for major bleeding). The safety analysis set included all the subjects who received at least 1 dose of study drug.

End point type	Secondary

End point timeframe:

Baseline up to 28 days after the last dose of study drug (up to Day 132)

End point values	Dalteparin Sodium: Group 1 (>=0 to <8 week)	Dalteparin Sodium: Group 2 (>=8 week to <2 year)	Dalteparin Sodium: Group 3 (>=2 year to <8 year)	Dalteparin Sodium: Group 4 (>=8 year to <12 year)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	2	8	7
Units: percentage of subjects				
number (confidence interval 95%)				
Major Bleeding	0 (0.00 to 97.50)	50.0 (1.26 to 98.74)	0 (0.00 to 36.94)	0 (0.00 to 40.96)
Minor Bleeding	0 (0.00 to 97.50)	0 (0.00 to 84.19)	50.0 (15.70 to 84.30)	57.1 (18.41 to 90.10)

End point values	Dalteparin Sodium: Group 5 (>=12 year to <19 year)			
Subject group type	Reporting group			
Number of subjects analysed	20			
Units: percentage of subjects				
number (confidence interval 95%)				
Major Bleeding	0 (0.00 to 16.84)			
Minor Bleeding	40.0 (19.12 to 63.95)			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With Treatment Emergent Adverse Events (AEs) and Serious Adverse Events (SAEs)

End point title	Number of Subjects With Treatment Emergent Adverse Events (AEs) and Serious Adverse Events (SAEs)

End point description:

An AE was any untoward medical occurrence in a subject who received study drug without regard to possibility of causal relationship. SAE was an AE resulting in any of the following outcomes or deemed significant for any other reason: death; initial or prolonged inpatient hospitalization; life-threatening experience (immediate risk of dying); persistent or significant disability/incapacity; congenital anomaly. Treatment-emergent are events between first dose of study drug and up to 28 days after the last dose of study drug (up to Day 132) that were absent before treatment or that worsened relative to pretreatment state. AEs included both SAEs and non-SAEs. The safety analysis set included all the subjects who received at least 1 dose of study drug. The safety analysis set included all the subjects who received at least 1 dose of study drug.

End point type	Secondary

End point timeframe:

Baseline up to 28 days after the last dose of study drug (up to Day 132)

End point values	Dalteparin Sodium: Group 1 (>=0 to <8 week)	Dalteparin Sodium: Group 2 (>=8 week to <2 year)	Dalteparin Sodium: Group 3 (>=2 year to <8 year)	Dalteparin Sodium: Group 4 (>=8 year to <12 year)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	2	8	7
Units: subjects				
AEs	1	2	7	7
SAEs	0	2	3	3

End point values	Dalteparin Sodium: Group 5 (>=12 year to <19 year)			
Subject group type	Reporting group			
Number of subjects analysed	20			
Units: subjects				
AEs	19			
SAEs	13			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With Laboratory Abnormalities

End point title	Number of Subjects With Laboratory Abnormalities

End point description:

Hematology:hemoglobin,hematocrit, erythrocytes <0.8*lower limit of normal (LLN), platelets <0.5*LLN >1.75*upper limit of normal (ULN),leukocytes <0.6* LLN >1.5* ULN, lymphocytes lymphocytes/Leukocytes%, neutrophils, neutrophils/leukocytes <0.8* LLN >1.2* ULN,basophils, basophils/leukocytes%,eosinophils,eosinophils/leukocytes, monocytes monocytes/leukocytes% >1.2*ULN, activated partial thromboplastin time, prothrombin time, prothrombin intl. normalized ratio >1.1* ULN.Chemistry: bilirubin >1.5*ULN, AST, ALT, lactate dehydrogenase, alkaline phosphatase >3.0*ULN, protein, albumin <0.8* LLN >1.2* ULN, blood urea nitrogen, creatinine >1.3* ULN, sodium <0.95*LLN >1.05*ULN, potassium, chloride, calcium, magnesium <0.9* LLN >1.1* ULN, phosphate <0.8* LLN >1.2* ULN, glucose <0.6*LLN >1.5*ULN, estimated creatinine clearance, estimated Glomerular filtration rate modified and bedside schwartz, >1.0*ULN. Urinalysis: creatinine >1.0*ULN.N=number of subjects evaluable for this end point.Safety set.

End point type	Secondary

End point timeframe:

Baseline up to 104 days

End point values	Dalteparin Sodium: Group 1 (>=0 to <8 week)	Dalteparin Sodium: Group 2 (>=8 week to <2 year)	Dalteparin Sodium: Group 3 (>=2 year to <8 year)	Dalteparin Sodium: Group 4 (>=8 year to <12 year)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	2	8	7
Units: subjects	1	2	8	5

End point values	Dalteparin Sodium: Group 5 (>=12 year to <19 year)			
Subject group type	Reporting group			
Number of subjects analysed	19			
Units: subjects	19			

Statistical analyses

No statistical analyses for this end point

Secondary: Absolute Values of Systolic Blood Pressure (SBP) and Diastolic Blood Pressure (DSBP) in Subjects

End point title	Absolute Values of Systolic Blood Pressure (SBP) and Diastolic Blood Pressure (DSBP) in Subjects

End point description:

Here "n" signifies the number of subjects evaluable at specific time points. The safety analysis set included all the subjects who received at least 1 dose of study drug.

End point type	Secondary

End point timeframe:

Baseline, Day 1, Day 2, Day 30, Day 60, Day 90

End point values	Dalteparin Sodium: Group 1 (>=0 to <8 week)	Dalteparin Sodium: Group 2 (>=8 week to <2 year)	Dalteparin Sodium: Group 3 (>=2 year to <8 year)	Dalteparin Sodium: Group 4 (>=8 year to <12 year)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	2	8	7
Units: millimeters of mercury (mmHg)				
median (full range (min-max))				
SBP: Baseline (n= 1,1,6,3,12)	101.00 (101.00 to 101.00)	50.00 (50.00 to 50.00)	110.50 (95.00 to 119.00)	96.00 (94.00 to 119.00)
SBP: Day 1 (n= 1,2,4,6,15)	97.00 (97.00 to 97.00)	105.50 (63.00 to 148.00)	112.00 (100.00 to 137.00)	111.00 (100.00 to 126.00)
SBP: Day 2 (n= 1,1,8,7,18)	94.00 (94.00 to 94.00)	75.00 (75.00 to 75.00)	107.00 (90.00 to 128.00)	112.00 (101.00 to 126.00)
SBP: Day 30 (n=1,1,7,5,17)	77.00 (77.00 to 77.00)	77.00 (77.00 to 77.00)	112.00 (100.00 to 123.00)	109.00 (100.00 to 113.00)
SBP: Day 60 (n=1,1,7,5,14)	74.00 (74.00 to 74.00)	102.00 (102.00 to 102.00)	101.00 (91.00 to 124.00)	118.00 (102.00 to 130.00)
SBP: Day 90(n=1,2,8,7,19)	76.00 (76.00 to 76.00)	105.00 (93.00 to 117.00)	97.50 (90.00 to 105.00)	116.00 (99.00 to 123.00)
DSBP:Baseline (n=1,1,6,3,12)	60.00 (60.00 to 60.00)	41.00 (41.00 to 41.00)	66.00 (50.00 to 77.00)	67.00 (60.00 to 75.00)
DSBP: Day 1(n=1,2,4,6,15)	61.00 (61.00 to 61.00)	57.00 (41.00 to 73.00)	65.50 (50.00 to 87.00)	66.50 (54.00 to 81.00)
DSBP:Day 2 (n= 1,1,8,7,18)	48.00 (48.00 to 48.00)	53.00 (53.00 to 53.00)	60.50 (53.00 to 70.00)	70.00 (65.00 to 79.00)
DSBP:Day 30 (n= 1,1,7,5,17)	53.00 (53.00 to 53.00)	61.00 (61.00 to 61.00)	64.00 (54.00 to 68.00)	68.00 (53.00 to 71.00)

DSBP: Day 60 (n= 1,1,7,5,14)	51.00 (51.00 to 51.00)	57.00 (57.00 to 57.00)	60.00 (46.00 to 73.00)	67.00 (59.00 to 70.00)
DSBP: Day 90 (n=1,2,8,7,19)	53.00 (53.00 to 53.00)	55.50 (51.00 to 60.00)	60.50 (52.00 to 70.00)	67.00 (56.00 to 80.00)

End point values	Dalteparin Sodium: Group 5 (>=12 year to <19 year)			
Subject group type	Reporting group			
Number of subjects analysed	20			
Units: millimeters of mercury (mmHg)				
median (full range (min-max))				
SBP: Baseline (n= 1,1,6,3,12)	117.50 (97.00 to 140.00)			
SBP: Day 1 (n= 1,2,4,6,15)	113.00 (92.00 to 130.00)			
SBP: Day 2 (n= 1,1,8,7,18)	119.50 (98.00 to 158.00)			
SBP: Day 30 (n=1,1,7,5,17)	118.00 (95.00 to 133.00)			
SBP: Day 60 (n=1,1,7,5,14)	117.50 (102.00 to 134.00)			
SBP: Day 90(n=1,2,8,7,19)	116.00 (89.00 to 151.00)			
DSBP:Baseline (n=1,1,6,3,12)	65.00 (46.00 to 80.00)			
DSBP: Day 1(n=1,2,4,6,15)	64.00 (48.00 to 80.00)			
DSBP:Day 2 (n= 1,1,8,7,18)	65.00 (53.00 to 95.00)			
DSBP:Day 30 (n= 1,1,7,5,17)	69.00 (55.00 to 87.00)			
DSBP: Day 60 (n= 1,1,7,5,14)	67.00 (57.00 to 80.00)			
DSBP: Day 90 (n=1,2,8,7,19)	69.00 (59.00 to 95.00)			

Statistical analyses

No statistical analyses for this end point

Secondary: Absolute Values of Heart Rate (HR) and Pulse Rate (PR) of Subjects

End point title	Absolute Values of Heart Rate (HR) and Pulse Rate (PR) of Subjects

End point description:

Heart rate and pulse rate of subjects were measured in terms of beats per minute. Here 99999 signifies that median and full range could not be calculated as no subjects were evaluable and "n" signifies the number of subjects evaluable at specific time points. The safety analysis set included all the subjects who received at least 1 dose of study drug.

End point type	Secondary

End point timeframe:
Baseline, Day 1, Day 2, Day 30, Day 60, Day 90

End point values	Dalteparin Sodium: Group 1 (>=0 to <8 week)	Dalteparin Sodium: Group 2 (>=8 week to <2 year)	Dalteparin Sodium: Group 3 (>=2 year to <8 year)	Dalteparin Sodium: Group 4 (>=8 year to <12 year)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	2	8	7
Units: beats per minute (bpm)				
median (full range (min-max))				
HR: Baseline (n=1,1,4,0,5)	148.00 (148.00 to 148.00)	146.00 (146.00 to 146.00)	115.00 (66.00 to 126.00)	99999 (-99999 to 99999)
HR: Day 1 (n=1,1,1,0,7)	146.00 (146.00 to 146.00)	142.00 (142.00 to 142.00)	112.00 (112.00 to 112.00)	99999 (-99999 to 99999)
HR: Day 2 (n=1,1,5,0,8)	136.00 (136.00 to 136.00)	130.00 (130.00 to 130.00)	114.00 (100.00 to 136.00)	99999 (-99999 to 99999)
HR: Day 30 (n=1,1,4,0,8)	138.00 (138.00 to 138.00)	130.00 (130.00 to 130.00)	120.50 (100.00 to 124.00)	99999 (-99999 to 99999)
HR: Day 60 (n=1,1,4,0,8)	132.00 (132.00 to 132.00)	184.00 (184.00 to 184.00)	120.00 (114.00 to 139.00)	99999 (-99999 to 99999)
HR: Day 90 (n=1,1,4,0,8)	122.00 (122.00 to 122.00)	134.00 (134.00 to 134.00)	107.00 (96.00 to 116.00)	99999 (-99999 to 99999)
PR: Baseline (n=0,0,2,3,7)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	96.50 (68.00 to 125.00)	114.00 (80.00 to 119.00)
PR: Day 1 (n=0,1,3,6,8)	99999 (-99999 to 99999)	108.00 (108.00 to 108.00)	121.00 (86.00 to 122.00)	87.00 (76.00 to 120.00)
PR: Day 2 (n=0,0,3,7,10)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	117.00 (113.00 to 138.00)	98.00 (84.00 to 127.00)
PR:Day 30 (n=0,0,3,5,9)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	88.00 (88.00 to 147.00)	101.00 (90.00 to 150.00)
PR: Day 60 (n=0,0,3,5,6)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	88.00 (88.00 to 99.00)	93.00 (75.00 to 108.00)
PR: Day 90 (n=0,1,3,7,11)	99999 (-99999 to 99999)	140.00 (140.00 to 140.00)	114.00 (113.00 to 120.00)	96.00 (67.00 to 109.00)

End point values	Dalteparin Sodium: Group 5 (>=12 year to <19 year)			
Subject group type	Reporting group			
Number of subjects analysed	20			
Units: beats per minute (bpm)				
median (full range (min-max))				
HR: Baseline (n=1,1,4,0,5)	70.00 (52.00 to 84.00)			

HR: Day 1 (n=1,1,1,0,7)	85.00 (46.00 to 139.00)			
HR: Day 2 (n=1,1,5,0,8)	75.00 (56.00 to 124.00)			
HR: Day 30 (n=1,1,4,0,8)	87.50 (56.00 to 126.00)			
HR: Day 60 (n=1,1,4,0,8)	94.50 (56.00 to 134.00)			
HR: Day 90 (n=1,1,4,0,8)	80.00 (66.00 to 118.00)			
PR: Baseline (n=0,0,2,3,7)	73.00 (67.00 to 150.00)			
PR: Day 1 (n=0,1,3,6,8)	94.50 (72.00 to 123.00)			
PR: Day 2 (n=0,0,3,7,10)	93.00 (57.00 to 161.00)			
PR:Day 30 (n=0,0,3,5,9)	102.00 (72.00 to 123.00)			
PR: Day 60 (n=0,0,3,5,6)	95.00 (62.00 to 117.00)			
PR: Day 90 (n=0,1,3,7,11)	92.00 (74.00 to 124.00)			

Statistical analyses

No statistical analyses for this end point

Secondary: Absolute Values of Height of Subjects

End point title	Absolute Values of Height of Subjects

End point description:

Here 99999 signifies that median and full range could not be calculated as no subjects were evaluable and "n" signifies the number of subjects evaluable at specific time points. The safety analysis set included all the subjects who received at least 1 dose of study drug.

End point type	Secondary

End point timeframe:

Baseline, Day 1, Day 2, Day 30, Day 60, Day 90

End point values	Dalteparin Sodium: Group 1 (>=0 to <8 week)	Dalteparin Sodium: Group 2 (>=8 week to <2 year)	Dalteparin Sodium: Group 3 (>=2 year to <8 year)	Dalteparin Sodium: Group 4 (>=8 year to <12 year)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	2	8	7
Units: centimeters (cm)				
median (full range (min-max))				
Baseline (n=1,1,4,2,9)	54.00 (54.00 to 54.00)	55.00 (55.00 to 55.00)	110.00 (98.00 to 125.50)	133.00 (126.00 to 140.00)
Day 1 (n=1,0,3,2,11)	54.00 (54.00 to 54.00)	99999 (-99999 to 99999)	115.80 (98.00 to 118.00)	134.00 (126.00 to 142.00)

Day 2 (n=0,0,6,5,15)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	107.90 (89.50 to 120.00)	142.00 (126.00 to 159.90)
Day 30 (n=1,1,5,6,14)	60.00 (60.00 to 60.00)	56.60 (56.60 to 56.60)	115.10 (89.50 to 124.50)	140.30 (128.00 to 159.90)
Day 60 (n=1,1,5,5,13)	63.00 (63.00 to 63.00)	60.00 (60.00 to 60.00)	115.00 (90.00 to 124.50)	139.70 (128.00 to 161.60)
Day 90 (n=1,1,6,5,18)	64.00 (64.00 to 64.00)	61.00 (61.00 to 61.00)	109.50 (91.50 to 127.00)	140.70 (129.00 to 161.60)

End point values	Dalteparin Sodium: Group 5 (>=12 year to <19 year)			
Subject group type	Reporting group			
Number of subjects analysed	20			
Units: centimeters (cm)				
median (full range (min-max))				
Baseline (n=1,1,4,2,9)	166.00 (142.00 to 178.00)			
Day 1 (n=1,0,3,2,11)	166.00 (113.50 to 184.00)			
Day 2 (n=0,0,6,5,15)	166.90 (113.60 to 189.00)			
Day 30 (n=1,1,5,6,14)	167.75 (113.90 to 184.00)			
Day 60 (n=1,1,5,5,13)	168.50 (114.20 to 183.60)			
Day 90 (n=1,1,6,5,18)	166.65 (115.00 to 184.00)			

Statistical analyses

No statistical analyses for this end point

Secondary: Absolute Values of Weight of Subjects

End point title	Absolute Values of Weight of Subjects

End point description:

Here "n" signifies the number of subjects evaluable at specific time points. The safety analysis set included all the subjects who received at least 1 dose of study drug.

End point type	Secondary

End point timeframe:

Baseline, Day 1, Day 2, Day 30, Day 60, Day 90

End point values	Dalteparin Sodium: Group 1 (>=0 to <8 week)	Dalteparin Sodium: Group 2 (>=8 week to <2 year)	Dalteparin Sodium: Group 3 (>=2 year to <8 year)	Dalteparin Sodium: Group 4 (>=8 year to <12 year)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	2	8	7
Units: kilograms (kg)				
median (full range (min-max))				
Baseline (n=1,1,6,3,9)	4.05 (4.05 to 4.05)	3.93 (3.93 to 3.93)	18.78 (12.80 to 34.70)	36.60 (25.40 to 45.80)
Day 1 (n=1,1,4,3,13)	4.17 (4.17 to 4.17)	4.04 (4.04 to 4.04)	17.23 (13.40 to 21.20)	37.00 (25.40 to 40.60)
Day 2 (n=1,1,7,6,16)	4.50 (4.50 to 4.50)	4.15 (4.15 to 4.15)	14.95 (11.90 to 34.70)	39.35 (25.40 to 64.50)
Day 30 (n=1,1,7,6,17)	6.30 (6.30 to 6.30)	4.56 (4.56 to 4.56)	15.50 (13.00 to 37.20)	39.20 (23.00 to 64.50)
Day 60 (n=1,1,7,5,14)	7.15 (7.15 to 7.15)	4.60 (4.60 to 4.60)	16.60 (12.70 to 37.20)	38.30 (24.10 to 68.60)
Day 90 (n=1,1,7,6,19)	7.70 (7.70 to 7.70)	4.70 (4.70 to 4.70)	21.50 (14.00 to 38.50)	39.30 (24.40 to 68.60)

End point values	Dalteparin Sodium: Group 5 (>=12 year to <19 year)			
Subject group type	Reporting group			
Number of subjects analysed	20			
Units: kilograms (kg)				
median (full range (min-max))				
Baseline (n=1,1,6,3,9)	60.00 (48.00 to 86.90)			
Day 1 (n=1,1,4,3,13)	63.40 (19.60 to 95.20)			
Day 2 (n=1,1,7,6,16)	58.00 (19.70 to 89.80)			
Day 30 (n=1,1,7,6,17)	63.80 (21.80 to 91.70)			
Day 60 (n=1,1,7,5,14)	65.80 (22.70 to 90.80)			
Day 90 (n=1,1,7,6,19)	59.60 (22.60 to 89.80)			

Statistical analyses

No statistical analyses for this end point

Secondary: Absolute Values of Respiratory Rate of Subjects

End point title	Absolute Values of Respiratory Rate of Subjects

End point description:

Respiratory rate was defined as the number of breaths per minute. Here "n" signifies the number of subjects evaluable at specific time points. The safety analysis set included all the subjects who received at least 1 dose of study drug.

End point type	Secondary

End point timeframe:

Baseline, Day 1, Day 2, Day 30, Day 60, Day 90

End point values	Dalteparin Sodium: Group 1 (>=0 to <8 week)	Dalteparin Sodium: Group 2 (>=8 week to <2 year)	Dalteparin Sodium: Group 3 (>=2 year to <8 year)	Dalteparin Sodium: Group 4 (>=8 year to <12 year)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	2	8	7
Units: breaths per minute				
median (full range (min-max))				
Baseline (n=1,1,6,3,12)	35.00 (35.00 to 35.00)	25.00 (25.00 to 25.00)	24.00 (18.00 to 24.00)	20.00 (18.00 to 30.00)
Day 1 (n=1,2,4,6,15)	34.00 (34.00 to 34.00)	36.00 (36.00 to 36.00)	21.00 (20.00 to 24.00)	18.00 (16.00 to 20.00)
Day 2 (n=1,1,7,7,17)	34.00 (34.00 to 34.00)	34.00 (34.00 to 34.00)	20.00 (18.00 to 24.00)	20.00 (18.00 to 24.00)
Day 30 (n=1,1,7,4,16)	34.00 (34.00 to 34.00)	36.00 (36.00 to 36.00)	22.00 (16.00 to 28.00)	22.00 (20.00 to 24.00)
Day 60 (n=1,1,7,4,14)	30.00 (30.00 to 30.00)	36.00 (36.00 to 36.00)	20.00 (16.00 to 24.00)	20.00 (18.00 to 20.00)
Day 90 (n=1,2,7,6,19)	24.00 (24.00 to 24.00)	34.00 (32.00 to 36.00)	22.00 (20.00 to 24.00)	20.00 (18.00 to 22.00)

End point values	Dalteparin Sodium: Group 5 (>=12 year to <19 year)			
Subject group type	Reporting group			
Number of subjects analysed	20			
Units: breaths per minute				
median (full range (min-max))				
Baseline (n=1,1,6,3,12)	20.00 (17.00 to 36.00)			
Day 1 (n=1,2,4,6,15)	18.00 (16.00 to 30.00)			
Day 2 (n=1,1,7,7,17)	18.00 (16.00 to 24.00)			
Day 30 (n=1,1,7,4,16)	18.00 (16.00 to 32.00)			
Day 60 (n=1,1,7,4,14)	20.00 (16.00 to 30.00)			
Day 90 (n=1,2,7,6,19)	18.00 (12.00 to 28.00)			

Statistical analyses

No statistical analyses for this end point

Secondary: Absolute Values of Body Temperature of Subjects

End point title	Absolute Values of Body Temperature of Subjects

End point description:

Here "n" signifies the number of subjects evaluable at specific time points. The safety analysis set included all the subjects who received at least 1 dose of study drug.

End point type	Secondary

End point timeframe:

Baseline, Day 1, Day 2, Day 30, Day 60, Day 90

End point values	Dalteparin Sodium: Group 1 (>=0 to <8 week)	Dalteparin Sodium: Group 2 (>=8 week to <2 year)	Dalteparin Sodium: Group 3 (>=2 year to <8 year)	Dalteparin Sodium: Group 4 (>=8 year to <12 year)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	2	8	7
Units: celsius				
median (full range (min-max))				
Baseline (n=1,1,6,3,12)	36.60 (36.60 to 36.60)	36.70 (36.70 to 36.70)	36.50 (36.10 to 37.30)	37.00 (36.20 to 37.20)
Day 1 (n=1,2,4,6,15)	36.70 (36.70 to 36.70)	36.85 (36.70 to 37.00)	36.80 (36.70 to 36.90)	36.70 (36.00 to 37.00)
Day 2 (n=1,1,8,7,18)	36.90 (36.90 to 36.90)	36.40 (36.40 to 36.40)	36.70 (35.30 to 37.30)	36.70 (36.60 to 36.80)
Day 30 (n=1,1,7,5,17)	36.50 (36.50 to 36.50)	36.50 (36.50 to 36.50)	36.60 (35.50 to 37.30)	36.50 (36.40 to 38.60)
Day 60 (n=1,1,7,5,13)	36.60 (36.60 to 36.60)	36.70 (36.70 to 36.70)	36.80 (36.40 to 38.60)	36.60 (35.60 to 36.90)
Day 90 (n=1,2,8,7,19)	36.70 (36.70 to 36.70)	37.15 (36.70 to 37.60)	36.75 (35.90 to 37.50)	36.90 (36.70 to 38.40)

End point values	Dalteparin Sodium: Group 5 (>=12 year to <19 year)			
Subject group type	Reporting group			
Number of subjects analysed	20			
Units: celsius				
median (full range (min-max))				
Baseline (n=1,1,6,3,12)	36.80 (35.60 to 39.30)			
Day 1 (n=1,2,4,6,15)	36.80 (36.10 to 37.10)			
Day 2 (n=1,1,8,7,18)	36.70 (36.40 to 37.70)			
Day 30 (n=1,1,7,5,17)	36.70 (35.10 to 37.10)			
Day 60 (n=1,1,7,5,13)	36.60 (35.70 to 37.00)			

Day 90 (n=1,2,8,7,19)	36.80 (36.10 to 38.40)			

Statistical analyses

No statistical analyses for this end point

Secondary: Absolute Values of Body Length of Subjects

End point title	Absolute Values of Body Length of Subjects

End point description:

Here 99999 signifies that median and full range could not be calculated as no subjects were evaluable and "n" signifies the number of subjects evaluable at specific time points. The safety analysis set included all the subjects who received at least 1 dose of study drug.

End point type	Secondary

End point timeframe:

Baseline, Day 1, Day 2, Day 30, Day 60, Day 90

End point values	Dalteparin Sodium: Group 1 (>=0 to <8 week)	Dalteparin Sodium: Group 2 (>=8 week to <2 year)	Dalteparin Sodium: Group 3 (>=2 year to <8 year)	Dalteparin Sodium: Group 4 (>=8 year to <12 year)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	2	8	7
Units: cm				
median (full range (min-max))				
Baseline (n= 1,1,1,0,1)	54.00 (54.00 to 54.00)	55.00 (55.00 to 55.00)	100.00 (100.00 to 100.00)	99999 (-99999 to 99999)
Day 1 (n=1,1,0,0,1)	54.00 (54.00 to 54.00)	55.00 (55.00 to 55.00)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
Day 2 (n= 1,1,2,0,1)	56.00 (56.00 to 56.00)	55.30 (55.30 to 55.30)	104.75 (89.50 to 120.00)	99999 (-99999 to 99999)
Day 30 (n=1,1,3,0,1)	60.00 (60.00 to 60.00)	56.60 (56.60 to 56.60)	100.00 (89.50 to 124.5)	99999 (-99999 to 99999)
Day 60 (n=1,1,3,0,1)	63.00 (63.00 to 63.00)	60.00 (60.00 to 60.00)	103.00 (90.00 to 124.50)	99999 (-99999 to 99999)
Day 90 (n=1,1,2,0,2)	64.00 (64.00 to 64.00)	61.00 (61.00 to 61.00)	97.75 (91.50 to 104.00)	99999 (-99999 to 99999)

End point values	Dalteparin Sodium: Group 5 (>=12 year to <19 year)			
Subject group type	Reporting group			
Number of subjects analysed	20			
Units: cm				
median (full range (min-max))				

Baseline (n= 1,1,1,0,1)	172.00 (172.00 to 172.00)			
Day 1 (n=1,1,0,0,1)	135.00 (135.00 to 135.00)			
Day 2 (n= 1,1,2,0,1)	135.00 (135.00 to 135.00)			
Day 30 (n=1,1,3,0,1)	135.00 (135.00 to 135.00)			
Day 60 (n=1,1,3,0,1)	135.00 (135.00 to 135.00)			
Day 90 (n=1,1,2,0,2)	151.75 (135.00 to 168.50)			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With Physical Examination Abnormalities of Subjects

End point title	Number of Subjects With Physical Examination Abnormalities of Subjects

End point description:

Physical examinations included head, eyes, ears, nose, throat, neck, heart, chest, lungs, abdomen, extremities, skin, neurological status and general appearance. Here, 9999 signifies as no subjects evaluable. Only those categories in which at least 1 subject had abnormality were reported and "n" signifies the number of subjects evaluable at specific time points. The safety analysis set included all the subjects who received at least 1 dose of study drug.

End point type	Secondary

End point timeframe:

Screening, Visit 2 (Baseline), Visit 3 (Day 1), Visit 4 (Day 2), Visit 5 (Day 30), Visit 6 (Day 60), Visit 7 (Day 90)

End point values	Dalteparin Sodium: Group 1 (>=0 to <8 week)	Dalteparin Sodium: Group 2 (>=8 week to <2 year)	Dalteparin Sodium: Group 3 (>=2 year to <8 year)	Dalteparin Sodium: Group 4 (>=8 year to <12 year)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	2	8	7
Units: subjects				
Abdomen: Screening (n=1,2,7,7,19)	0	1	2	0
Abdomen: Visit 2 (n=1,1,4,0,7)	0	0	2	9999
Abdomen: Visit 3 (n=1,2,4,6,12)	0	1	1	0
Abdomen: Visit 4 (n=1,2,7,7,18)	0	0	1	1
Abdomen: Visit 5 (n=1,1,7,6,17)	0	0	0	1
Abdomen: Visit 6 (n=1,1,7,4,14)	0	0	0	1
Abdomen: Visit 7 (n=1,2,7,7,18)	0	1	0	1
Chest: Screening (n=1,2,7,7,19)	0	0	1	2

Chest: Visit 2 (n=1,1,4,0,7)	0	0	2	9999
Chest: Visit 3 (n=1,2,4,5,12)	0	0	0	2
Chest: Visit 4 (n=1,2,7,6,18)	0	0	0	3
Chest: Visit 5 (n=1,1,7,5,17)	0	0	0	1
Chest: Visit 6 (n=1,1,7,3,14)	0	0	0	1
Chest: Visit 7 (n=1,2,7,6,18)	0	0	0	2
Extremities: Screening (n=1,2,7,7,19)	0	0	0	4
Extremities: Visit 2 (n=1,1,4,0,7)	0	0	1	9999
Extremities: Visit 3 (n=1,2,4,6,12)	0	0	1	3
Extremities: Visit 4 (n=1,2,7,7,17)	0	0	0	4
Extremities: Visit 5 (n=1,1,7,6,16)	0	0	0	1
Extremities: Visit 6 (n=1,1,7,4,14)	0	0	0	1
Extremities: Visit 7 (n=1,2,7,7,18)	0	0	0	2
Eyes: Screening (n=1,1,5,0,8)	0	0	1	9999
Eyes: Visit 2 (n=1,1,3,0,5)	0	0	0	9999
Eyes: Visit 3 (n=1,1,1,0,7)	0	0	0	9999
Eyes: Visit 4 (n=1,1,4,0,8)	0	0	0	9999
Eyes: Visit 5 (n=1,1,4,0,8)	0	0	0	9999
Eyes: Visit 6 (n=1,1,4,0,8)	0	0	0	9999
Eyes: Visit 7 (n=1,1,4,0,8)	0	0	0	9999
Eyes, ears, nose, throat:Screening (n= 0,1,2,7,11)	9999	1	1	0
Eyes, ears, nose, throat: Visit 3 (n= 0,1,3,6,5)	9999	0	1	0
Eyes, ears, nose, throat: Visit 4 (n= 0,1,3,7,10)	9999	0	0	0
Eyes, ears, nose, throat: Visit 5 (n=0,0,3,6,9)	9999	9999	0	0
Eyes, ears, nose, throat: Visit 6 (n=0,0,3,4,6)	9999	9999	2	0
Eyes, ears, nose, throat: Visit 7 (n= 0,1,3,7,10)	9999	0	1	0
General appearance: Screening (n= 1,2,7,7,19)	0	0	2	1
General appearance: Visit 2 (n=1,1,4,0,7)	0	0	1	9999
General appearance: Visit 3 (n=1,2,4,6,12)	0	0	1	0
General appearance: Visit 4 (n=1,2,7,7,18)	0	0	0	1
General appearance: Visit 5 (n=1,1,7,6,17)	0	0	0	0
General appearance: Visit 6 (n=1,1,7,4,14)	0	1	0	0
General appearance: Visit 7 (n=1,2,7,7,18)	0	0	1	2
Head: Screening (n=1,2,7,7,19)	0	0	1	1
Head: Visit 3 (n=1,2,4,6,12)	0	0	1	0
Head: Visit 4 (n=1,2,7,7,18)	0	0	1	0
Head: Visit 5 (n=1,1,7,6,17)	0	0	1	1
Head: Visit 6 (n=1,1,7,4,14)	0	0	1	1
Head: Visit 7 (n=1,2,7,7,18)	0	0	1	1
Heart: Screening (n=1,2,7,7,19)	0	0	1	1
Heart: Visit 3 (n=1,2,4,6,12)	0	1	0	0
Heart: Visit 4 (n=1,2,7,7,18)	0	1	1	0
Heart: Visit 7 (n=1,2,7,7,18)	0	1	0	0

Lungs: Screening (n=1,2,7,7,19)	0	0	0	1
Lungs: Visit 4 (n=1,2,7,7,18)	0	0	0	0
Lungs: Visit 6 (n=1,1,7,4,14)	0	0	0	0
Lungs: Visit 7 (n=1,2,7,7,18)	0	0	0	0
Neck: Screening (n=1,2,7,7,19)	0	1	1	1
Neck: Visit 4 (n=1,2,7,5,18)	0	0	0	0
Neurological: Screening (n=1,2,7,7,19)	0	0	2	0
Neurological: Visit 2 (n=1,1,4,0,7)	0	0	1	9999
Neurological: Visit 3 (n=1,2,4,6,12)	0	0	1	0
Neurological: Visit 4 (n=1,2,7,6,18)	0	0	0	0
Neurological: Visit 5 (n=1,1,7,6,17)	0	0	0	0
Neurological: Visit 7 (n=1,2,7,7,18)	0	1	0	0
Nose: Screening (n=1,1,5,0,8)	0	0	1	9999
Nose: Visit 2 (n=1,1,3,0,5)	0	0	1	9999
Skin: Screening (n=1,2,7,7,19)	1	1	1	3
Skin: Visit 2 (n=1,1,4,0,7)	1	0	0	9999
Skin: Visit 3 (n=1,2,4,6,12)	1	1	1	1
Skin: Visit 4 (n=1,2,7,7,18)	0	1	2	2
Skin: Visit 5 (n=1,1,7,6,17)	0	0	2	2
Skin: Visit 6 (n=1,1,7,4,14)	0	0	0	2
Skin: Visit 7 (n=1,2,7,7,18)	0	1	1	3

End point values	Dalteparin Sodium: Group 5 (>=12 year to <19 year)			
Subject group type	Reporting group			
Number of subjects analysed	20			
Units: subjects				
Abdomen: Screening (n=1,2,7,7,19)	2			
Abdomen: Visit 2 (n=1,1,4,0,7)	0			
Abdomen: Visit 3 (n=1,2,4,6,12)	2			
Abdomen: Visit 4 (n=1,2,7,7,18)	3			
Abdomen: Visit 5 (n=1,1,7,6,17)	4			
Abdomen: Visit 6 (n=1,1,7,4,14)	1			
Abdomen: Visit 7 (n=1,2,7,7,18)	3			
Chest: Screening (n=1,2,7,7,19)	2			
Chest: Visit 2 (n=1,1,4,0,7)	0			
Chest: Visit 3 (n=1,2,4,5,12)	0			
Chest: Visit 4 (n=1,2,7,6,18)	1			
Chest: Visit 5 (n=1,1,7,5,17)	0			
Chest: Visit 6 (n=1,1,7,3,14)	0			
Chest: Visit 7 (n=1,2,7,6,18)	3			
Extremities: Screening (n=1,2,7,7,19)	10			
Extremities: Visit 2 (n=1,1,4,0,7)	1			
Extremities: Visit 3 (n=1,2,4,6,12)	3			
Extremities: Visit 4 (n=1,2,7,7,17)	8			
Extremities: Visit 5 (n=1,1,7,6,16)	3			
Extremities: Visit 6 (n=1,1,7,4,14)	2			
Extremities: Visit 7 (n=1,2,7,7,18)	2			

Eyes: Screening (n=1,1,5,0,8)	1			
Eyes: Visit 2 (n=1,1,3,0,5)	1			
Eyes: Visit 3 (n=1,1,1,0,7)	1			
Eyes: Visit 4 (n=1,1,4,0,8)	2			
Eyes: Visit 5 (n=1,1,4,0,8)	1			
Eyes: Visit 6 (n=1,1,4,0,8)	1			
Eyes: Visit 7 (n=1,1,4,0,8)	1			
Eyes, ears, nose, throat:Screening (n= 0,1,2,7,11)	2			
Eyes, ears, nose, throat: Visit 3 (n= 0,1,3,6,5)	1			
Eyes, ears, nose, throat: Visit 4 (n= 0,1,3,7,10)	2			
Eyes, ears, nose, throat: Visit 5 (n=0,0,3,6,9)	3			
Eyes, ears, nose, throat: Visit 6 (n=0,0,3,4,6)	1			
Eyes, ears, nose, throat: Visit 7 (n= 0,1,3,7,10)	2			
General appearance: Screening (n= 1,2,7,7,19)	3			
General appearance: Visit 2 (n=1,1,4,0,7)	0			
General appearance: Visit 3 (n=1,2,4,6,12)	1			
General appearance: Visit 4 (n=1,2,7,7,18)	2			
General appearance: Visit 5 (n=1,1,7,6,17)	2			
General appearance: Visit 6 (n=1,1,7,4,14)	1			
General appearance: Visit 7 (n=1,2,7,7,18)	2			
Head: Screening (n=1,2,7,7,19)	4			
Head: Visit 3 (n=1,2,4,6,12)	2			
Head: Visit 4 (n=1,2,7,7,18)	5			
Head: Visit 5 (n=1,1,7,6,17)	4			
Head: Visit 6 (n=1,1,7,4,14)	3			
Head: Visit 7 (n=1,2,7,7,18)	5			
Heart: Screening (n=1,2,7,7,19)	0			
Heart: Visit 3 (n=1,2,4,6,12)	0			
Heart: Visit 4 (n=1,2,7,7,18)	1			
Heart: Visit 7 (n=1,2,7,7,18)	2			
Lungs: Screening (n=1,2,7,7,19)	0			
Lungs: Visit 4 (n=1,2,7,7,18)	1			
Lungs: Visit 6 (n=1,1,7,4,14)	1			
Lungs: Visit 7 (n=1,2,7,7,18)	1			
Neck: Screening (n=1,2,7,7,19)	2			
Neck: Visit 4 (n=1,2,7,5,18)	1			
Neurological: Screening (n=1,2,7,7,19)	0			
Neurological: Visit 2 (n=1,1,4,0,7)	0			
Neurological: Visit 3 (n=1,2,4,6,12)	0			
Neurological: Visit 4 (n=1,2,7,6,18)	1			
Neurological: Visit 5 (n=1,1,7,6,17)	1			
Neurological: Visit 7 (n=1,2,7,7,18)	0			
Nose: Screening (n=1,1,5,0,8)	0			

Nose: Visit 2 (n=1,1,3,0,5)	0			
Skin: Screening (n=1,2,7,7,19)	5			
Skin: Visit 2 (n=1,1,4,0,7)	1			
Skin: Visit 3 (n=1,2,4,6,12)	3			
Skin: Visit 4 (n=1,2,7,7,18)	6			
Skin: Visit 5 (n=1,1,7,6,17)	7			
Skin: Visit 6 (n=1,1,7,4,14)	5			
Skin: Visit 7 (n=1,2,7,7,18)	4			

Statistical analyses

No statistical analyses for this end point

Secondary: Time to First Occurrence of Major Bleeding Event

End point title	Time to First Occurrence of Major Bleeding Event

End point description:

Time to first occurrence of major bleeding event was defined as the time interval (in days) between date of first study treatment and date of documentation of first major bleeding event. A bleeding event was considered as major if it was clinically overt and satisfies 1 or more of the following criteria: fatal bleeding, bleeding accompanied by a decrease in hemoglobin of at least 2 grams per deciliter, overt bleeding deemed by the attending physician to necessitate permanent discontinuation of trial medication, overt bleeding deemed by the attending physician to be unrelated to the subject's underlying condition and accompanied by blood product administration, bleeding occurred at a critical site (intraocular, intracranial, retroperitoneal or intraspinal). The safety analysis set included all the subjects who received at least 1 dose of study drug.

End point type	Secondary

End point timeframe:

Baseline up to 28 days after the last dose of study drug (up to Day 132)

End point values	Dalteparin Sodium: All Subjects (>= 0 to < 19 years)			
Subject group type	Subject analysis set			
Number of subjects analysed	0[5]			
Units: days				
median (confidence interval 95%)	(to)			

Notes:

[5] - Median and 95% CI was not estimable due to the low number of subjects who had bleeding episodes.

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Who Remained Within Prespecified Therapeutic Anti-Factor Xa Levels at Day 30, 60 and 90 in Follow up Phase

End point title	Percentage of Subjects Who Remained Within Prespecified Therapeutic Anti-Factor Xa Levels at Day 30, 60 and 90 in Follow up Phase[6]

End point description:

Prespecified therapeutic anti-factor Xa range was 0.5-1.0 IU/mL. The percentage of subjects who had anti-factor Xa levels outside the prespecified therapeutic range at Day 30, 60 and 90 during the follow up phase were reported in this endpoint. PD analysis set included all subjects who received at least 1 dose of study drug and achieved therapeutic range of anti-factor Xa during dose adjustment phase. Here, "n" signifies number of subjects analysed at specific time points. Data for this endpoint was not planned to be collected and analysed for age group of >=0 to <8 weeks.

End point type	Secondary

End point timeframe:

Day 30, Day 60, Day 90 in follow up phase

Notes:

[6] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Justification: Descriptive analysis was planned to be reported for arms Dalteparin Sodium: Group 2 (>=8 week to <2 year), Group 3 (>=2 year to <8 year), Group 4 (>=8 year to <12 year) and Group 5 (>=12 year to <19 year

End point values	Dalteparin Sodium: Group 2 (>=8 week to <2 year)	Dalteparin Sodium: Group 3 (>=2 year to <8 year)	Dalteparin Sodium: Group 4 (>=8 year to <12 year)	Dalteparin Sodium: Group 5 (>=12 year to <19 year)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	8	7	17
Units: percentage of subjects				
number (confidence interval 95%)				
Day 30 (n=1,5,6,15)	100.0 (2.50 to 100.0)	100.0 (47.82 to 100.0)	33.3 (4.33 to 77.72)	93.3 (68.05 to 99.83)
Day 60 (n= 1,5,4,11)	100.0 (2.50 to 100.0)	100.0 (47.82 to 100.0)	75.0 (19.41 to 99.37)	81.8 (48.22 to 97.72)
Day 90 (n= 1,4,2,11)	100.0 (2.50 to 100.0)	100.0 (39.76 to 100.0)	50.0 (1.26 to 98.74)	72.7 (39.03 to 93.98)

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With Anti-Factor Xa Levels Outside the Prespecified Range at Day 30, 60 and 90 in Follow up Phase

End point title	Percentage of Subjects With Anti-Factor Xa Levels Outside the Prespecified Range at Day 30, 60 and 90 in Follow up Phase[7]

End point description:

Prespecified therapeutic anti-factor Xa range was 0.5-1.0 IU/mL. The percentage of subjects who had anti-factor Xa levels outside the prespecified therapeutic range at Day 30, 60 and 90 during the follow up phase were reported in this endpoint. Here, "n" signifies the number of subjects analysed at specific time points. The PD analysis set included all subjects who received at least 1 dose of study drug and achieved therapeutic range of anti-factor Xa during dose adjustment phase.

End point type	Secondary

End point timeframe:

Day 30, Day 60, Day 90 in follow-up phase

Notes:

[7] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Justification: Descriptive analysis was planned to be reported for arms Dalteparin Sodium: Group 2 (>=8 week to <2 year), Group 3 (>=2 year to <8 year), Group 4 (>=8 year to <12 year) and Group 5 (>=12 year to <19 year

End point values	Dalteparin Sodium: Group 2 (>=8 week to <2 year)	Dalteparin Sodium: Group 3 (>=2 year to <8 year)	Dalteparin Sodium: Group 4 (>=8 year to <12 year)	Dalteparin Sodium: Group 5 (>=12 year to <19 year)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	8	7	17
Units: percentage of subjects				
number (confidence interval 95%)				
Day 30 (n= 1,5,6,15)	0 (0.00 to 97.50)	0 (0.00 to 52.18)	66.7 (22.28 to 95.67)	6.7 (0.17 to 31.95)
Day 60 (n= 1,5,4,11)	0 (0.00 to 97.50)	0 (0.00 to 52.18)	25.0 (0.63 to 80.59)	18.2 (2.28 to 51.78)
Day 90 (n= 1,4,2,11)	0 (0.00 to 97.50)	0 (0.00 to 60.24)	50.0 (1.26 to 98.74)	27.3 (6.02 to 60.97)

Statistical analyses

No statistical analyses for this end point

Secondary: Maintenance Dose of Dalteparin Required to Achieve Prespecified Therapeutic Anti- Factor Xa Levels

End point title	Maintenance Dose of Dalteparin Required to Achieve Prespecified Therapeutic Anti- Factor Xa Levels[8]

End point description:

Prespecified therapeutic anti-factor Xa level was 0.5-1.0 IU/mL. Cumulative data for day 1 to 7 has been reported. The PD analysis set included all subjects who received at least 1 dose of study drug and achieved therapeutic range of anti-factor Xa during dose adjustment phase. Here, "n" signifies number of subjects analysed at specific time points. Data for this endpoint was not planned to be collected and analysed for age group of >=0 to <8 weeks.

End point type	Secondary

End point timeframe:

4 hours post-dose at each Day 1 to 7 in dose adjustment phase

Notes:

[8] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Justification: Descriptive analysis was planned to be reported for arms Dalteparin Sodium: Group 2 (>=8 week to <2 year), Group 3 (>=2 year to <8 year), Group 4 (>=8 year to <12 year) and Group 5 (>=12 year to <19 year

End point values	Dalteparin Sodium: Group 2 (>=8 week to <2 year)	Dalteparin Sodium: Group 3 (>=2 year to <8 year)	Dalteparin Sodium: Group 4 (>=8 year to <12 year)	Dalteparin Sodium: Group 5 (>=12 year to <19 year)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	8	7	17
Units: IU/kg				
arithmetic mean (standard deviation)	207.50 (± 8.485)	141.85 (± 23.550)	132.40 (± 12.934)	115.06 (± 17.164)

Statistical analyses

No statistical analyses for this end point

Secondary: Time to Achieve Prespecified Therapeutic Anti- Factor Xa Levels

End point title	Time to Achieve Prespecified Therapeutic Anti- Factor Xa Levels[9]

End point description:

Time to achieve the target range (prespecified therapeutic anti- factor Xa levels) was defined as the number of days from the first dose of study drug to the final dose that achieves the target anti-factor Xa level. Prespecified therapeutic anti-factor Xa level was 0.5-1.0 IU/mL. Cumulative data of Day 1 to 7 is reported. PD analysis set included all subjects who received at least 1 dose of study drug and achieved therapeutic range of anti-factor Xa during dose adjustment phase. Data for this endpoint was not planned to be collected and analysed for age group of >=0 to <8 weeks.

End point type	Secondary

End point timeframe:

4 hours post-dose at each Day 1 to 7 in dose adjustment phase

Notes:

[9] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Justification: Descriptive analysis was planned to be reported for arms Dalteparin Sodium: Group 2 (>=8 week to <2 year), Group 3 (>=2 year to <8 year), Group 4 (>=8 year to <12 year) and Group 5 (>=12 year to <19 year

End point values	Dalteparin Sodium: Group 2 (>=8 week to <2 year)	Dalteparin Sodium: Group 3 (>=2 year to <8 year)	Dalteparin Sodium: Group 4 (>=8 year to <12 year)	Dalteparin Sodium: Group 5 (>=12 year to <19 year)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	8	7	17
Units: days				
median (full range (min-max))	4.5 (4 to 5)	3.0 (1 to 7)	2.0 (1 to 3)	2.0 (1 to 4)

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Dose Adjustments Required to Achieve Prespecified Therapeutic Anti-Xa Levels

End point title	Number of Dose Adjustments Required to Achieve Prespecified Therapeutic Anti-Xa Levels[10]

End point description:

During dose adjustment phase, doses were adjusted according to prespecified therapeutic anti-Xa levels in order to achieve target prespecified therapeutic anti-factor Xa levels (0.5 to 1.0 IU/mL). Number of dose adjustments which were done within the specified time window of up to 4 hours post dose on all days (1 to 7) to achieve the prespecified therapeutic anti-Xa levels are reported. PD analysis set included all subjects who received at least 1 dose of study drug and achieved therapeutic range of anti-factor Xa during dose adjustment phase. Data for this endpoint was not planned to be collected and analysed for age group of >=0 to <8 weeks.

End point type	Secondary

End point timeframe:

4 hours post-dose at each Day 1 to 7 in dose adjustment phase

Notes:

[10] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Justification: Descriptive analysis was planned to be reported for arms Dalteparin Sodium: Group 2 (>=8 week to <2 year), Group 3 (>=2 year to <8 year), Group 4 (>=8 year to <12 year) and Group 5 (>=12 year to <19 year

End point values	Dalteparin Sodium: Group 2 (>=8 week to <2 year)	Dalteparin Sodium: Group 3 (>=2 year to <8 year)	Dalteparin Sodium: Group 4 (>=8 year to <12 year)	Dalteparin Sodium: Group 5 (>=12 year to <19 year)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	8	7	17
Units: dose adjustment				
median (full range (min-max))	3.5 (3 to 4)	0.5 (0 to 2)	0.0 (0 to 1)	0.0 (0 to 2)

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Total Body Clearance of Dalteparin

End point title	Total Body Clearance of Dalteparin

End point description:

Drug clearance is a quantitative measure of the rate at which a drug substance is removed from the blood (rate at which a drug is metabolized or eliminated by normal biological processes). Clearance obtained after intravenous infusion dose (apparent clearance) is influenced by the fraction of the dose absorbed. Data not reported for the endpoint, since the PK data was collected and analysed in a pooled analysis, together with data from two external studies; the results of this pooled analysis will be reported separately.

End point type	Other pre-specified

End point timeframe:

4 hours post-dose at each Day 1 to 7 in dose adjustment phase

End point values	Dalteparin Sodium: All Subjects (>= 0 to < 19 years)			
Subject group type	Subject analysis set			
Number of subjects analysed	0[11]			
Units: milliliter per hour				

Notes:

[11] - Data was not reported for the endpoint.

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Volume of Distribution of Dalteparin

End point title	Volume of Distribution of Dalteparin

End point description:

Volume of distribution is defined as the theoretical volume in which the total amount of drug would need to be uniformly distributed to produce the desired blood concentration of a drug. Data not reported for the endpoint, since the PK data was collected and analysed in a pooled analysis, together with data from two external studies; the results of this pooled analysis will be reported separately.

End point type	Other pre-specified

End point timeframe:

4 hours post-dose at each Day 1 to 7 in dose adjustment phase

End point values	Dalteparin Sodium: All Subjects (>= 0 to < 19 years)			
Subject group type	Subject analysis set			
Number of subjects analysed	0[12]			
Units: milliliter				

Notes:

[12] - Data was not reported for the endpoint.

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Absorption Rate Constant (Ka) of Dalteparin

End point title	Absorption Rate Constant (Ka) of Dalteparin

End point description:

Data not reported for the endpoint, since the PK data was collected and analysed in a pooled analysis, together with data from two external studies; the results of this pooled analysis will be reported separately.

End point type	Other pre-specified

End point timeframe:

4 hours post-dose at each Day 1 to 7 in dose adjustment phase

End point values	Dalteparin Sodium: All Subjects (>= 0 to < 19 years)			
Subject group type	Subject analysis set			
Number of subjects analysed	0[13]			
Units: 1/hour (hr)				

Notes:

[13] - Data was not reported for the endpoint.

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Baseline up to 28 days after the last dose of study drug (up to Day 132)

Adverse event reporting additional description:

Same event may appear as both an adverse event (AE) and serious adverse event (SAE). However, what is presented are distinct events. An event may be categorized as serious in one subject and as non-serious in another, or a subject may have experienced both a serious and non-serious event.

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	v21.0

Reporting groups

Reporting group title	Dalteparin Sodium: Group 1 (>=0 to <8 Week)

Reporting group description:

Subjects aged >=0 to <8 weeks were administered 125 IU/kg of dalteparin sodium injection subcutaneously twice daily from Day 1 to 7 in DA phase, Day 8 to 14 in PD phase and from Day 15 in FU phase (up to 104 days). Subjects were to participate in the study for up to 104 days of study drug treatment to monitor the status of the qualifying venous thromboembolism (VTE). Subjects were followed up for safety for up to 28 days after last dose of study drug (up to 132 days).

Reporting group title	Dalteparin Sodium: Group 2 (>=8 week to <2 year)

Reporting group description:

Subjects aged >=8 weeks to <2 years were administered 150 IU/kg of dalteparin sodium injection subcutaneously twice daily from Day 1 to 7 in DA phase, Day 8 to 14 in PD phase and from Day 15 in FU phase (up to 104 days). Subjects were to participate in the study for up to 104 days of study drug treatment to monitor the status of the qualifying VTE. Subjects were followed up for safety for up to 28 days after last dose of study drug (up to 132 days).

Reporting group title	Dalteparin Sodium: Group 3 (>=2 year to <8 year)

Reporting group description:

Subjects aged >=2 years to <8 years were administered 125 IU/kg of dalteparin sodium injection subcutaneously twice daily from Day 1 to 7 in DA phase, Day 8 to 14 in PD phase and from Day 15 in FU phase (up to 104 days). Subjects were to participate in the study for up to 104 days of study drug treatment to monitor the status of the qualifying VTE. Subjects were followed up for safety for up to 28 days after last dose of study drug (up to 132 days).

Reporting group title	Dalteparin Sodium: Group 4 (>=8 year to <12 year)

Reporting group description:

Subjects aged >=8 years to <12 years were administered 125 IU/kg of dalteparin sodium injection subcutaneously twice daily from Day 1 to 7 in DA phase, Day 8 to 14 in PD phase and from Day 15 in FU phase (up to 104 days). Subjects were to participate in the study for up to 104 days of study drug treatment to monitor the status of the qualifying VTE. Subjects were followed up for safety for up to 28 days after last dose of study drug (up to 132 days).

Reporting group title	Dalteparin Sodium: Group 5 (>=12 year to <19 year)

Reporting group description:

Subjects aged >=12 years to <19 years were administered 100 IU/kg of dalteparin sodium injection subcutaneously twice daily from Day 1 to 7 in DA phase, Day 8 to 14 in PD phase and from Day 15 in FU phase (up to 104 days). Subjects were to participate in the study for up to 104 days of study drug treatment to monitor the status of the qualifying VTE. Subjects were followed up for safety for up to 28 days after last dose of study drug (up to 132 days).

Serious adverse events	Dalteparin Sodium: Group 1 (>=0 to <8 Week)	Dalteparin Sodium: Group 2 (>=8 week to <2 year)	Dalteparin Sodium: Group 3 (>=2 year to <8 year)
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 1 (0.00%)	2 / 2 (100.00%)	3 / 8 (37.50%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Vascular disorders			
Hypertension			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotension			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombophlebitis superficial			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Tachycardia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Dizziness			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure like phenomena			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			

subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile neutropenia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	1 / 8 (12.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Leukocytosis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	1 / 8 (12.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancytopenia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombocytopenia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Mucosal inflammation			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			

subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	1 / 8 (12.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Anaphylactic reaction			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Drug hypersensitivity			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Intestinal haematoma			
subjects affected / exposed	0 / 1 (0.00%)	1 / 2 (50.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal obstruction			
subjects affected / exposed	0 / 1 (0.00%)	1 / 2 (50.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Hypoxia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Productive cough			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory distress			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematuria			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Bacterial infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oral herpes			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Pneumonia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory syncytial virus infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	1 / 8 (12.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vulvovaginal candidiasis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Electrolyte imbalance			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malnutrition			
subjects affected / exposed	0 / 1 (0.00%)	1 / 2 (50.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Dalteparin Sodium: Group 4 (>=8 year to <12 year)	Dalteparin Sodium: Group 5 (>=12 year to <19 year)	
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 7 (42.86%)	13 / 20 (65.00%)	
number of deaths (all causes)	0	1	
number of deaths resulting from adverse events	0	0	
Vascular disorders			
Hypertension			
subjects affected / exposed	0 / 7 (0.00%)	1 / 20 (5.00%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypotension			
subjects affected / exposed	0 / 7 (0.00%)	1 / 20 (5.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombophlebitis superficial			
subjects affected / exposed	1 / 7 (14.29%)	0 / 20 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Tachycardia			
subjects affected / exposed	0 / 7 (0.00%)	1 / 20 (5.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Dizziness			
subjects affected / exposed	0 / 7 (0.00%)	1 / 20 (5.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Seizure like phenomena			
subjects affected / exposed	1 / 7 (14.29%)	0 / 20 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood and lymphatic system disorders			
Anaemia			

subjects affected / exposed	0 / 7 (0.00%)	1 / 20 (5.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Febrile neutropenia			
subjects affected / exposed	1 / 7 (14.29%)	3 / 20 (15.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Leukocytosis			
subjects affected / exposed	0 / 7 (0.00%)	1 / 20 (5.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neutropenia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 20 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancytopenia			
subjects affected / exposed	0 / 7 (0.00%)	1 / 20 (5.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombocytopenia			
subjects affected / exposed	0 / 7 (0.00%)	2 / 20 (10.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
Mucosal inflammation			
subjects affected / exposed	0 / 7 (0.00%)	2 / 20 (10.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pain			
subjects affected / exposed	0 / 7 (0.00%)	1 / 20 (5.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyrexia			

subjects affected / exposed	1 / 7 (14.29%)	3 / 20 (15.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Immune system disorders			
Anaphylactic reaction			
subjects affected / exposed	0 / 7 (0.00%)	1 / 20 (5.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Drug hypersensitivity			
subjects affected / exposed	0 / 7 (0.00%)	1 / 20 (5.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Intestinal haematoma			
subjects affected / exposed	0 / 7 (0.00%)	0 / 20 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nausea			
subjects affected / exposed	0 / 7 (0.00%)	1 / 20 (5.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Small intestinal obstruction			
subjects affected / exposed	0 / 7 (0.00%)	0 / 20 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vomiting			
subjects affected / exposed	0 / 7 (0.00%)	1 / 20 (5.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Hypoxia			
subjects affected / exposed	0 / 7 (0.00%)	2 / 20 (10.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	

Productive cough			
subjects affected / exposed	0 / 7 (0.00%)	1 / 20 (5.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory distress			
subjects affected / exposed	0 / 7 (0.00%)	1 / 20 (5.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 7 (0.00%)	1 / 20 (5.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haematuria			
subjects affected / exposed	0 / 7 (0.00%)	1 / 20 (5.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Bacterial infection			
subjects affected / exposed	0 / 7 (0.00%)	1 / 20 (5.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cellulitis			
subjects affected / exposed	0 / 7 (0.00%)	1 / 20 (5.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Influenza			
subjects affected / exposed	0 / 7 (0.00%)	1 / 20 (5.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oral herpes			
subjects affected / exposed	0 / 7 (0.00%)	1 / 20 (5.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Pneumonia			
subjects affected / exposed	0 / 7 (0.00%)	3 / 20 (15.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory syncytial virus infection			
subjects affected / exposed	0 / 7 (0.00%)	1 / 20 (5.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sepsis			
subjects affected / exposed	0 / 7 (0.00%)	2 / 20 (10.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Viral infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 20 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vulvovaginal candidiasis			
subjects affected / exposed	0 / 7 (0.00%)	1 / 20 (5.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 7 (0.00%)	5 / 20 (25.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Electrolyte imbalance			
subjects affected / exposed	0 / 7 (0.00%)	1 / 20 (5.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malnutrition			
subjects affected / exposed	0 / 7 (0.00%)	0 / 20 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Frequency threshold for reporting non-serious adverse events: 0 %

Non-serious adverse events	Dalteparin Sodium: Group 1 (>=0 to <8 Week)	Dalteparin Sodium: Group 2 (>=8 week to <2 year)	Dalteparin Sodium: Group 3 (>=2 year to <8 year)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	1 / 1 (100.00%)	2 / 2 (100.00%)	7 / 8 (87.50%)
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Haematoma			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	2
Hypertension			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Vein disorder			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 1 (0.00%)	1 / 2 (50.00%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Catheter site bruise			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Catheter site haematoma			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Catheter site pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Gait disturbance			

subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Infusion site bruising			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Infusion site haemorrhage			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Injection site bruising			
subjects affected / exposed	0 / 1 (0.00%)	1 / 2 (50.00%)	2 / 8 (25.00%)
occurrences (all)	0	1	3
Injection site haematoma			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Injection site haemorrhage			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Injection site mass			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Injection site nodule			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Injection site pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Localised oedema			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Mucosal haemorrhage			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Mucosal inflammation			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Nodule			

subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	0 / 1 (0.00%)	1 / 2 (50.00%)	2 / 8 (25.00%)
occurrences (all)	0	2	3
Swelling			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Catheter site inflammation			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Drug hypersensitivity			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hypocomplementaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Vulvovaginal pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Atelectasis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Cough			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	2 / 8 (25.00%)
occurrences (all)	0	0	3
Epistaxis			

subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Haemoptysis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Pharyngeal erythema			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Pulmonary mass			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Pulmonary oedema			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Rhinitis allergic			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Rhinorrhoea			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	2 / 8 (25.00%)
occurrences (all)	0	0	2
Sinus disorder			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Tachypnoea			
subjects affected / exposed	0 / 1 (0.00%)	1 / 2 (50.00%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0

Mental disorder			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Investigations			
Activated partial thromboplastin time prolonged			
subjects affected / exposed	0 / 1 (0.00%)	1 / 2 (50.00%)	2 / 8 (25.00%)
occurrences (all)	0	1	2
Alanine aminotransferase increased			
subjects affected / exposed	1 / 1 (100.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Aspergillus test positive			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Blood calcium increased			
subjects affected / exposed	0 / 1 (0.00%)	1 / 2 (50.00%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Blood fibrinogen decreased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Blood fibrinogen increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Blood urea increased			
subjects affected / exposed	0 / 1 (0.00%)	1 / 2 (50.00%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Body temperature increased			
subjects affected / exposed	0 / 1 (0.00%)	1 / 2 (50.00%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
C-reactive protein increased			

subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Haematocrit decreased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Haemoglobin decreased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hepatitis A virus test positive			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
International normalised ratio increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Lymphocyte count decreased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Neutrophil count decreased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Platelet count decreased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Platelet count increased			
subjects affected / exposed	1 / 1 (100.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Prothrombin time prolonged			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Transaminases increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed	0 / 1 (0.00%)	1 / 2 (50.00%)	0 / 8 (0.00%)
occurrences (all)	0	1	0

White blood cell count decreased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Bone contusion			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Contusion			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Fall			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Laceration			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Ligament sprain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Refractoriness to platelet transfusion			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Skin abrasion			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Tachycardia			
subjects affected / exposed	0 / 1 (0.00%)	1 / 2 (50.00%)	2 / 8 (25.00%)
occurrences (all)	0	1	3
Nervous system disorders			
Altered state of consciousness			
subjects affected / exposed	0 / 1 (0.00%)	1 / 2 (50.00%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Ataxia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0

Dizziness			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	2 / 8 (25.00%)
occurrences (all)	0	0	2
Hypoaesthesia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Neuralgia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Neuropathy peripheral			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 1 (0.00%)	1 / 2 (50.00%)	3 / 8 (37.50%)
occurrences (all)	0	1	4
Coagulopathy			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Febrile neutropenia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Leukopenia			
subjects affected / exposed	0 / 1 (0.00%)	1 / 2 (50.00%)	0 / 8 (0.00%)
occurrences (all)	0	2	0
Neutropenia			
subjects affected / exposed	0 / 1 (0.00%)	1 / 2 (50.00%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Pancytopenia			

subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Thrombocytopenia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	2 / 8 (25.00%)
occurrences (all)	0	0	2
Ear and labyrinth disorders			
Cerumen impaction			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Ear pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Dry eye			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Eye swelling			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Ocular hyperaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Photophobia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Vision blurred			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal distension			
subjects affected / exposed	0 / 1 (0.00%)	1 / 2 (50.00%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Abdominal pain upper			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Abdominal tenderness			

subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Anal fissure			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Ascites			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Chapped lips			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Cheilitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Colitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Constipation			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Diarrhoea			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	3 / 8 (37.50%)
occurrences (all)	0	0	3
Dry mouth			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Dyspepsia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Erosive oesophagitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Gingival bleeding			

subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Haematemesis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Haematochezia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Intestinal dilatation			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Intra-abdominal haematoma			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Lip dry			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Lip haemorrhage			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Mouth ulceration			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	0 / 1 (0.00%)	1 / 2 (50.00%)	2 / 8 (25.00%)
occurrences (all)	0	1	2
Oesophageal pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Perianal erythema			
subjects affected / exposed	0 / 1 (0.00%)	1 / 2 (50.00%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Proctalgia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Stomatitis			

subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Vomiting			
subjects affected / exposed	0 / 1 (0.00%)	2 / 2 (100.00%)	1 / 8 (12.50%)
occurrences (all)	0	2	1
Hepatobiliary disorders			
Cholelithiasis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hyperbilirubinaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Acanthosis nigricans			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Alopecia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Dermatitis contact			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	2 / 8 (25.00%)
occurrences (all)	0	0	2
Dry skin			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Ecchymosis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Eczema			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Erythema			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Pain of skin			

subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Petechiae			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Pruritus generalised			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Rash erythematous			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Rash macular			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Rash maculo-papular			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Red man syndrome			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Skin discolouration			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Skin disorder			
subjects affected / exposed	0 / 1 (0.00%)	1 / 2 (50.00%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Skin induration			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Urticaria contact			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Renal and urinary disorders			

Haematuria			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Leukocyturia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Back pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Haemarthrosis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	4
Muscular weakness			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Musculoskeletal chest pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Neck pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Pain in jaw			

subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Spinal pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Aspergillus infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Bacterial infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Bacteriuria			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Clostridium difficile colitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Clostridium difficile infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Genitourinary tract infection			
subjects affected / exposed	0 / 1 (0.00%)	1 / 2 (50.00%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Influenza			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Infusion site cellulitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Paronychia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0

Pharyngitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Rhinovirus infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Sinusitis bacteria			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Skin infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Stoma site cellulitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Vaginal infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Viral diarrhoea			
subjects affected / exposed	0 / 1 (0.00%)	1 / 2 (50.00%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Viral infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 1 (0.00%)	1 / 2 (50.00%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Fluid overload			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hyperglycaemia			

subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hyperkalaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hyperuricaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hypoalbuminaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hypocalcaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Hypokalaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hypomagnesaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hyponatraemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hypophosphataemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Magnesium deficiency			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1

Non-serious adverse events	Dalteparin Sodium: Group 4 (>=8 year to <12 year)	Dalteparin Sodium: Group 5 (>=12 year to <19 year)	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	7 / 7 (100.00%)	16 / 20 (80.00%)	
Vascular disorders			

Deep vein thrombosis			
subjects affected / exposed	1 / 7 (14.29%)	0 / 20 (0.00%)	
occurrences (all)	2	0	
Haematoma			
subjects affected / exposed	0 / 7 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Hypertension			
subjects affected / exposed	0 / 7 (0.00%)	2 / 20 (10.00%)	
occurrences (all)	0	2	
Vein disorder			
subjects affected / exposed	0 / 7 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Catheter site bruise			
subjects affected / exposed	0 / 7 (0.00%)	1 / 20 (5.00%)	
occurrences (all)	0	1	
Catheter site haematoma			
subjects affected / exposed	0 / 7 (0.00%)	1 / 20 (5.00%)	
occurrences (all)	0	1	
Catheter site pain			
subjects affected / exposed	1 / 7 (14.29%)	0 / 20 (0.00%)	
occurrences (all)	2	0	
Fatigue			
subjects affected / exposed	0 / 7 (0.00%)	2 / 20 (10.00%)	
occurrences (all)	0	2	
Gait disturbance			
subjects affected / exposed	0 / 7 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Infusion site bruising			
subjects affected / exposed	0 / 7 (0.00%)	1 / 20 (5.00%)	
occurrences (all)	0	1	
Infusion site haemorrhage			

subjects affected / exposed	0 / 7 (0.00%)	1 / 20 (5.00%)	
occurrences (all)	0	1	
Injection site bruising			
subjects affected / exposed	4 / 7 (57.14%)	8 / 20 (40.00%)	
occurrences (all)	23	14	
Injection site haematoma			
subjects affected / exposed	0 / 7 (0.00%)	1 / 20 (5.00%)	
occurrences (all)	0	1	
Injection site haemorrhage			
subjects affected / exposed	1 / 7 (14.29%)	1 / 20 (5.00%)	
occurrences (all)	2	1	
Injection site mass			
subjects affected / exposed	0 / 7 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Injection site nodule			
subjects affected / exposed	1 / 7 (14.29%)	1 / 20 (5.00%)	
occurrences (all)	1	1	
Injection site pain			
subjects affected / exposed	0 / 7 (0.00%)	4 / 20 (20.00%)	
occurrences (all)	0	5	
Localised oedema			
subjects affected / exposed	0 / 7 (0.00%)	1 / 20 (5.00%)	
occurrences (all)	0	1	
Mucosal haemorrhage			
subjects affected / exposed	0 / 7 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Mucosal inflammation			
subjects affected / exposed	1 / 7 (14.29%)	2 / 20 (10.00%)	
occurrences (all)	2	2	
Nodule			
subjects affected / exposed	1 / 7 (14.29%)	0 / 20 (0.00%)	
occurrences (all)	4	0	
Oedema peripheral			
subjects affected / exposed	2 / 7 (28.57%)	1 / 20 (5.00%)	
occurrences (all)	2	1	
Pain			

subjects affected / exposed	2 / 7 (28.57%)	1 / 20 (5.00%)	
occurrences (all)	0	1	
Pyrexia			
subjects affected / exposed	2 / 7 (28.57%)	2 / 20 (10.00%)	
occurrences (all)	5	2	
Swelling			
subjects affected / exposed	0 / 7 (0.00%)	1 / 20 (5.00%)	
occurrences (all)	0	1	
Catheter site inflammation			
subjects affected / exposed	1 / 7 (14.29%)	0 / 20 (0.00%)	
occurrences (all)	1	0	
Immune system disorders			
Drug hypersensitivity			
subjects affected / exposed	0 / 7 (0.00%)	1 / 20 (5.00%)	
occurrences (all)	0	3	
Hypocomplementaemia			
subjects affected / exposed	0 / 7 (0.00%)	1 / 20 (5.00%)	
occurrences (all)	0	1	
Reproductive system and breast disorders			
Vulvovaginal pain			
subjects affected / exposed	0 / 7 (0.00%)	1 / 20 (5.00%)	
occurrences (all)	0	1	
Respiratory, thoracic and mediastinal disorders			
Atelectasis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Cough			
subjects affected / exposed	0 / 7 (0.00%)	1 / 20 (5.00%)	
occurrences (all)	0	1	
Epistaxis			
subjects affected / exposed	0 / 7 (0.00%)	3 / 20 (15.00%)	
occurrences (all)	0	9	
Haemoptysis			
subjects affected / exposed	0 / 7 (0.00%)	1 / 20 (5.00%)	
occurrences (all)	0	1	
Oropharyngeal pain			

subjects affected / exposed	1 / 7 (14.29%)	4 / 20 (20.00%)	
occurrences (all)	1	5	
Pharyngeal erythema			
subjects affected / exposed	0 / 7 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Pulmonary mass			
subjects affected / exposed	1 / 7 (14.29%)	0 / 20 (0.00%)	
occurrences (all)	1	0	
Pulmonary oedema			
subjects affected / exposed	0 / 7 (0.00%)	1 / 20 (5.00%)	
occurrences (all)	0	1	
Rhinitis allergic			
subjects affected / exposed	0 / 7 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Rhinorrhoea			
subjects affected / exposed	0 / 7 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Sinus disorder			
subjects affected / exposed	0 / 7 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Tachypnoea			
subjects affected / exposed	0 / 7 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 7 (0.00%)	1 / 20 (5.00%)	
occurrences (all)	0	1	
Insomnia			
subjects affected / exposed	0 / 7 (0.00%)	1 / 20 (5.00%)	
occurrences (all)	0	1	
Mental disorder			
subjects affected / exposed	1 / 7 (14.29%)	0 / 20 (0.00%)	
occurrences (all)	1	0	
Investigations			
Activated partial thromboplastin time prolonged			

subjects affected / exposed	0 / 7 (0.00%)	2 / 20 (10.00%)	
occurrences (all)	0	2	
Alanine aminotransferase increased			
subjects affected / exposed	1 / 7 (14.29%)	2 / 20 (10.00%)	
occurrences (all)	2	2	
Aspartate aminotransferase increased			
subjects affected / exposed	1 / 7 (14.29%)	2 / 20 (10.00%)	
occurrences (all)	4	2	
Aspergillus test positive			
subjects affected / exposed	0 / 7 (0.00%)	1 / 20 (5.00%)	
occurrences (all)	0	1	
Blood calcium increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Blood fibrinogen decreased			
subjects affected / exposed	0 / 7 (0.00%)	1 / 20 (5.00%)	
occurrences (all)	0	1	
Blood fibrinogen increased			
subjects affected / exposed	0 / 7 (0.00%)	1 / 20 (5.00%)	
occurrences (all)	0	1	
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Blood urea increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Body temperature increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
C-reactive protein increased			
subjects affected / exposed	0 / 7 (0.00%)	1 / 20 (5.00%)	
occurrences (all)	0	1	
Haematocrit decreased			

subjects affected / exposed	0 / 7 (0.00%)	1 / 20 (5.00%)		
occurrences (all)	0	1		
Haemoglobin decreased				
subjects affected / exposed	2 / 7 (28.57%)	1 / 20 (5.00%)		
occurrences (all)	16	2		
Hepatitis A virus test positive				
subjects affected / exposed	0 / 7 (0.00%)	1 / 20 (5.00%)		
occurrences (all)	0	1		
International normalised ratio increased				
subjects affected / exposed	0 / 7 (0.00%)	1 / 20 (5.00%)		
occurrences (all)	0	1		
Lymphocyte count decreased				
subjects affected / exposed	0 / 7 (0.00%)	1 / 20 (5.00%)		
occurrences (all)	0	1		
Neutrophil count decreased				
subjects affected / exposed	1 / 7 (14.29%)	1 / 20 (5.00%)		
occurrences (all)	3	1		
Platelet count decreased				
subjects affected / exposed	2 / 7 (28.57%)	1 / 20 (5.00%)		
occurrences (all)	9	1		
Platelet count increased				
subjects affected / exposed	0 / 7 (0.00%)	0 / 20 (0.00%)		
occurrences (all)	0	0		
Prothrombin time prolonged				
subjects affected / exposed	0 / 7 (0.00%)	2 / 20 (10.00%)		
occurrences (all)	0	2		
Transaminases increased				
subjects affected / exposed	2 / 7 (28.57%)	0 / 20 (0.00%)		
occurrences (all)	5	0		
Weight decreased				
subjects affected / exposed	0 / 7 (0.00%)	1 / 20 (5.00%)		
occurrences (all)	0	2		
White blood cell count decreased				
subjects affected / exposed	1 / 7 (14.29%)	1 / 20 (5.00%)		
occurrences (all)	8	1		

Injury, poisoning and procedural complications			
Bone contusion			
subjects affected / exposed	0 / 7 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Contusion			
subjects affected / exposed	2 / 7 (28.57%)	3 / 20 (15.00%)	
occurrences (all)	3	6	
Fall			
subjects affected / exposed	0 / 7 (0.00%)	1 / 20 (5.00%)	
occurrences (all)	0	1	
Laceration			
subjects affected / exposed	1 / 7 (14.29%)	0 / 20 (0.00%)	
occurrences (all)	1	0	
Ligament sprain			
subjects affected / exposed	0 / 7 (0.00%)	1 / 20 (5.00%)	
occurrences (all)	0	1	
Refractoriness to platelet transfusion			
subjects affected / exposed	0 / 7 (0.00%)	1 / 20 (5.00%)	
occurrences (all)	0	1	
Skin abrasion			
subjects affected / exposed	0 / 7 (0.00%)	1 / 20 (5.00%)	
occurrences (all)	0	1	
Cardiac disorders			
Tachycardia			
subjects affected / exposed	2 / 7 (28.57%)	0 / 20 (0.00%)	
occurrences (all)	2	0	
Nervous system disorders			
Altered state of consciousness			
subjects affected / exposed	0 / 7 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Ataxia			
subjects affected / exposed	1 / 7 (14.29%)	0 / 20 (0.00%)	
occurrences (all)	1	0	
Dizziness			
subjects affected / exposed	0 / 7 (0.00%)	2 / 20 (10.00%)	
occurrences (all)	0	2	

Headache			
subjects affected / exposed	2 / 7 (28.57%)	2 / 20 (10.00%)	
occurrences (all)	3	2	
Hypoaesthesia			
subjects affected / exposed	1 / 7 (14.29%)	0 / 20 (0.00%)	
occurrences (all)	1	0	
Neuralgia			
subjects affected / exposed	0 / 7 (0.00%)	1 / 20 (5.00%)	
occurrences (all)	0	1	
Neuropathy peripheral			
subjects affected / exposed	1 / 7 (14.29%)	1 / 20 (5.00%)	
occurrences (all)	1	1	
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 7 (0.00%)	1 / 20 (5.00%)	
occurrences (all)	0	1	
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 7 (14.29%)	2 / 20 (10.00%)	
occurrences (all)	1	3	
Coagulopathy			
subjects affected / exposed	1 / 7 (14.29%)	0 / 20 (0.00%)	
occurrences (all)	1	0	
Febrile neutropenia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Leukopenia			
subjects affected / exposed	0 / 7 (0.00%)	1 / 20 (5.00%)	
occurrences (all)	0	1	
Neutropenia			
subjects affected / exposed	0 / 7 (0.00%)	3 / 20 (15.00%)	
occurrences (all)	0	4	
Pancytopenia			
subjects affected / exposed	1 / 7 (14.29%)	0 / 20 (0.00%)	
occurrences (all)	1	0	
Thrombocytopenia			

subjects affected / exposed	0 / 7 (0.00%)	1 / 20 (5.00%)	
occurrences (all)	0	3	
Ear and labyrinth disorders			
Cerumen impaction			
subjects affected / exposed	0 / 7 (0.00%)	1 / 20 (5.00%)	
occurrences (all)	0	1	
Ear pain			
subjects affected / exposed	0 / 7 (0.00%)	1 / 20 (5.00%)	
occurrences (all)	0	1	
Eye disorders			
Dry eye			
subjects affected / exposed	1 / 7 (14.29%)	1 / 20 (5.00%)	
occurrences (all)	1	1	
Eye swelling			
subjects affected / exposed	0 / 7 (0.00%)	1 / 20 (5.00%)	
occurrences (all)	0	1	
Ocular hyperaemia			
subjects affected / exposed	1 / 7 (14.29%)	0 / 20 (0.00%)	
occurrences (all)	1	0	
Photophobia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Vision blurred			
subjects affected / exposed	0 / 7 (0.00%)	1 / 20 (5.00%)	
occurrences (all)	0	1	
Gastrointestinal disorders			
Abdominal distension			
subjects affected / exposed	0 / 7 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Abdominal pain upper			
subjects affected / exposed	0 / 7 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Abdominal tenderness			
subjects affected / exposed	0 / 7 (0.00%)	1 / 20 (5.00%)	
occurrences (all)	0	1	
Anal fissure			

subjects affected / exposed	1 / 7 (14.29%)	1 / 20 (5.00%)	
occurrences (all)	1	1	
Ascites			
subjects affected / exposed	0 / 7 (0.00%)	1 / 20 (5.00%)	
occurrences (all)	0	1	
Chapped lips			
subjects affected / exposed	0 / 7 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Cheilitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Colitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Constipation			
subjects affected / exposed	0 / 7 (0.00%)	1 / 20 (5.00%)	
occurrences (all)	0	0	
Diarrhoea			
subjects affected / exposed	1 / 7 (14.29%)	1 / 20 (5.00%)	
occurrences (all)	1	2	
Dry mouth			
subjects affected / exposed	0 / 7 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Dyspepsia			
subjects affected / exposed	0 / 7 (0.00%)	1 / 20 (5.00%)	
occurrences (all)	0	1	
Erosive oesophagitis			
subjects affected / exposed	1 / 7 (14.29%)	0 / 20 (0.00%)	
occurrences (all)	1	0	
Gastrointestinal pain			
subjects affected / exposed	1 / 7 (14.29%)	0 / 20 (0.00%)	
occurrences (all)	1	0	
Gingival bleeding			
subjects affected / exposed	1 / 7 (14.29%)	1 / 20 (5.00%)	
occurrences (all)	1	1	
Haematemesis			

subjects affected / exposed	1 / 7 (14.29%)	1 / 20 (5.00%)	
occurrences (all)	1	1	
Haematochezia			
subjects affected / exposed	0 / 7 (0.00%)	1 / 20 (5.00%)	
occurrences (all)	0	1	
Intestinal dilatation			
subjects affected / exposed	0 / 7 (0.00%)	1 / 20 (5.00%)	
occurrences (all)	0	1	
Intra-abdominal haematoma			
subjects affected / exposed	1 / 7 (14.29%)	0 / 20 (0.00%)	
occurrences (all)	1	0	
Lip dry			
subjects affected / exposed	0 / 7 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Lip haemorrhage			
subjects affected / exposed	0 / 7 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Mouth ulceration			
subjects affected / exposed	1 / 7 (14.29%)	0 / 20 (0.00%)	
occurrences (all)	1	0	
Nausea			
subjects affected / exposed	1 / 7 (14.29%)	0 / 20 (0.00%)	
occurrences (all)	1	0	
Oesophageal pain			
subjects affected / exposed	0 / 7 (0.00%)	1 / 20 (5.00%)	
occurrences (all)	0	1	
Perianal erythema			
subjects affected / exposed	0 / 7 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Proctalgia			
subjects affected / exposed	0 / 7 (0.00%)	1 / 20 (5.00%)	
occurrences (all)	0	1	
Stomatitis			
subjects affected / exposed	1 / 7 (14.29%)	2 / 20 (10.00%)	
occurrences (all)	1	2	
Vomiting			

subjects affected / exposed	2 / 7 (28.57%)	1 / 20 (5.00%)	
occurrences (all)	2	1	
Hepatobiliary disorders			
Cholelithiasis			
subjects affected / exposed	0 / 7 (0.00%)	1 / 20 (5.00%)	
occurrences (all)	0	1	
Hyperbilirubinaemia			
subjects affected / exposed	1 / 7 (14.29%)	0 / 20 (0.00%)	
occurrences (all)	1	0	
Skin and subcutaneous tissue disorders			
Acanthosis nigricans			
subjects affected / exposed	0 / 7 (0.00%)	1 / 20 (5.00%)	
occurrences (all)	0	1	
Alopecia			
subjects affected / exposed	1 / 7 (14.29%)	2 / 20 (10.00%)	
occurrences (all)	1	2	
Dermatitis contact			
subjects affected / exposed	0 / 7 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Dry skin			
subjects affected / exposed	0 / 7 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Ecchymosis			
subjects affected / exposed	1 / 7 (14.29%)	1 / 20 (5.00%)	
occurrences (all)	1	1	
Eczema			
subjects affected / exposed	0 / 7 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Erythema			
subjects affected / exposed	0 / 7 (0.00%)	1 / 20 (5.00%)	
occurrences (all)	0	1	
Pain of skin			
subjects affected / exposed	1 / 7 (14.29%)	1 / 20 (5.00%)	
occurrences (all)	1	1	
Petechiae			

subjects affected / exposed	0 / 7 (0.00%)	1 / 20 (5.00%)	
occurrences (all)	0	1	
Pruritus generalised			
subjects affected / exposed	1 / 7 (14.29%)	0 / 20 (0.00%)	
occurrences (all)	1	0	
Rash			
subjects affected / exposed	0 / 7 (0.00%)	1 / 20 (5.00%)	
occurrences (all)	0	1	
Rash erythematous			
subjects affected / exposed	0 / 7 (0.00%)	1 / 20 (5.00%)	
occurrences (all)	0	1	
Rash macular			
subjects affected / exposed	0 / 7 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Rash maculo-papular			
subjects affected / exposed	1 / 7 (14.29%)	0 / 20 (0.00%)	
occurrences (all)	1	0	
Red man syndrome			
subjects affected / exposed	0 / 7 (0.00%)	1 / 20 (5.00%)	
occurrences (all)	0	1	
Skin discolouration			
subjects affected / exposed	0 / 7 (0.00%)	1 / 20 (5.00%)	
occurrences (all)	0	1	
Skin disorder			
subjects affected / exposed	0 / 7 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Skin induration			
subjects affected / exposed	0 / 7 (0.00%)	1 / 20 (5.00%)	
occurrences (all)	0	1	
Urticaria contact			
subjects affected / exposed	0 / 7 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Renal and urinary disorders			
Haematuria			
subjects affected / exposed	0 / 7 (0.00%)	1 / 20 (5.00%)	
occurrences (all)	0	1	

Leukocyturia			
subjects affected / exposed	0 / 7 (0.00%)	1 / 20 (5.00%)	
occurrences (all)	0	1	
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	1 / 7 (14.29%)	2 / 20 (10.00%)	
occurrences (all)	1	2	
Back pain			
subjects affected / exposed	0 / 7 (0.00%)	1 / 20 (5.00%)	
occurrences (all)	0	1	
Haemarthrosis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Muscular weakness			
subjects affected / exposed	0 / 7 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Musculoskeletal chest pain			
subjects affected / exposed	0 / 7 (0.00%)	1 / 20 (5.00%)	
occurrences (all)	0	2	
Musculoskeletal pain			
subjects affected / exposed	0 / 7 (0.00%)	1 / 20 (5.00%)	
occurrences (all)	0	1	
Myalgia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Neck pain			
subjects affected / exposed	0 / 7 (0.00%)	1 / 20 (5.00%)	
occurrences (all)	0	1	
Pain in extremity			
subjects affected / exposed	1 / 7 (14.29%)	2 / 20 (10.00%)	
occurrences (all)	1	2	
Pain in jaw			
subjects affected / exposed	1 / 7 (14.29%)	0 / 20 (0.00%)	
occurrences (all)	1	0	
Spinal pain			

subjects affected / exposed	0 / 7 (0.00%)	1 / 20 (5.00%)	
occurrences (all)	0	1	
Infections and infestations			
Aspergillus infection			
subjects affected / exposed	1 / 7 (14.29%)	0 / 20 (0.00%)	
occurrences (all)	1	0	
Bacterial infection			
subjects affected / exposed	0 / 7 (0.00%)	1 / 20 (5.00%)	
occurrences (all)	0	1	
Bacteriuria			
subjects affected / exposed	0 / 7 (0.00%)	1 / 20 (5.00%)	
occurrences (all)	0	1	
Clostridium difficile colitis			
subjects affected / exposed	1 / 7 (14.29%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Clostridium difficile infection			
subjects affected / exposed	1 / 7 (14.29%)	0 / 20 (0.00%)	
occurrences (all)	1	0	
Conjunctivitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Genitourinary tract infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Influenza			
subjects affected / exposed	0 / 7 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Infusion site cellulitis			
subjects affected / exposed	0 / 7 (0.00%)	1 / 20 (5.00%)	
occurrences (all)	0	1	
Paronychia			
subjects affected / exposed	0 / 7 (0.00%)	1 / 20 (5.00%)	
occurrences (all)	0	2	
Pharyngitis			
subjects affected / exposed	0 / 7 (0.00%)	1 / 20 (5.00%)	
occurrences (all)	0	1	

Rhinitis			
subjects affected / exposed	0 / 7 (0.00%)	1 / 20 (5.00%)	
occurrences (all)	0	1	
Rhinovirus infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Sinusitis bacteria			
subjects affected / exposed	1 / 7 (14.29%)	0 / 20 (0.00%)	
occurrences (all)	1	0	
Skin infection			
subjects affected / exposed	0 / 7 (0.00%)	1 / 20 (5.00%)	
occurrences (all)	0	1	
Stoma site cellulitis			
subjects affected / exposed	0 / 7 (0.00%)	1 / 20 (5.00%)	
occurrences (all)	0	1	
Vaginal infection			
subjects affected / exposed	0 / 7 (0.00%)	1 / 20 (5.00%)	
occurrences (all)	0	1	
Viral diarrhoea			
subjects affected / exposed	0 / 7 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Viral infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 7 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Fluid overload			
subjects affected / exposed	0 / 7 (0.00%)	1 / 20 (5.00%)	
occurrences (all)	0	1	
Hyperglycaemia			
subjects affected / exposed	1 / 7 (14.29%)	0 / 20 (0.00%)	
occurrences (all)	1	0	
Hyperkalaemia			

subjects affected / exposed	1 / 7 (14.29%)	0 / 20 (0.00%)	
occurrences (all)	1	0	
Hyperuricaemia			
subjects affected / exposed	0 / 7 (0.00%)	1 / 20 (5.00%)	
occurrences (all)	0	1	
Hypoalbuminaemia			
subjects affected / exposed	1 / 7 (14.29%)	0 / 20 (0.00%)	
occurrences (all)	6	0	
Hypocalcaemia			
subjects affected / exposed	1 / 7 (14.29%)	2 / 20 (10.00%)	
occurrences (all)	3	2	
Hypokalaemia			
subjects affected / exposed	1 / 7 (14.29%)	2 / 20 (10.00%)	
occurrences (all)	5	2	
Hypomagnesaemia			
subjects affected / exposed	1 / 7 (14.29%)	0 / 20 (0.00%)	
occurrences (all)	1	0	
Hyponatraemia			
subjects affected / exposed	1 / 7 (14.29%)	1 / 20 (5.00%)	
occurrences (all)	8	1	
Hypophosphataemia			
subjects affected / exposed	1 / 7 (14.29%)	1 / 20 (5.00%)	
occurrences (all)	1	1	
Magnesium deficiency			
subjects affected / exposed	0 / 7 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
04 September 2008	1. Clarified the timing of dose adjustments was to be within 12 to 30 hours if the target therapeutic range was not achieved. 2. Clarified the definition of a major bleeding event. 3. Updated the exclusion criteria to remove overt bleeding deemed by the investigator to necessitate discontinuation of study medication. 4. Clarified guidelines for subject withdrawal from the study due to an elevated platelet count to be consistent with the standard of care. 5. Removed glucose tolerance test from list of clinical chemistry assessments.
20 February 2009	1. Refined the age groups to the following: 0 to <8 weeks (newborns); >=8 weeks to <1 year (infants); >=1 year to <6 years (preschool); >=6 years to <13 years (school); >=13 years to <19 years. 2. Removed the first-dose-only requirement for daily anti-Xa level measurements at 4 hours postdose during the Dose Adjustment Phase. 3. Removed the requirement to receive at least 5 doses after achieving the target therapeutic range before entering the PD Phase. 4. Updated the exclusion criteria to allow newborns with a creatinine clearance less than 60 mL/min. 5. Updated the exclusion criteria to exclude subjects with uncontrolled hypertension characterized by sustained systolic or diastolic blood pressure greater than the 99th percentile of age- and height-related norms. 6. Updated the exclusion criteria to allow subjects with common fungal infections that would not interfere with the study. 7. Updated the exclusion criteria to allow subjects presently or previously, within 30 days, enrolled in a study evaluating erwinia asparaginase. 8. Updated to allow for redrawing of PD samples for active subjects any time prior to the last study visit. 9. Added direction regarding the management of subjects with platelet counts below 50,000/mm3. 10. Added direction regarding procedures that required interruption of study treatment.
15 September 2010	1. The determination of PD profiles for treatment doses of dalteparin in pediatric subjects of different ages with cancer and VTE was updated to a primary objective rather than a secondary objective. 2. Updated the target enrollment to a total of 50 subjects who completed the PD Phase. 3. Revised the inclusion criteria to simplify the definition for cancer/malignancy, specify the appropriate age range, and include informed consent. 4. Updated the exclusion criteria for clarification, primarily investigator determination of bleeding risk and clarity regarding clotting disorders. 5. Updated dosing windows to every 12 hours for clarification. 6. Added details to the definition for treatment discontinuation and treatment according to the standard of care. Also added guidance regarding subjects that experienced renal impairment. 7. Added a description of dalteparin dose adjustments for subjects with renal dysfunction.

01 September 2011	1. Updated exclusion criteria to allow subjects participating in other studies to be eligible for this study. 2. Removed the Day 90 imaging requirement for subjects with clot resolution prior to Day 90. 3. Allowed for the first anti-Xa blood draw to be after the first, second, or third study drug dose. 4. Changed the 15-hour washout period to greater than 12 hours for subjects switching from LMWH to Fragmin.
21 April 2015	Safety sections were updated per Pfizer safety reporting processes and procedures, and other relevant sections per Pfizer, Inc. processes and procedures.
18 November 2015	The primary purpose of this Pfizer amendment was to include protocol modifications endorsed by the FDA in a Type C Meeting conducted on 05 November 2015, including updates to the age cohort groups, inclusion of all subjects with VTE
18 October 2016	The Schwartz Method and Revised Schwartz Method for creatinine clearance calculations were added, as well as other minor changes.
27 September 2017	The primary purpose of this letter was to clarify the starting dose and the window for the baseline anti-Xa and anti-IIa sample.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported