



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	v1
This version publication date	03 October 2018
First version publication date	03 October 2018

Trial information

Trial identification

Sponsor protocol code	A6301094
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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. Subjects received treatment in overall study treatment period (total duration: 90 days) which included dose adjustment (DA) phase (Day 1-7), pharmacodynamic (PD) phase (Day 8-14) and follow up (FU) phase (Day 15-90).

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 (\geq) 0 to less than ($<$) 8 weeks were administered 125 IU/kg of dalteparin sodium injection subcutaneously twice daily from Day 1 to 7 in DA phase, Day 8-14 in PD phase and from Day 15 in FU 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 90 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)
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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 8-14 in PD phase and from Day 15 in FU 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 90 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)
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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 8-14 in PD phase and from Day 15 in FU 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 90 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)
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Arm description:

Subjects aged ≥ 8 weeks to < 12 years were administered 125 IU/kg of dalteparin sodium injection subcutaneously twice daily from Day 1 to 7 in DA phase, Day 8-14 in PD phase and from Day 15 in FU 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 90 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)
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Arm description:

Subjects aged ≥ 12 weeks to < 19 years were administered 100 IU/kg of dalteparin sodium injection subcutaneously twice daily from Day 1 to 7 in DA phase, Day 8-14 in PD phase and from Day 15 in FU 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 90 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
Adverse event, non-fatal	-	1	-
Unspecified	-	-	1
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
Adverse event, non-fatal	-	3
Unspecified	3	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 (\geq) 0 to less than ($<$) 8 weeks were administered 125 IU/kg of dalteparin sodium injection subcutaneously twice daily from Day 1 to 7 in DA phase, Day 8-14 in PD phase and from Day 15 in FU 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 90 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 8-14 in PD phase and from Day 15 in FU 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 90 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 8-14 in PD phase and from Day 15 in FU 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 90 days).	
Reporting group title	Dalteparin Sodium: Group 4 (≥ 8 year to < 12 year)
Reporting group description: Subjects aged ≥ 8 weeks to < 12 years were administered 125 IU/kg of dalteparin sodium injection subcutaneously twice daily from Day 1 to 7 in DA phase, Day 8-14 in PD phase and from Day 15 in FU 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 90 days).	
Reporting group title	Dalteparin Sodium: Group 5 (≥ 12 year to < 19 year)
Reporting group description: Subjects aged ≥ 12 weeks to < 19 years were administered 100 IU/kg of dalteparin sodium injection subcutaneously twice daily from Day 1 to 7 in DA phase, Day 8-14 in PD phase and from Day 15 in FU 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 90 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 full range (min-max)	0.0684 0.0684 to 0.0684	1.0569 0.1999 to 1.9138	5.3676 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 full range (min-max)	10.0287 8.3833 to 11.8741	15.7208 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)
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Reporting group description:

Subjects aged greater than or equal to (\geq) 0 to less than ($<$) 8 weeks were administered 125 IU/kg of dalteparin sodium injection subcutaneously twice daily from Day 1 to 7 in DA phase, Day 8-14 in PD phase and from Day 15 in FU 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 90 days).

Reporting group title	Dalteparin Sodium: Group 2 (≥ 8 week to < 2 year)
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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 8-14 in PD phase and from Day 15 in FU 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 90 days).

Reporting group title	Dalteparin Sodium: Group 3 (≥ 2 year to < 8 year)
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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 8-14 in PD phase and from Day 15 in FU 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 90 days).

Reporting group title	Dalteparin Sodium: Group 4 (≥ 8 year to < 12 year)
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Reporting group description:

Subjects aged ≥ 8 weeks to < 12 years were administered 125 IU/kg of dalteparin sodium injection subcutaneously twice daily from Day 1 to 7 in DA phase, Day 8-14 in PD phase and from Day 15 in FU 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 90 days).

Reporting group title	Dalteparin Sodium: Group 5 (≥ 12 year to < 19 year)
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Reporting group description:

Subjects aged ≥ 12 weeks to < 19 years were administered 100 IU/kg of dalteparin sodium injection subcutaneously twice daily from Day 1 to 7 in DA phase, Day 8-14 in PD phase and from Day 15 in FU 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 90 days).

Subject analysis set title	Dalteparin Sodium: All Subjects (≥ 0 to < 19 years)
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Subject analysis set type	Safety analysis
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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 90 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]
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End point description:

Prespecified therapeutic anti-factor Xa level was 0.5-1.0 IU/milliliter (mL). Cumulative data for Day 1 to 7 has been reported. Here, "Number of Subjects Analyzed" signifies those subjects who were evaluable for this end point. 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
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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: Only descriptive data was planned to be analysed for this endpoint.

End point values	Dalteparin Sodium: All Subjects (≥ 0 to < 19 years)			
Subject group type	Subject analysis set			
Number of subjects analysed	34			
Units: international unit per milliliter(IU/mL)				
number (not applicable)	125			

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
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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. Percentage of subjects who had achieved the prespecified level during the dose adjustment phase were reported in this endpoint. The safety analysis set included all the subjects who received at least 1 dose of study drug.

End point type	Secondary
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End point timeframe:

4 hours post-dose at each 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)			
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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]
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End point description:

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 a venous thromboembolism. Symptomatic 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, pain or tenderness, pitting edema, erythema or cyanosis. Progression may be defined as the progression of clot burden on a follow-up study 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.

End point type	Secondary
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End point timeframe:

Baseline up to 25 days after the last dose of study drug (up to Day 115)

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: 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)
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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 DVT and 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. It 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. Here, 99999 signifies that median and 95% CI was not estimable due to the low number of subjects who had VTE. PD analysis set.

End point type	Secondary
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End point timeframe:

Baseline up to 25 days after the last dose of study drug (up to Day 115)

End point values	Dalteparin Sodium: All Subjects (≥ 0 to < 19 years)			
Subject group type	Subject analysis set			
Number of subjects analysed	34			
Units: days				
median (confidence interval 95%)	99999 (-99999 to 99999)			

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) ^[3]
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End point description:

VTEs included both DVT and 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. Clinical response of progression was defined as progression of clot burden on a follow-up study in terms of severity of occlusion, or involvement of new venous segments at any time after the initial diagnosis. Clinical response of regression: Follow-up study demonstrating regressed clot burden utilizing the same imaging modality as the screening visit. Clinical response of resolution: Thrombus resolution of the qualifying event was measured by repeat imaging at the end of study (EOS) visit. Subjects had been categorized based upon the severity of the clinical response in the qualifying VTE as progression, no change, regression and resolution. PD analysis set.

End point type	Secondary
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End point timeframe:

Baseline up to 25 days after the last dose of study drug (up to Day 115)

Notes:

[3] - 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: 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
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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, 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). A bleeding event was considered as minor if it was clinically overt but not meeting the criteria for major or clinically relevant non-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
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End point timeframe:

Baseline up to 25 days after the last dose of study drug (up to Day 115)

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)
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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 25 days after the last dose of study drug (up to Day 115) 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.

End point type	Secondary
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End point timeframe:

Baseline up to 25 days after the last dose of study drug (up to Day 115)

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)			
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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 $<0.8 \times$ lower limit of normal (LLN), platelets $<0.5 \times$ LLN $>1.75 \times$ upper limit of normal (ULN), leukocytes $<0.6 \times$ LLN $>1.5 \times$ ULN, lymphocytes lymphocytes/Leukocytes%, neutrophils, neutrophils/leukocytes $<0.8 \times$ LLN $>1.2 \times$ ULN, basophils, basophils/leukocytes%, eosinophils, eosinophils/leukocytes, monocytes monocytes/leukocytes% $>1.2 \times$ ULN, activated partial thromboplastin time, prothrombin time, prothrombin intl. normalized ratio $>1.1 \times$ ULN. Chemistry: bilirubin $>1.5 \times$ ULN, AST, ALT, lactate dehydrogenase, alkaline phosphatase $>3.0 \times$ ULN, protein, albumin $<0.8 \times$ LLN $>1.2 \times$ ULN, blood urea nitrogen, creatinine $>1.3 \times$ ULN, sodium $<0.95 \times$ LLN $>1.05 \times$ ULN, potassium, chloride, calcium, magnesium $<0.9 \times$ LLN $>1.1 \times$ ULN, phosphate $<0.8 \times$ LLN $>1.2 \times$ ULN, glucose $<0.6 \times$ LLN $>1.5 \times$ ULN, estimated creatinine clearance, estimated Glomerular filtration rate modified and bedside schwartz, $>1.0 \times$ ULN. Urinalysis: creatinine $>1.0 \times$ ULN. N=number of subjects evaluable for this end point. Safety set.	
End point type	Secondary
End point timeframe:	
Baseline up to 25 days after the last dose of study drug (up to Day 115)	

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

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

End point title	Absolute Values of Systolic Blood Pressure (SBP) and Diastolic Blood Pressure (DSBP)
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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
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End point timeframe:

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: millimeters of mercury (mmHg)				
median (full range (min-max))				
SBP: Visit 2 (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: Visit 3 (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: Visit 4 (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: Visit 5 (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: Visit 6 (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: Visit 7 (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: Visit 2 (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: Visit 3 (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: Visit 4 (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: Visit 5 (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: Visit 6 (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: Visit 7 (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			
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	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: Visit 2 (n= 1,1,6,3,12)	117.50 (97.00 to 140.00)			
SBP: Visit 3 (n= 1,2,4,6,15)	113.00 (92.00 to 130.00)			
SBP: Visit 4 (n= 1,1,8,7,18)	119.50 (98.00 to 158.00)			
SBP: Visit 5 (n=1,1,7,5,17)	118.00 (95.00 to 133.00)			
SBP: Visit 6 (n=1,1,7,5,14)	117.50 (102.00 to 134.00)			
SBP: Visit 7 (n=1,2,8,7,19)	116.00 (89.00 to 151.00)			
DSBP: Visit 2 (n=1,1,6,3,12)	65.00 (46.00 to 80.00)			
DSBP: Visit 3 (n=1,2,4,6,15)	64.00 (48.00 to 80.00)			
DSBP: Visit 4 (n= 1,1,8,7,18)	65.00 (53.00 to 95.00)			
DSBP: Visit 5 (n= 1,1,7,5,17)	69.00 (55.00 to 87.00)			
DSBP: Visit 6 (n= 1,1,7,5,14)	67.00 (57.00 to 80.00)			
DSBP: Visit 7 (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)

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

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: beats per minute (bpm)				
median (full range (min-max))				
HR: Visit 2 (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: Visit 3 (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: Visit 4 (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: Visit 5 (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: Visit 6 (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: Visit 7 (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: Visit 2 (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: Visit 3 (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: Visit 4 (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: Visit 5 (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: Visit 6 (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: Visit 7 (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: Visit 2 (n=1,1,4,0,5)	70.00 (52.00 to 84.00)			
HR: Visit 3 (n=1,1,1,0,7)	85.00 (46.00 to 139.00)			
HR: Visit 4 (n=1,1,5,0,8)	75.00 (56.00 to 124.00)			
HR: Visit 5 (n=1,1,4,0,8)	87.50 (56.00 to 126.00)			

HR: Visit 6 (n=1,1,4,0,8)	94.50 (56.00 to 134.00)			
HR: Visit 7 (n=1,1,4,0,8)	80.00 (66.00 to 118.00)			
PR: Visit 2 (n=0,0,2,3,7)	73.00 (67.00 to 150.00)			
PR: Visit 3 (n=0,1,3,6,8)	94.50 (72.00 to 123.00)			
PR: Visit 4 (n=0,0,3,7,10)	93.00 (57.00 to 161.00)			
PR: Visit 5 (n=0,0,3,5,9)	102.00 (72.00 to 123.00)			
PR: Visit 6 (n=0,0,3,5,6)	95.00 (62.00 to 117.00)			
PR: Visit 7 (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

End point title	Absolute Values of Height
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: 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: centimeters (cm)				
median (full range (min-max))				
Visit 2 (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)
Visit 3 (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)
Visit 4 (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)
Visit 5 (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)

Visit 6 (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)
Visit 7 (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))				
Visit 2 (n=1,1,4,2,9)	166.00 (142.00 to 178.00)			
Visit 3 (n=1,0,3,2,11)	166.00 (113.50 to 184.00)			
Visit 4 (n=0,0,6,5,15)	166.90 (113.60 to 189.00)			
Visit 5 (n=1,1,5,6,14)	167.75 (113.90 to 184.00)			
Visit 6 (n=1,1,5,5,13)	168.50 (114.20 to 183.60)			
Visit 7 (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

End point title	Absolute Values of Weight
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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
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End point timeframe:

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: kilograms (kg)				
median (full range (min-max))				
Visit 2 (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)
Visit 3 (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)
Visit 4 (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)
Visit 5 (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)
Visit 6 (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)
Visit 7 (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))				
Visit 2 (n=1,1,6,3,9)	60.00 (48.00 to 86.90)			
Visit 3 (n=1,1,4,3,13)	63.40 (19.60 to 95.20)			
Visit 4 (n=1,1,7,6,16)	58.00 (19.70 to 89.80)			
Visit 5 (n=1,1,7,6,17)	63.80 (21.80 to 91.70)			
Visit 6 (n=1,1,7,5,14)	65.80 (22.70 to 90.80)			
Visit 7 (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

End point title	Absolute Values of Respiratory Rate
End point description:	
Respiratory rate was defined as the number of inspirations 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:

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: breaths per minute				
median (full range (min-max))				
Visit 2 (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)
Visit 3 (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)
Visit 4 (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)
Visit 5 (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)
Visit 6 (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)
Visit 7 (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))				
Visit 2 (n=1,1,6,3,12)	20.00 (17.00 to 36.00)			
Visit 3 (n=1,2,4,6,15)	18.00 (16.00 to 30.00)			
Visit 4 (n=1,1,7,7,17)	18.00 (16.00 to 24.00)			
Visit 5 (n=1,1,7,4,16)	18.00 (16.00 to 32.00)			
Visit 6 (n=1,1,7,4,14)	20.00 (16.00 to 30.00)			
Visit 7 (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

End point title	Absolute Values of Body Temperature
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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
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End point timeframe:

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: celsius				
median (full range (min-max))				
Visit 2 (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)
Visit 3 (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)
Visit 4 (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)
Visit 5 (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)
Visit 6 (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)
Visit 7 (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))				
Visit 2 (n=1,1,6,3,12)	36.80 (35.60 to 39.30)			
Visit 3 (n=1,2,4,6,15)	36.80 (36.10 to 37.10)			
Visit 4 (n=1,1,8,7,18)	36.70 (36.40 to 37.70)			
Visit 5 (n=1,1,7,5,17)	36.70 (35.10 to 37.10)			
Visit 6 (n=1,1,7,5,13)	36.60 (35.70 to 37.00)			
Visit 7 (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

End point title	Absolute Values of Body Length
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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
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End point timeframe:

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: cm				
median (full range (min-max))				
Visit 2 (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)
Visit 3 (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)
Visit 4 (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)
Visit 5 (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)
Visit 6 (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)
Visit 7 (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))				

Visit 2 (n= 1,1,1,0,1)	172.00 (172.00 to 172.00)			
Visit 3 (n=1,1,0,0,1)	135.00 (135.00 to 135.00)			
Visit 4 (n= 1,1,2,0,1)	135.00 (135.00 to 135.00)			
Visit 5 (n=1,1,3,0,1)	135.00 (135.00 to 135.00)			
Visit 6 (n=1,1,3,0,1)	135.00 (135.00 to 135.00)			
Visit 7 (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

End point title	Number of Subjects With Physical Examination Abnormalities
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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
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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). Here, 99999 signifies that median and 95% CI was not estimable due to the low number of subjects who had major bleeding event. Safety analysis set.	
End point type	Secondary
End point timeframe:	
Baseline up to 25 days after the last dose of study drug (up to Day 115)	

End point values	Dalteparin Sodium: All Subjects (≥ 0 to < 19 years)			
Subject group type	Subject analysis set			
Number of subjects analysed	38			
Units: days				
median (confidence interval 95%)	99999 (-99999 to 99999)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Who Remained Within Prespecified Therapeutic Anti-Factor Xa Levels During the Follow up Phase

End point title	Percentage of Subjects Who Remained Within Prespecified Therapeutic Anti-Factor Xa Levels During the Follow up Phase ^[4]
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End point description:

Prespecified therapeutic anti-factor Xa level was 0.5-1.0 IU/mL. The percentage of subjects who had anti factor-Xa levels within 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 analyzed 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
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End point timeframe:

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

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: 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=1,5,2,14)	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= 1,5,3,19)	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= 1,4,1,8)	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 During Follow up Phase

End point title	Percentage of Subjects With Anti-Factor Xa Levels Outside the Prespecified Range During Follow up Phase ^[5]
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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 analyzed 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
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End point timeframe:

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

Notes:

[5] - 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: 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= 0,0,4,1)	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= 0,0,1,2)	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= 0,0,1,3)	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 ^[6]
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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.

End point type	Secondary
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End point timeframe:

4 hours post-dose at each Day 1 to 7 in dose adjustment 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: 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/mL				
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 ^[7]
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End point description:

The time to achieve the target range was defined as the number of days from the first dose to the final dose that achieves the target Anti-Xa level. 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.

End point type	Secondary
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End point timeframe:

4 hours post-dose at each Day 1 to 7 in dose adjustment 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: 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: hours				
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: Mean Number of Dose Adjustments Required to Achieve Prespecified Therapeutic Anti-Xa Levels

End point title	Mean Number of Dose Adjustments Required to Achieve Prespecified Therapeutic Anti-Xa Levels ^[8]
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End point description:

During dose adjustment phase, doses were adjusted according to anti-Xa levels. Doses were adjusted in increments or decrements of 25 IU/kg 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. Cumulative data for Day 1 to 7 has been reported. The PD analysis set included all subjects who received at least one dose of study drug and achieved therapeutic range of anti-factor Xa during dose adjustment phase.

End point type	Secondary
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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: 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

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Baseline up to 25 days after the last dose of study drug (up to Day 115)

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
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	v21.0
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Reporting groups

Reporting group title	Dalteparin Sodium: Group 1 (≥ 0 to < 8 Week)
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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 8-14 in PD phase and from Day 15 in FU 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 90 days).

Reporting group title	Dalteparin Sodium: Group 2 (≥ 8 week to < 2 year)
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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 8-14 in PD phase and from Day 15 in FU 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 90 days).

Reporting group title	Dalteparin Sodium: Group 3 (≥ 2 year to < 8 year)
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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 8-14 in PD phase and from Day 15 in FU 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 90 days).

Reporting group title	Dalteparin Sodium: Group 4 (≥ 8 year to < 12 year)
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Reporting group description:

Subjects aged ≥ 8 weeks to < 12 years were administered 125 IU/kg of dalteparin sodium injection subcutaneously twice daily from Day 1 to 7 in DA phase, Day 8-14 in PD phase and from Day 15 in FU 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 90 days).

Reporting group title	Dalteparin Sodium: Group 5 (≥ 12 year to < 19 year)
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Reporting group description:

Subjects aged ≥ 12 weeks to < 19 years were administered 100 IU/kg of dalteparin sodium injection subcutaneously twice daily from Day 1 to 7 in DA phase, Day 8-14 in PD phase and from Day 15 in FU 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 90 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 occurrences (all)	0 / 1 (0.00%) 0	0 / 2 (0.00%) 0	0 / 8 (0.00%) 0
Investigations			
Activated partial thromboplastin time prolonged subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	1 / 2 (50.00%) 1	2 / 8 (25.00%) 2
Alanine aminotransferase increased subjects affected / exposed occurrences (all)	1 / 1 (100.00%) 1	0 / 2 (0.00%) 0	0 / 8 (0.00%) 0
Aspartate aminotransferase increased subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 2 (0.00%) 0	0 / 8 (0.00%) 0
Aspergillus test positive subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 2 (0.00%) 0	0 / 8 (0.00%) 0
Blood calcium increased subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	1 / 2 (50.00%) 1	0 / 8 (0.00%) 0
Blood fibrinogen decreased subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 2 (0.00%) 0	0 / 8 (0.00%) 0
Blood fibrinogen increased subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 2 (0.00%) 0	0 / 8 (0.00%) 0
Blood lactate dehydrogenase increased subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 2 (0.00%) 0	1 / 8 (12.50%) 1
Blood urea increased subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	1 / 2 (50.00%) 1	0 / 8 (0.00%) 0
Body temperature increased subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	1 / 2 (50.00%) 1	0 / 8 (0.00%) 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 occurrences (all)	0 / 1 (0.00%) 0	0 / 2 (0.00%) 0	0 / 8 (0.00%) 0
Injury, poisoning and procedural complications			
Bone contusion subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 2 (0.00%) 0	1 / 8 (12.50%) 1
Contusion subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 2 (0.00%) 0	1 / 8 (12.50%) 1
Fall subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 2 (0.00%) 0	0 / 8 (0.00%) 0
Laceration subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 2 (0.00%) 0	0 / 8 (0.00%) 0
Ligament sprain subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 2 (0.00%) 0	0 / 8 (0.00%) 0
Refractoriness to platelet transfusion subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 2 (0.00%) 0	0 / 8 (0.00%) 0
Skin abrasion subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 2 (0.00%) 0	0 / 8 (0.00%) 0
Cardiac disorders			
Tachycardia subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	1 / 2 (50.00%) 1	2 / 8 (25.00%) 3
Nervous system disorders			
Altered state of consciousness subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	1 / 2 (50.00%) 1	0 / 8 (0.00%) 0
Ataxia subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 2 (0.00%) 0	0 / 8 (0.00%) 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 occurrences (all)	0 / 1 (0.00%) 0	0 / 2 (0.00%) 0	0 / 8 (0.00%) 0
Thrombocytopenia subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 2 (0.00%) 0	2 / 8 (25.00%) 2
Ear and labyrinth disorders			
Cerumen impaction subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 2 (0.00%) 0	0 / 8 (0.00%) 0
Ear pain subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 2 (0.00%) 0	0 / 8 (0.00%) 0
Eye disorders			
Dry eye subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 2 (0.00%) 0	0 / 8 (0.00%) 0
Eye swelling subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 2 (0.00%) 0	0 / 8 (0.00%) 0
Ocular hyperaemia subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 2 (0.00%) 0	0 / 8 (0.00%) 0
Photophobia subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 2 (0.00%) 0	1 / 8 (12.50%) 1
Vision blurred subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 2 (0.00%) 0	0 / 8 (0.00%) 0
Gastrointestinal disorders			
Abdominal distension subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	1 / 2 (50.00%) 1	0 / 8 (0.00%) 0
Abdominal pain upper subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 2 (0.00%) 0	1 / 8 (12.50%) 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%)	1 / 2 (50.00%)	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 occurrences (all)	1 / 7 (14.29%) 2	0 / 20 (0.00%) 0	
Haematoma subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 20 (0.00%) 0	
Hypertension subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	2 / 20 (10.00%) 2	
Vein disorder subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 20 (0.00%) 0	
General disorders and administration site conditions			
Asthenia subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 20 (0.00%) 0	
Catheter site bruise subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	1 / 20 (5.00%) 1	
Catheter site haematoma subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	1 / 20 (5.00%) 1	
Catheter site pain subjects affected / exposed occurrences (all)	1 / 7 (14.29%) 2	0 / 20 (0.00%) 0	
Fatigue subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	2 / 20 (10.00%) 2	
Gait disturbance subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 20 (0.00%) 0	
Infusion site bruising subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	1 / 20 (5.00%) 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		

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

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 occurrences (all)	0 / 7 (0.00%) 0	1 / 20 (5.00%) 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 occurrences (all)	2 / 7 (28.57%) 2	1 / 20 (5.00%) 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 occurrences (all)	0 / 7 (0.00%) 0	1 / 20 (5.00%) 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	0 / 7 (0.00%)	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	<ol style="list-style-type: none">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	<ol style="list-style-type: none">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	<ol style="list-style-type: none">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	<ol style="list-style-type: none"> 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

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

Data for PD endpoints (total body clearance, volume of distribution and absorption rate constant) will be detailed in a separated population modeling analysis plan.

Notes: