Clinical trial results:
Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Dose-Finding Study to Evaluate the Effect of continuous infusion of Tafoxiparin as an Adjunct Treatment to Oxytocin for up to 36 hours in Term Pregnant, Nulliparous Women to treat Primary Slow Progress of Labor including prolonged latent phase and Primary Labor Arrest

Summary

EudraCT number	2016-002118-40
Trial protocol	SE FI DK
Global end of trial date	05 March 2019

Results information

Result version number	v1 (current)
This version publication date	29 March 2020
First version publication date	29 March 2020

Trial information

Trial identification

Sponsor protocol code	PPL07

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03001193
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Dilafor AB
Sponsor organisation address	Fogdevreten 2A, Solna, Sweden, 17165
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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	10 May 2019
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	05 March 2019
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To assess the dose-response relationship of tafoxiparin on the labor time defined as the time from the start of continuous infusion of tafoxiparin/placebo as an Adjunct Treatment to Oxytocin, until partus in term-pregnant, nulliparous women requiring labor augmentation due to Primary Slow Progress of Labor including prolonged latent phase and Primary Labor Arrest

Protection of trial subjects:

Women in established labor were observed in the clinic during labor until discharge. Safety was evaluated through rate and frequency of AEs and SAEs, complete and symptom-directed physical evaluations, vital signs, safety blood samples (hematology and clinical chemistry).

Background therapy:

30-45 minutes after start of treatment (IMP) intravenous infusion of oxytocin was to start according to study-specific instruction.

Evidence for comparator: -

Actual start date of recruitment	26 September 2016
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	Sweden: 262
Country: Number of subjects enrolled	Denmark: 9
Country: Number of subjects enrolled	Finland: 90
Worldwide total number of subjects	361
EEA total number of subjects	361

Notes:

Subjects enrolled per age group

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

Adolescents (12-17 years)	0
Adults (18-64 years)	361
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

The study aimed to include 360 subjects at 12 study sites in 4 groups of 90 subjects each. The study was conducted in three countries, Sweden, Finland and Denmark. First enrollment was on 27 Dec 2016 and last patient last visit was on 05 Mar 2019.
Term-pregnant, nulliparous women at the delivery ward were potential study patients.

Pre-assignment

Screening details:

The study included pregnant, nulliparous women in a state of primary labor arrest including prolonged latent phase of labor and slow progress of labor that were given emergency treatment with oxytocin to support labor augmentation and to prevent protracted labor.

Period 1

Period 1 title	Baseline
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Monitor, Data analyst, Assessor

Blinding implementation details:

All study site and CRO personnel involved in the monitoring or conduct of the study were blinded to the individual subject treatment assignment. The formal un-blinding was performed when the main efficacy analysis data set was locked. However, study subjects and operative study personnel remained blinded to treatment allocation until all data in the study had been entered, verified, and validated and the complete study database locked.

Arms

Are arms mutually exclusive?	Yes
Arm title	Placebo

Arm description: -

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous bolus use

Dosage and administration details:

Matching placebo saline solutions indistinguishable from the active solutions in appearance, smell and packaging were used.

Arm title	Tafoxiparin 5 mg/h

Arm description:

Tafoxiparin was given as a continuous 5 mg/h IV-infusion for a maximum of 36 hours or until partus, whichever came first.

Arm type	Experimental
Investigational medicinal product name	Tafoxiparin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous bolus use

Dosage and administration details:

The study medication was a liquid formulation containing 30 mg, 90 mg, and 150 mg Tafoxiparin per ml (depending on treatment group). The infusion-solution was prepared by mixing 2.6 ml of the study drug (1.3 ml from two different vials) into 100 ml of 0.9 mg/ml NaCl in water (saline). At the start of treatment, a bolus dose was given as 9 ml of the infusion-solution during 1 minute. Thereafter, 6.5 ml

per hour of the infusion-solution was given. A new bag of infusion-solution was prepared and replaced every 12th hour. A bolus dose was only given from the first bag.

Arm title	Tafoxiparin 15 mg/h

Arm description:

Tafoxiparin was given as a continuous 15 mg/h IV-infusion for a maximum of 36 hours or until partus, whichever came first.

Arm type	Experimental
Investigational medicinal product name	Tafoxiparin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous bolus use

Dosage and administration details:

The study medication was a liquid formulation containing 30 mg, 90 mg, and 150 mg Tafoxiparin per ml (depending on treatment group). The infusion-solution was prepared by mixing 2.6 ml of the study drug (1.3 ml from two different vials) into 100 ml of 0.9 mg/ml NaCl in water (saline). At the start of treatment, a bolus dose was given as 9 ml of the infusion-solution during 1 minute. Thereafter, 6.5 ml per hour of the infusion-solution was given. A new bag of infusion-solution was prepared and replaced every 12th hour. A bolus dose was only given from the first bag.

Arm title	Tafoxiparin 25 mg/h

Arm description:

Tafoxiparin was given as a continuous 25 mg/h IV-infusion for a maximum of 36 hours or until partus, whichever came first.

Arm type	Experimental
Investigational medicinal product name	Tafoxiparin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous bolus use

Dosage and administration details:

The study medication was a liquid formulation containing 30 mg, 90 mg, and 150 mg Tafoxiparin per ml (depending on treatment group). The infusion-solution was prepared by mixing 2.6 ml of the study drug (1.3 ml from two different vials) into 100 ml of 0.9 mg/ml NaCl in water (saline). At the start of treatment, a bolus dose was given as 9 ml of the infusion-solution during 1 minute. Thereafter, 6.5 ml per hour of the infusion-solution was given. A new bag of infusion-solution was prepared and replaced every 12th hour. A bolus dose was only given from the first bag.

Number of subjects in period 1[1]	Placebo	Tafoxiparin 5 mg/h	Tafoxiparin 15 mg/h
Started	91	88	87
Completed	91	88	87

Number of subjects in period 1[1]	Tafoxiparin 25 mg/h
Started	90
Completed	90

Notes:

[1] - The number of subjects reported to be in the baseline period are not the same as the worldwide number enrolled in the trial. It is expected that these numbers will be the same.
Justification: Five patients that were randomized did not receive any treatment (IMP not administrated).

Period 2

Period 2 title	Treatment
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Monitor, Data analyst, Assessor

Arms

Are arms mutually exclusive?	Yes
Arm title	Placebo

Arm description:

Matching placebo saline solutions indistinguishable from the active solutions in appearance, smell and packaging were used.

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous bolus use

Dosage and administration details:

Matching placebo saline solutions indistinguishable from the active solutions in appearance, smell and packaging were used.

Arm title	Tafoxiparin 5 mg/h

Arm description:

Tafoxiparin was given as a continuous 5 mg/h IV-infusion for a maximum of 36 hours or until partus, whichever came first.

Arm type	Experimental
Investigational medicinal product name	Tafoxiparin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous bolus use

Dosage and administration details:

The study medication was a liquid formulation containing 30 mg, 90 mg, and 150 mg Tafoxiparin per ml (depending on treatment group). The infusion-solution was prepared by mixing 2.6 ml of the study drug (1.3 ml from two different vials) into 100 ml of 0.9 mg/ml NaCl in water (saline). At the start of treatment, a bolus dose was given as 9 ml of the infusion-solution during 1 minute. Thereafter, 6.5 ml per hour of the infusion-solution was given. A new bag of infusion-solution was prepared and replaced every 12th hour. A bolus dose was only given from the first bag.

Arm title	Tafoxiparin 15 mg/h

Arm description:

Tafoxiparin was given as a continuous 15 mg/h IV-infusion for a maximum of 36 hours or until partus, whichever came first.

Arm type	Experimental
Investigational medicinal product name	Tafoxiparin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous bolus use

Dosage and administration details:

The study medication was a liquid formulation containing 30 mg, 90 mg, and 150 mg Tafoxiparin per ml (depending on treatment group). The infusion-solution was prepared by mixing 2.6 ml of the study drug (1.3 ml from two different vials) into 100 ml of 0.9 mg/ml NaCl in water (saline). At the start of treatment, a bolus dose was given as 9 ml of the infusion-solution during 1 minute. Thereafter, 6.5 ml per hour of the infusion-solution was given. A new bag of infusion-solution was prepared and replaced every 12th hour. A bolus dose was only given from the first bag.

Arm title	Tafoxiparin 25 mg/h

Arm description:

Tafoxiparin was given as a continuous 25 mg/h IV-infusion for a maximum of 36 hours or until partus, whichever came first.

Arm type	Experimental
Investigational medicinal product name	Tafoxiparin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous bolus use

Dosage and administration details:

The study medication was a liquid formulation containing 30 mg, 90 mg, and 150 mg Tafoxiparin per ml (depending on treatment group). The infusion-solution was prepared by mixing 2.6 ml of the study drug (1.3 ml from two different vials) into 100 ml of 0.9 mg/ml NaCl in water (saline). At the start of treatment, a bolus dose was given as 9 ml of the infusion-solution during 1 minute. Thereafter, 6.5 ml per hour of the infusion-solution was given. A new bag of infusion-solution was prepared and replaced every 12th hour. A bolus dose was only given from the first bag.

Number of subjects in period 2	Placebo	Tafoxiparin 5 mg/h	Tafoxiparin 15 mg/h
Started	91	88	87
Completed	91	88	87

Number of subjects in period 2	Tafoxiparin 25 mg/h
Started	90
Completed	90

Baseline characteristics

Reporting groups	
Reporting group title	Placebo
Reporting group description: -	
Reporting group title	Tafoxiparin 5 mg/h
Reporting group description:	
Tafoxiparin was given as a continuous 5 mg/h IV-infusion for a maximum of 36 hours or until partus, whichever came first.	
Reporting group title	Tafoxiparin 15 mg/h
Reporting group description:	
Tafoxiparin was given as a continuous 15 mg/h IV-infusion for a maximum of 36 hours or until partus, whichever came first.	
Reporting group title	Tafoxiparin 25 mg/h
Reporting group description:	
Tafoxiparin was given as a continuous 25 mg/h IV-infusion for a maximum of 36 hours or until partus, whichever came first.	

Reporting group values	Placebo	Tafoxiparin 5 mg/h	Tafoxiparin 15 mg/h
Number of subjects	91	88	87
Age categorical			
Units: Subjects			
In utero			
Preterm newborn infants (gestational age < 37 wks)			
Newborns (0-27 days)			
Infants and toddlers (28 days-23 months)			
Children (2-11 years)			
Adolescents (12-17 years)			
Adults (18-64 years)			
From 65-84 years			
85 years and over			
Age continuous			
Units: years			
arithmetic mean	29.3	29.8	29.1
standard deviation	± 4.7	± 5	± 5
Gender categorical			
Units: Subjects			
Female	91	88	87
Male	0	0	0

Reporting group values	Tafoxiparin 25 mg/h	Total	
Number of subjects	90	356	
Age categorical			
Units: Subjects			
In utero		0	
Preterm newborn infants (gestational age < 37 wks)		0	
Newborns (0-27 days)		0	

Infants and toddlers (28 days-23 months)		0	
Children (2-11 years)		0	
Adolescents (12-17 years)		0	
Adults (18-64 years)		0	
From 65-84 years		0	
85 years and over		0	
Age continuous			
Units: years			
arithmetic mean	30.2		
standard deviation	± 4.6	-	
Gender categorical			
Units: Subjects			
Female	90	356	
Male	0	0	

End points

End points reporting groups

Reporting group title	Placebo
Reporting group description: -	
Reporting group title	Tafoxiparin 5 mg/h
Reporting group description:	
Tafoxiparin was given as a continuous 5 mg/h IV-infusion for a maximum of 36 hours or until partus, whichever came first.	
Reporting group title	Tafoxiparin 15 mg/h
Reporting group description:	
Tafoxiparin was given as a continuous 15 mg/h IV-infusion for a maximum of 36 hours or until partus, whichever came first.	
Reporting group title	Tafoxiparin 25 mg/h
Reporting group description:	
Tafoxiparin was given as a continuous 25 mg/h IV-infusion for a maximum of 36 hours or until partus, whichever came first.	
Reporting group title	Placebo
Reporting group description:	
Matching placebo saline solutions indistinguishable from the active solutions in appearance, smell and packaging were used.	
Reporting group title	Tafoxiparin 5 mg/h
Reporting group description:	
Tafoxiparin was given as a continuous 5 mg/h IV-infusion for a maximum of 36 hours or until partus, whichever came first.	
Reporting group title	Tafoxiparin 15 mg/h
Reporting group description:	
Tafoxiparin was given as a continuous 15 mg/h IV-infusion for a maximum of 36 hours or until partus, whichever came first.	
Reporting group title	Tafoxiparin 25 mg/h
Reporting group description:	
Tafoxiparin was given as a continuous 25 mg/h IV-infusion for a maximum of 36 hours or until partus, whichever came first.	

Primary: Time from start of continuous infusion of tafoxiparin/placebo until vaginal partus

End point title	Time from start of continuous infusion of tafoxiparin/placebo until vaginal partus
End point description:	
End point type	Primary
End point timeframe:	
Time from start of continuous infusion of IMP until vaginal partus	

End point values	Placebo	Tafoxiparin 5 mg/h	Tafoxiparin 15 mg/h	Tafoxiparin 25 mg/h
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	91	88	87	90
Units: Hours				
median (inter-quartile range (Q1-Q3))	6.07 (4.60 to 10.38)	7.00 (4.67 to 10.40)	7.48 (4.98 to 10.65)	7.32 (4.95 to 11.48)

Statistical analyses

Statistical analysis title	Dose response test, sigEmax

Statistical analysis description:

The primary analysis follows the MCP-Mod methodology to evaluate the dose-response relationship. This statistical analysis presents the result for the pre-specified candidate dose-response model sigEmax.

Comparison groups	Placebo v Tafoxiparin 5 mg/h v Tafoxiparin 15 mg/h v Tafoxiparin 25 mg/h
Number of subjects included in analysis	356
Analysis specification	Pre-specified
Analysis type	superiority[1]
P-value	= 0.76 [2]
Method	MCP-Mod Analysis

Notes:

[1] - This analysis tests if a significant dose-response signal could be established.

[2] - The p-value is adjusted for multiplicity on the set of four candidate dose-response models. The null hypothesis of no dose-response was discarded if at least one of the p-values were below the 5% level.

Statistical analysis title	Dose response test, logistic

Statistical analysis description:

The primary analysis follows the MCP-Mod methodology to evaluate the dose-response relationship. This statistical analysis presents the result for the pre-specified candidate dose-response model logistic.

Comparison groups	Placebo v Tafoxiparin 5 mg/h v Tafoxiparin 15 mg/h v Tafoxiparin 25 mg/h
Number of subjects included in analysis	356
Analysis specification	Pre-specified
Analysis type	superiority[3]
P-value	= 0.77 [4]
Method	MCP-Mod Analysis

Notes:

[3] - This analysis tests if a significant dose-response signal could be established.

[4] - The p-value is adjusted for multiplicity on the set of four candidate dose-response models. The null hypothesis of no dose-response was discarded if at least one of the p-values were below the 5% level.

Statistical analysis title	Dose response test, linear

Statistical analysis description:

The primary analysis follows the MCP-Mod methodology to evaluate the dose-response relationship. This statistical analysis presents the result for the pre-specified candidate dose-response model linear.

Comparison groups	Placebo v Tafoxiparin 5 mg/h v Tafoxiparin 15 mg/h v Tafoxiparin 25 mg/h

Number of subjects included in analysis	356
Analysis specification	Pre-specified
Analysis type	superiority[5]
P-value	= 0.81 [6]
Method	MCP-Mod Analysis

Notes:

[5] - This analysis tests if a significant dose-response signal could be established.

[6] - The p-value is adjusted for multiplicity on the set of four candidate dose-response models. The null hypothesis of no dose-response was discarded if at least one of the p-values were below the 5% level.

Statistical analysis title	Dose response test, emax

Statistical analysis description:

The primary analysis follows the MCP-Mod methodology to evaluate the dose-response relationship. This statistical analysis presents the result for the pre-specified candidate dose-response model emax.

Comparison groups	Placebo v Tafoxiparin 5 mg/h v Tafoxiparin 15 mg/h v Tafoxiparin 25 mg/h
Number of subjects included in analysis	356
Analysis specification	Pre-specified
Analysis type	superiority[7]
P-value	= 0.85 [8]
Method	MCP-Mod Analysis

Notes:

[7] - This analysis tests if a significant dose-response signal could be established.

[8] - The p-value is adjusted for multiplicity on the set of four candidate dose-response models. The null hypothesis of no dose-response was discarded if at least one of the p-values were below the 5% level.

Secondary: Caesarian sections

End point title	Caesarian sections

End point description:

Proportion of caesarian sections

End point type	Secondary

End point timeframe:

At labor

End point values	Placebo	Tafoxiparin 5 mg/h	Tafoxiparin 15 mg/h	Tafoxiparin 25 mg/h
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	91	88	87	89
Units: Yes/No				
Yes	13	13	13	14
No	78	75	74	75

Statistical analyses

Statistical analysis title	Probability of caesarian section

Statistical analysis description:

Analysis of the probability of caesarian section (FAS) using logistic regression model including covariates

as specified in the SAP.

Comparison groups	Placebo v Tafoxiparin 5 mg/h v Tafoxiparin 15 mg/h v Tafoxiparin 25 mg/h
Number of subjects included in analysis	355
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.9957 [9]
Method	Regression, Logistic

Notes:

[9] - P-value for Wald Chi2-test of null hypothesis of equal effect in all treatment groups.

Secondary: Instrumental deliveries

End point title	Instrumental deliveries

End point description:

End point type	Secondary

End point timeframe:

At labor.

End point values	Placebo	Tafoxiparin 5 mg/h	Tafoxiparin 15 mg/h	Tafoxiparin 25 mg/h
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	91	88	87	89
Units: Yes/No				
Yes	16	24	19	16
No	75	64	68	73

Statistical analyses

Statistical analysis title	Proportion of instrumental deliveries

Statistical analysis description:

Analysis of the probability of instrumental deliveries (FAS) using logistic regression model including covariates as specified in the SAP.

Comparison groups	Placebo v Tafoxiparin 5 mg/h v Tafoxiparin 15 mg/h v Tafoxiparin 25 mg/h
Number of subjects included in analysis	355
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.3094 [10]
Method	Regression, Logistic

Notes:

[10] - P-value for Wald Chi2-test of null hypothesis of equal effect in all treatment groups.

Secondary: Proportion Postpartum Hemorrhage

End point title	Proportion Postpartum Hemorrhage

End point description:	
Postpartum hemorrhage >1000 ml (Yes or No)	
End point type	Secondary
End point timeframe:	
Hemorrhage measured post partum.	

End point values	Placebo	Tafoxiparin 5 mg/h	Tafoxiparin 15 mg/h	Tafoxiparin 25 mg/h
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	91	88	87	89
Units: Yes/No				
Yes	7	13	9	7
No	84	75	78	82

Statistical analyses

Statistical analysis title	Proportion Postpartum Hemorrhage >1000 ml
Statistical analysis description:	
Analysis of the proportion Postpartum Hemorrhage >1000 ml (FAS) using logistic regression model including covariates as specified in the SAP.	
Comparison groups	Placebo v Tafoxiparin 5 mg/h v Tafoxiparin 15 mg/h v Tafoxiparin 25 mg/h
Number of subjects included in analysis	355
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.3705 [11]
Method	Regression, Logistic

Notes:

[11] - P-value for Wald Chi2-test of null hypothesis of equal effect in all treatment groups.

Secondary: Proportion fetals with Apgar 5min <=7

End point title	Proportion fetals with Apgar 5min <=7
End point description:	
End point type	Secondary
End point timeframe:	
Directly after labor	

End point values	Placebo	Tafoxiparin 5 mg/h	Tafoxiparin 15 mg/h	Tafoxiparin 25 mg/h
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	91	88	87	88
Units: Yes/No				
Yes	3	5	5	7
No	88	83	82	81

Statistical analyses

Statistical analysis title	Proportion of fetals with Apgar 5min <=7

Statistical analysis description:

Analysis of the probability of fetal Apgar score (5 min) <=7 (FAS) using logistic regression model including covariates as specified in the SAP.
Missing Apgar score 5 minutes was imputed as available Apgar score 1 minute.

Comparison groups	Placebo v Tafoxiparin 5 mg/h v Tafoxiparin 15 mg/h v Tafoxiparin 25 mg/h
Number of subjects included in analysis	354
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.5656 [12]
Method	Regression, Logistic

Notes:

[12] - P-value for Wald Chi2-test of null hypothesis of equal effect in all treatment groups.

Secondary: Proportion NICU admission > 48 hours

End point title	Proportion NICU admission > 48 hours

End point description:

Proportion fetals requiring emergency (NICU admission) treatment for more than 48 hours

End point type	Secondary

End point timeframe:

At discharge

End point values	Placebo	Tafoxiparin 5 mg/h	Tafoxiparin 15 mg/h	Tafoxiparin 25 mg/h
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	91	88	87	89
Units: Yes/No				
Yes	5	6	9	5
No	86	82	78	84

Statistical analyses

Statistical analysis title	Proportion NICU admission > 48 hours

Statistical analysis description:

Analysis of the probability of NICU admission longer than 48 hours (FAS) using logistic regression model including covariates as specified in the SAP.

Comparison groups	Placebo v Tafoxiparin 5 mg/h v Tafoxiparin 15 mg/h v Tafoxiparin 25 mg/h
Number of subjects included in analysis	355
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.5009 [13]
Method	Regression, Logistic

Notes:

[13] - P-value for Wald Chi2-test of null hypothesis of equal effect in all treatment groups.

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Adverse Events for the mothers were collected from ICF to the 8-week follow-up.
For the infants AEs were recorded from labor until the 6-months follow-up.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	18.1

Reporting groups

Reporting group title	Placebo-Mother

Reporting group description:

This group consisted of pregnant women who received placebo saline solution.

Reporting group title	Tafoxiparin 5 mg/h-Mother

Reporting group description:

This group consisted of pregnant women who received Tafoxiparin as a continuous 5 mg/h IV-infusion.

Reporting group title	Tafoxiparin 15 mg/h-Mother

Reporting group description:

This group consisted of pregnant women who received Tafoxiparin as a continuous 15 mg/h IV-infusion.

Reporting group title	Tafoxiparin 25 mg/h-Mother

Reporting group description:

This group consisted of pregnant women who received Tafoxiparin as a continuous 25 mg/h IV-infusion.

Reporting group title	Placebo-Infant

Reporting group description:

This group consisted of infants whos mother received placebo saline solution.

Reporting group title	Tafoxiparin 5 mg/h-Infant

Reporting group description:

This group consisted of infants whos mother received Tafoxiparin as a continuous 5 mg/h IV-infusion.

Reporting group title	Tafoxiparin 15 mg/h-Infant

Reporting group description:

This group consisted of infants whos mother received Tafoxiparin as a continuous 15 mg/h IV-infusion.

Reporting group title	Tafoxiparin 25 mg/h-Infant

Reporting group description:

This group consisted of infants whos mother received Tafoxiparin as a continuous 25 mg/h IV-infusion.

Serious adverse events	Placebo-Mother	Tafoxiparin 5 mg/h-Mother	Tafoxiparin 15 mg/h-Mother
Total subjects affected by serious adverse events			
subjects affected / exposed	4 / 91 (4.40%)	6 / 88 (6.82%)	7 / 87 (8.05%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Vascular disorders			
Deep vein thrombosis			

subjects affected / exposed	0 / 91 (0.00%)	0 / 88 (0.00%)	1 / 87 (1.15%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhage			
subjects affected / exposed	0 / 91 (0.00%)	1 / 88 (1.14%)	0 / 87 (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
Hypertension			
subjects affected / exposed	0 / 91 (0.00%)	0 / 88 (0.00%)	0 / 87 (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
Subgaleal haematoma			
subjects affected / exposed	0 / 91 (0.00%)	0 / 88 (0.00%)	0 / 87 (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
Surgical and medical procedures			
Caesarean section			
subjects affected / exposed	0 / 91 (0.00%)	0 / 88 (0.00%)	0 / 87 (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
Evacuation of retained products of conception			
subjects affected / exposed	0 / 91 (0.00%)	0 / 88 (0.00%)	0 / 87 (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
Perineoplasty			
subjects affected / exposed	0 / 91 (0.00%)	1 / 88 (1.14%)	0 / 87 (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
Pregnancy, puerperium and perinatal conditions			
Postpartum haemorrhage			
subjects affected / exposed	0 / 91 (0.00%)	2 / 88 (2.27%)	2 / 87 (2.30%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Pre-eclampsia			
subjects affected / exposed	0 / 91 (0.00%)	1 / 88 (1.14%)	0 / 87 (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
Retained placenta or membranes			
subjects affected / exposed	0 / 91 (0.00%)	0 / 88 (0.00%)	1 / 87 (1.15%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cephalhaematoma			
subjects affected / exposed	0 / 91 (0.00%)	0 / 88 (0.00%)	0 / 87 (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
Foetal distress syndrome			
subjects affected / exposed	0 / 91 (0.00%)	0 / 88 (0.00%)	0 / 87 (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
Low birth weight baby			
subjects affected / exposed	0 / 91 (0.00%)	0 / 88 (0.00%)	0 / 87 (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
Weight decrease neonatal			
subjects affected / exposed	0 / 91 (0.00%)	0 / 88 (0.00%)	0 / 87 (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			
Pyrexia			
subjects affected / exposed	0 / 91 (0.00%)	0 / 88 (0.00%)	0 / 87 (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 physical health deterioration			
subjects affected / exposed	0 / 91 (0.00%)	0 / 88 (0.00%)	0 / 87 (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			
Asphyxia			
subjects affected / exposed	0 / 91 (0.00%)	0 / 88 (0.00%)	0 / 87 (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
Dyspnoea			
subjects affected / exposed	0 / 91 (0.00%)	0 / 88 (0.00%)	0 / 87 (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
Meconium aspiration syndrome			
subjects affected / exposed	0 / 91 (0.00%)	0 / 88 (0.00%)	0 / 87 (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
Neonatal asphyxia			
subjects affected / exposed	0 / 91 (0.00%)	0 / 88 (0.00%)	0 / 87 (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
Neonatal hypoxia			
subjects affected / exposed	0 / 91 (0.00%)	0 / 88 (0.00%)	0 / 87 (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
Neonatal respiratory distress syndrome			
subjects affected / exposed	0 / 91 (0.00%)	0 / 88 (0.00%)	0 / 87 (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 aspiration			
subjects affected / exposed	0 / 91 (0.00%)	0 / 88 (0.00%)	0 / 87 (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
Pneumothorax			
subjects affected / exposed	0 / 91 (0.00%)	0 / 88 (0.00%)	0 / 87 (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 disorder neonatal			
subjects affected / exposed	0 / 91 (0.00%)	0 / 88 (0.00%)	0 / 87 (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 / 91 (0.00%)	0 / 88 (0.00%)	0 / 87 (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
Transient tachypnoea of the newborn			
subjects affected / exposed	0 / 91 (0.00%)	0 / 88 (0.00%)	0 / 87 (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
Investigations			
Blood pressure increased			
subjects affected / exposed	0 / 91 (0.00%)	0 / 88 (0.00%)	0 / 87 (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
Haemoglobin decreased			
subjects affected / exposed	1 / 91 (1.10%)	0 / 88 (0.00%)	0 / 87 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Heart rate increased			
subjects affected / exposed	0 / 91 (0.00%)	0 / 88 (0.00%)	1 / 87 (1.15%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Platelet count decreased			
subjects affected / exposed	0 / 91 (0.00%)	0 / 88 (0.00%)	0 / 87 (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
Biopsy rectum			
subjects affected / exposed	0 / 91 (0.00%)	0 / 88 (0.00%)	0 / 87 (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 murmur			

subjects affected / exposed	0 / 91 (0.00%)	0 / 88 (0.00%)	0 / 87 (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
Heart rate decreased			
subjects affected / exposed	0 / 91 (0.00%)	0 / 88 (0.00%)	0 / 87 (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 test positive			
subjects affected / exposed	0 / 91 (0.00%)	0 / 88 (0.00%)	0 / 87 (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
Injury, poisoning and procedural complications			
Anal injury			
subjects affected / exposed	0 / 91 (0.00%)	0 / 88 (0.00%)	0 / 87 (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
Injury to brachial plexus due to birth trauma			
subjects affected / exposed	0 / 91 (0.00%)	0 / 88 (0.00%)	0 / 87 (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
Post procedural haemorrhage			
subjects affected / exposed	0 / 91 (0.00%)	0 / 88 (0.00%)	0 / 87 (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
Procedural haemorrhage			
subjects affected / exposed	0 / 91 (0.00%)	0 / 88 (0.00%)	0 / 87 (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
Procedural pain			
subjects affected / exposed	0 / 91 (0.00%)	0 / 88 (0.00%)	0 / 87 (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

Uterine cervical laceration			
subjects affected / exposed	0 / 91 (0.00%)	1 / 88 (1.14%)	0 / 87 (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
Congenital, familial and genetic disorders			
Cleft palate			
subjects affected / exposed	0 / 91 (0.00%)	0 / 88 (0.00%)	0 / 87 (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
Fallot's tetralogy			
subjects affected / exposed	0 / 91 (0.00%)	0 / 88 (0.00%)	0 / 87 (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
Patent ductus arteriosus			
subjects affected / exposed	0 / 91 (0.00%)	0 / 88 (0.00%)	0 / 87 (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
Persistent foetal circulation			
subjects affected / exposed	0 / 91 (0.00%)	0 / 88 (0.00%)	0 / 87 (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
Pyloric stenosis			
subjects affected / exposed	0 / 91 (0.00%)	0 / 88 (0.00%)	0 / 87 (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
Tracheo-oesophageal fistula			
subjects affected / exposed	0 / 91 (0.00%)	0 / 88 (0.00%)	0 / 87 (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
Trisomy 21			
subjects affected / exposed	0 / 91 (0.00%)	0 / 88 (0.00%)	0 / 87 (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

Ventricular septal defect			
subjects affected / exposed	0 / 91 (0.00%)	0 / 88 (0.00%)	0 / 87 (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			
Supraventricular extrasystoles			
subjects affected / exposed	0 / 91 (0.00%)	0 / 88 (0.00%)	0 / 87 (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
Supraventricular tachycardia			
subjects affected / exposed	0 / 91 (0.00%)	0 / 88 (0.00%)	0 / 87 (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 / 91 (0.00%)	0 / 88 (0.00%)	1 / 87 (1.15%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal pain lower			
subjects affected / exposed	0 / 91 (0.00%)	0 / 88 (0.00%)	1 / 87 (1.15%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 91 (0.00%)	0 / 88 (0.00%)	0 / 87 (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
Hepatobiliary disorders			
Cholelithiasis			
subjects affected / exposed	0 / 91 (0.00%)	1 / 88 (1.14%)	0 / 87 (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
Hyperbilirubinaemia			

subjects affected / exposed	0 / 91 (0.00%)	0 / 88 (0.00%)	0 / 87 (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
Hyperbilirubinaemia neonatal			
subjects affected / exposed	0 / 91 (0.00%)	0 / 88 (0.00%)	0 / 87 (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
Jaundice			
subjects affected / exposed	0 / 91 (0.00%)	0 / 88 (0.00%)	0 / 87 (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
Musculoskeletal and connective tissue disorders			
Hypotonia neonatal			
subjects affected / exposed	0 / 91 (0.00%)	0 / 88 (0.00%)	0 / 87 (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
Muscle spasms			
subjects affected / exposed	0 / 91 (0.00%)	0 / 88 (0.00%)	0 / 87 (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			
Amniotic cavity infection			
subjects affected / exposed	0 / 91 (0.00%)	0 / 88 (0.00%)	1 / 87 (1.15%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendicitis			
subjects affected / exposed	1 / 91 (1.10%)	0 / 88 (0.00%)	0 / 87 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endometritis decidual			
subjects affected / exposed	0 / 91 (0.00%)	0 / 88 (0.00%)	1 / 87 (1.15%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Infection			
subjects affected / exposed	0 / 91 (0.00%)	0 / 88 (0.00%)	0 / 87 (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
Neonatal infection			
subjects affected / exposed	0 / 91 (0.00%)	0 / 88 (0.00%)	0 / 87 (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
Neonatal infective mastitis			
subjects affected / exposed	0 / 91 (0.00%)	0 / 88 (0.00%)	0 / 87 (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
Pyelonephritis			
subjects affected / exposed	2 / 91 (2.20%)	0 / 88 (0.00%)	0 / 87 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	0 / 91 (0.00%)	0 / 88 (0.00%)	0 / 87 (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
Staphylococcal sepsis			
subjects affected / exposed	0 / 91 (0.00%)	0 / 88 (0.00%)	0 / 87 (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
Upper respiratory tract infection			
subjects affected / exposed	0 / 91 (0.00%)	0 / 88 (0.00%)	0 / 87 (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			
Poor feeding infant			
subjects affected / exposed	0 / 91 (0.00%)	0 / 88 (0.00%)	0 / 87 (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

Serious adverse events	Tafoxiparin 25 mg/h-Mother	Placebo-Infant	Tafoxiparin 5 mg/h-Infant
Total subjects affected by serious adverse events			
subjects affected / exposed	11 / 90 (12.22%)	11 / 91 (12.09%)	18 / 88 (20.45%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 88 (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
Haemorrhage			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 88 (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
Hypertension			
subjects affected / exposed	1 / 90 (1.11%)	0 / 91 (0.00%)	0 / 88 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subgaleal haematoma			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	1 / 88 (1.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures			
Caesarean section			
subjects affected / exposed	1 / 90 (1.11%)	0 / 91 (0.00%)	0 / 88 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Evacuation of retained products of conception			
subjects affected / exposed	1 / 90 (1.11%)	0 / 91 (0.00%)	0 / 88 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Perineoplasty			

subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 88 (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
Pregnancy, puerperium and perinatal conditions			
Postpartum haemorrhage			
subjects affected / exposed	1 / 90 (1.11%)	0 / 91 (0.00%)	0 / 88 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pre-eclampsia			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 88 (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
Retained placenta or membranes			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 88 (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
Cephalhaematoma			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	1 / 88 (1.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foetal distress syndrome			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 88 (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
Low birth weight baby			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	1 / 88 (1.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Weight decrease neonatal			
subjects affected / exposed	0 / 90 (0.00%)	1 / 91 (1.10%)	2 / 88 (2.27%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			

Pyrexia			
subjects affected / exposed	1 / 90 (1.11%)	0 / 91 (0.00%)	1 / 88 (1.14%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General physical health deterioration			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 88 (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			
Asphyxia			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	1 / 88 (1.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	1 / 88 (1.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meconium aspiration syndrome			
subjects affected / exposed	0 / 90 (0.00%)	1 / 91 (1.10%)	0 / 88 (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
Neonatal asphyxia			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 88 (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
Neonatal hypoxia			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 88 (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
Neonatal respiratory distress syndrome			
subjects affected / exposed	0 / 90 (0.00%)	1 / 91 (1.10%)	3 / 88 (3.41%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Pneumonia aspiration			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 88 (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
Pneumothorax			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	1 / 88 (1.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory disorder neonatal			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 88 (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 / 90 (0.00%)	0 / 91 (0.00%)	1 / 88 (1.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient tachypnoea of the newborn			
subjects affected / exposed	0 / 90 (0.00%)	1 / 91 (1.10%)	2 / 88 (2.27%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Blood pressure increased			
subjects affected / exposed	1 / 90 (1.11%)	0 / 91 (0.00%)	0 / 88 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemoglobin decreased			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 88 (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
Heart rate increased			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 88 (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
Platelet count decreased			

subjects affected / exposed	1 / 90 (1.11%)	0 / 91 (0.00%)	0 / 88 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Biopsy rectum			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 88 (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 murmur			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	1 / 88 (1.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Heart rate decreased			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 88 (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 test positive			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 88 (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
Injury, poisoning and procedural complications			
Anal injury			
subjects affected / exposed	1 / 90 (1.11%)	0 / 91 (0.00%)	0 / 88 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury to brachial plexus due to birth trauma			
subjects affected / exposed	0 / 90 (0.00%)	1 / 91 (1.10%)	0 / 88 (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
Post procedural haemorrhage			
subjects affected / exposed	2 / 90 (2.22%)	0 / 91 (0.00%)	0 / 88 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Procedural haemorrhage			
subjects affected / exposed	1 / 90 (1.11%)	0 / 91 (0.00%)	0 / 88 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Procedural pain			
subjects affected / exposed	1 / 90 (1.11%)	0 / 91 (0.00%)	0 / 88 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Uterine cervical laceration			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 88 (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
Congenital, familial and genetic disorders			
Cleft palate			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	1 / 88 (1.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fallot's tetralogy			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 88 (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
Patent ductus arteriosus			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 88 (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
Persistent foetal circulation			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 88 (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
Pyloric stenosis			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 88 (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

Tracheo-oesophageal fistula			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 88 (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
Trisomy 21			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 88 (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
Ventricular septal defect			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 88 (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			
Supraventricular extrasystoles			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 88 (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
Supraventricular tachycardia			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 88 (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 / 90 (0.00%)	0 / 91 (0.00%)	0 / 88 (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			
Abdominal pain lower			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 88 (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
Vomiting			

subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 88 (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
Hepatobiliary disorders			
Cholelithiasis			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 88 (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
Hyperbilirubinaemia			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 88 (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
Hyperbilirubinaemia neonatal			
subjects affected / exposed	0 / 90 (0.00%)	1 / 91 (1.10%)	0 / 88 (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
Jaundice			
subjects affected / exposed	0 / 90 (0.00%)	1 / 91 (1.10%)	2 / 88 (2.27%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Hypotonia neonatal			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 88 (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
Muscle spasms			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 88 (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			
Amniotic cavity infection			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 88 (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

Appendicitis			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 88 (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
Endometritis decidual			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 88 (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
Infection			
subjects affected / exposed	1 / 90 (1.11%)	0 / 91 (0.00%)	0 / 88 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neonatal infection			
subjects affected / exposed	0 / 90 (0.00%)	1 / 91 (1.10%)	0 / 88 (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
Neonatal infective mastitis			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	1 / 88 (1.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis			
subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 88 (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 / 90 (0.00%)	0 / 91 (0.00%)	0 / 88 (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
Staphylococcal sepsis			
subjects affected / exposed	0 / 90 (0.00%)	1 / 91 (1.10%)	0 / 88 (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
Upper respiratory tract infection			

subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 88 (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			
Poor feeding infant			
subjects affected / exposed	0 / 90 (0.00%)	1 / 91 (1.10%)	0 / 88 (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	Tafoxiparin 15 mg/h-Infant	Tafoxiparin 25 mg/h-Infant	
Total subjects affected by serious adverse events			
subjects affected / exposed	11 / 87 (12.64%)	20 / 90 (22.22%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 87 (0.00%)	0 / 90 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhage			
subjects affected / exposed	0 / 87 (0.00%)	0 / 90 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertension			
subjects affected / exposed	0 / 87 (0.00%)	0 / 90 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subgaleal haematoma			
subjects affected / exposed	0 / 87 (0.00%)	0 / 90 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Surgical and medical procedures			
Caesarean section			

subjects affected / exposed	0 / 87 (0.00%)	0 / 90 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Evacuation of retained products of conception			
subjects affected / exposed	0 / 87 (0.00%)	0 / 90 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Perineoplasty			
subjects affected / exposed	0 / 87 (0.00%)	0 / 90 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pregnancy, puerperium and perinatal conditions			
Postpartum haemorrhage			
subjects affected / exposed	0 / 87 (0.00%)	0 / 90 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pre-eclampsia			
subjects affected / exposed	0 / 87 (0.00%)	0 / 90 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retained placenta or membranes			
subjects affected / exposed	0 / 87 (0.00%)	0 / 90 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cephalhaematoma			
subjects affected / exposed	0 / 87 (0.00%)	0 / 90 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Foetal distress syndrome			
subjects affected / exposed	0 / 87 (0.00%)	1 / 90 (1.11%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Low birth weight baby			

subjects affected / exposed	0 / 87 (0.00%)	0 / 90 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Weight decrease neonatal			
subjects affected / exposed	0 / 87 (0.00%)	1 / 90 (1.11%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	0 / 87 (0.00%)	0 / 90 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
General physical health deterioration			
subjects affected / exposed	0 / 87 (0.00%)	1 / 90 (1.11%)	
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			
Asphyxia			
subjects affected / exposed	0 / 87 (0.00%)	0 / 90 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dyspnoea			
subjects affected / exposed	0 / 87 (0.00%)	0 / 90 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Meconium aspiration syndrome			
subjects affected / exposed	1 / 87 (1.15%)	0 / 90 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neonatal asphyxia			
subjects affected / exposed	0 / 87 (0.00%)	2 / 90 (2.22%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	

Neonatal hypoxia			
subjects affected / exposed	1 / 87 (1.15%)	0 / 90 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neonatal respiratory distress syndrome			
subjects affected / exposed	1 / 87 (1.15%)	0 / 90 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia aspiration			
subjects affected / exposed	1 / 87 (1.15%)	0 / 90 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumothorax			
subjects affected / exposed	0 / 87 (0.00%)	0 / 90 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory disorder neonatal			
subjects affected / exposed	1 / 87 (1.15%)	1 / 90 (1.11%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory distress			
subjects affected / exposed	1 / 87 (1.15%)	0 / 90 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transient tachypnoea of the newborn			
subjects affected / exposed	0 / 87 (0.00%)	5 / 90 (5.56%)	
occurrences causally related to treatment / all	0 / 0	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Investigations			
Blood pressure increased			
subjects affected / exposed	0 / 87 (0.00%)	0 / 90 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Haemoglobin decreased			
subjects affected / exposed	0 / 87 (0.00%)	0 / 90 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Heart rate increased			
subjects affected / exposed	0 / 87 (0.00%)	0 / 90 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Platelet count decreased			
subjects affected / exposed	0 / 87 (0.00%)	0 / 90 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Biopsy rectum			
subjects affected / exposed	0 / 87 (0.00%)	1 / 90 (1.11%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac murmur			
subjects affected / exposed	0 / 87 (0.00%)	0 / 90 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Heart rate decreased			
subjects affected / exposed	0 / 87 (0.00%)	1 / 90 (1.11%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory syncytial virus test positive			
subjects affected / exposed	0 / 87 (0.00%)	1 / 90 (1.11%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Anal injury			
subjects affected / exposed	0 / 87 (0.00%)	0 / 90 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Injury to brachial plexus due to birth trauma			
subjects affected / exposed	0 / 87 (0.00%)	0 / 90 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural haemorrhage			
subjects affected / exposed	0 / 87 (0.00%)	0 / 90 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Procedural haemorrhage			
subjects affected / exposed	0 / 87 (0.00%)	0 / 90 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Procedural pain			
subjects affected / exposed	0 / 87 (0.00%)	0 / 90 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uterine cervical laceration			
subjects affected / exposed	0 / 87 (0.00%)	0 / 90 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Congenital, familial and genetic disorders			
Cleft palate			
subjects affected / exposed	0 / 87 (0.00%)	0 / 90 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fallot's tetralogy			
subjects affected / exposed	0 / 87 (0.00%)	1 / 90 (1.11%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Patent ductus arteriosus			
subjects affected / exposed	0 / 87 (0.00%)	1 / 90 (1.11%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Persistent foetal circulation			
subjects affected / exposed	1 / 87 (1.15%)	0 / 90 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyloric stenosis			
subjects affected / exposed	0 / 87 (0.00%)	1 / 90 (1.11%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tracheo-oesophageal fistula			
subjects affected / exposed	1 / 87 (1.15%)	0 / 90 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Trisomy 21			
subjects affected / exposed	0 / 87 (0.00%)	1 / 90 (1.11%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ventricular septal defect			
subjects affected / exposed	1 / 87 (1.15%)	0 / 90 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Supraventricular extrasystoles			
subjects affected / exposed	1 / 87 (1.15%)	0 / 90 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Supraventricular tachycardia			
subjects affected / exposed	1 / 87 (1.15%)	0 / 90 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 87 (0.00%)	0 / 90 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Gastrointestinal disorders			
Abdominal pain lower			
subjects affected / exposed	0 / 87 (0.00%)	0 / 90 (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 / 87 (0.00%)	1 / 90 (1.11%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Cholelithiasis			
subjects affected / exposed	0 / 87 (0.00%)	0 / 90 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperbilirubinaemia			
subjects affected / exposed	1 / 87 (1.15%)	2 / 90 (2.22%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperbilirubinaemia neonatal			
subjects affected / exposed	0 / 87 (0.00%)	2 / 90 (2.22%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Jaundice			
subjects affected / exposed	1 / 87 (1.15%)	0 / 90 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
Hypotonia neonatal			
subjects affected / exposed	1 / 87 (1.15%)	0 / 90 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Muscle spasms			

subjects affected / exposed	1 / 87 (1.15%)	0 / 90 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Amniotic cavity infection			
subjects affected / exposed	0 / 87 (0.00%)	0 / 90 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Appendicitis			
subjects affected / exposed	0 / 87 (0.00%)	0 / 90 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endometritis decidual			
subjects affected / exposed	0 / 87 (0.00%)	0 / 90 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infection			
subjects affected / exposed	2 / 87 (2.30%)	0 / 90 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neonatal infection			
subjects affected / exposed	0 / 87 (0.00%)	0 / 90 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neonatal infective mastitis			
subjects affected / exposed	0 / 87 (0.00%)	0 / 90 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyelonephritis			
subjects affected / exposed	0 / 87 (0.00%)	0 / 90 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sepsis			

subjects affected / exposed	1 / 87 (1.15%)	0 / 90 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Staphylococcal sepsis			
subjects affected / exposed	0 / 87 (0.00%)	0 / 90 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Upper respiratory tract infection			
subjects affected / exposed	0 / 87 (0.00%)	1 / 90 (1.11%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Poor feeding infant			
subjects affected / exposed	0 / 87 (0.00%)	0 / 90 (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: 5 %

Non-serious adverse events	Placebo-Mother	Tafoxiparin 5 mg/h-Mother	Tafoxiparin 15 mg/h-Mother
Total subjects affected by non-serious adverse events			
subjects affected / exposed	68 / 91 (74.73%)	76 / 88 (86.36%)	71 / 87 (81.61%)
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	5 / 91 (5.49%)	2 / 88 (2.27%)	2 / 87 (2.30%)
occurrences (all)	5	2	2
Aspartate aminotransferase increased			
subjects affected / exposed	5 / 91 (5.49%)	2 / 88 (2.27%)	1 / 87 (1.15%)
occurrences (all)	5	2	1
Haemoglobin decreased			
subjects affected / exposed	3 / 91 (3.30%)	5 / 88 (5.68%)	4 / 87 (4.60%)
occurrences (all)	3	5	4
Nervous system disorders			

Dizziness			
subjects affected / exposed	4 / 91 (4.40%)	6 / 88 (6.82%)	2 / 87 (2.30%)
occurrences (all)	5	6	2
Pregnancy, puerperium and perinatal conditions			
Afterbirth pain			
subjects affected / exposed	6 / 91 (6.59%)	9 / 88 (10.23%)	6 / 87 (6.90%)
occurrences (all)	7	9	7
Postpartum haemorrhage			
subjects affected / exposed	8 / 91 (8.79%)	10 / 88 (11.36%)	9 / 87 (10.34%)
occurrences (all)	8	10	9
Retained placenta or membranes			
subjects affected / exposed	2 / 91 (2.20%)	6 / 88 (6.82%)	3 / 87 (3.45%)
occurrences (all)	2	6	3
Weight decrease neonatal			
subjects affected / exposed	0 / 91 (0.00%)	0 / 88 (0.00%)	0 / 87 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	5 / 91 (5.49%)	6 / 88 (6.82%)	10 / 87 (11.49%)
occurrences (all)	5	6	10
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	13 / 91 (14.29%)	14 / 88 (15.91%)	12 / 87 (13.79%)
occurrences (all)	13	16	12
Mastitis			
subjects affected / exposed	1 / 91 (1.10%)	2 / 88 (2.27%)	5 / 87 (5.75%)
occurrences (all)	1	2	5
Nasopharyngitis			
subjects affected / exposed	0 / 91 (0.00%)	0 / 88 (0.00%)	0 / 87 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Constipation			
subjects affected / exposed	1 / 91 (1.10%)	3 / 88 (3.41%)	6 / 87 (6.90%)
occurrences (all)	1	3	6
Abdominal pain			

subjects affected / exposed	1 / 91 (1.10%)	0 / 88 (0.00%)	1 / 87 (1.15%)
occurrences (all)	1	0	1
Vomiting			
subjects affected / exposed	6 / 91 (6.59%)	3 / 88 (3.41%)	9 / 87 (10.34%)
occurrences (all)	6	4	9
Reproductive system and breast disorders			
Genital pain			
subjects affected / exposed	5 / 91 (5.49%)	6 / 88 (6.82%)	4 / 87 (4.60%)
occurrences (all)	5	6	4
Renal and urinary disorders			
Dysuria			
subjects affected / exposed	5 / 91 (5.49%)	4 / 88 (4.55%)	1 / 87 (1.15%)
occurrences (all)	5	4	2
Urinary retention			
subjects affected / exposed	13 / 91 (14.29%)	10 / 88 (11.36%)	12 / 87 (13.79%)
occurrences (all)	13	10	12
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	0 / 91 (0.00%)	3 / 88 (3.41%)	0 / 87 (0.00%)
occurrences (all)	0	3	0
Infections and infestations			
Influenza			
subjects affected / exposed	0 / 91 (0.00%)	0 / 88 (0.00%)	0 / 87 (0.00%)
occurrences (all)	0	0	0
Vaginal laceration			
subjects affected / exposed	8 / 91 (8.79%)	8 / 88 (9.09%)	8 / 87 (9.20%)
occurrences (all)	9	8	8

Non-serious adverse events	Tafoxiparin 25 mg/h-Mother	Placebo-Infant	Tafoxiparin 5 mg/h-Infant
Total subjects affected by non-serious adverse events			
subjects affected / exposed	72 / 90 (80.00%)	68 / 91 (74.73%)	57 / 88 (64.77%)
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	4 / 90 (4.44%)	0 / 91 (0.00%)	0 / 88 (0.00%)
occurrences (all)	4	0	0
Aspartate aminotransferase increased			

subjects affected / exposed	0 / 90 (0.00%)	0 / 91 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Haemoglobin decreased			
subjects affected / exposed	5 / 90 (5.56%)	0 / 91 (0.00%)	0 / 88 (0.00%)
occurrences (all)	5	0	0
Nervous system disorders			
Dizziness			
subjects affected / exposed	2 / 90 (2.22%)	0 / 91 (0.00%)	0 / 88 (0.00%)
occurrences (all)	2	0	0
Pregnancy, puerperium and perinatal conditions			
Afterbirth pain			
subjects affected / exposed	4 / 90 (4.44%)	0 / 91 (0.00%)	0 / 88 (0.00%)
occurrences (all)	6	0	0
Postpartum haemorrhage			
subjects affected / exposed	10 / 90 (11.11%)	0 / 91 (0.00%)	0 / 88 (0.00%)
occurrences (all)	10	0	0
Retained placenta or membranes			
subjects affected / exposed	3 / 90 (3.33%)	0 / 91 (0.00%)	0 / 88 (0.00%)
occurrences (all)	3	0	0
Weight decrease neonatal			
subjects affected / exposed	0 / 90 (0.00%)	5 / 91 (5.49%)	2 / 88 (2.27%)
occurrences (all)	0	5	2
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	8 / 90 (8.89%)	0 / 91 (0.00%)	0 / 88 (0.00%)
occurrences (all)	8	0	0
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	16 / 90 (17.78%)	10 / 91 (10.99%)	5 / 88 (5.68%)
occurrences (all)	16	10	5
Mastitis			
subjects affected / exposed	1 / 90 (1.11%)	0 / 91 (0.00%)	0 / 88 (0.00%)
occurrences (all)	1	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 90 (0.00%)	8 / 91 (8.79%)	7 / 88 (7.95%)
occurrences (all)	0	8	8

Gastrointestinal disorders			
Constipation			
subjects affected / exposed	2 / 90 (2.22%)	1 / 91 (1.10%)	4 / 88 (4.55%)
occurrences (all)	2	1	4
Abdominal pain			
subjects affected / exposed	0 / 90 (0.00%)	3 / 91 (3.30%)	6 / 88 (6.82%)
occurrences (all)	0	3	6
Vomiting			
subjects affected / exposed	6 / 90 (6.67%)	3 / 91 (3.30%)	1 / 88 (1.14%)
occurrences (all)	7	3	1
Reproductive system and breast disorders			
Genital pain			
subjects affected / exposed	8 / 90 (8.89%)	0 / 91 (0.00%)	0 / 88 (0.00%)
occurrences (all)	8	0	0
Renal and urinary disorders			
Dysuria			
subjects affected / exposed	2 / 90 (2.22%)	0 / 91 (0.00%)	0 / 88 (0.00%)
occurrences (all)	3	0	0
Urinary retention			
subjects affected / exposed	15 / 90 (16.67%)	0 / 91 (0.00%)	0 / 88 (0.00%)
occurrences (all)	15	0	0
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	5 / 90 (5.56%)	0 / 91 (0.00%)	0 / 88 (0.00%)
occurrences (all)	5	0	0
Infections and infestations			
Influenza			
subjects affected / exposed	0 / 90 (0.00%)	5 / 91 (5.49%)	2 / 88 (2.27%)
occurrences (all)	0	5	2
Vaginal laceration			
subjects affected / exposed	6 / 90 (6.67%)	0 / 91 (0.00%)	0 / 88 (0.00%)
occurrences (all)	6	0	0

Non-serious adverse events	Tafoxiparin 15 mg/h-Infant	Tafoxiparin 25 mg/h-Infant	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	60 / 87 (68.97%)	61 / 90 (67.78%)	

Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 87 (0.00%)	0 / 90 (0.00%)	
occurrences (all)	0	0	
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 87 (0.00%)	0 / 90 (0.00%)	
occurrences (all)	0	0	
Haemoglobin decreased			
subjects affected / exposed	1 / 87 (1.15%)	0 / 90 (0.00%)	
occurrences (all)	1	0	
Nervous system disorders			
Dizziness			
subjects affected / exposed	0 / 87 (0.00%)	0 / 90 (0.00%)	
occurrences (all)	0	0	
Pregnancy, puerperium and perinatal conditions			
Afterbirth pain			
subjects affected / exposed	0 / 87 (0.00%)	0 / 90 (0.00%)	
occurrences (all)	0	0	
Postpartum haemorrhage			
subjects affected / exposed	0 / 87 (0.00%)	0 / 90 (0.00%)	
occurrences (all)	0	0	
Retained placenta or membranes			
subjects affected / exposed	0 / 87 (0.00%)	0 / 90 (0.00%)	
occurrences (all)	0	0	
Weight decrease neonatal			
subjects affected / exposed	5 / 87 (5.75%)	2 / 90 (2.22%)	
occurrences (all)	5	2	
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 87 (0.00%)	0 / 90 (0.00%)	
occurrences (all)	0	0	
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	3 / 87 (3.45%)	4 / 90 (4.44%)	
occurrences (all)	3	4	
Mastitis			

subjects affected / exposed	0 / 87 (0.00%)	0 / 90 (0.00%)	
occurrences (all)	0	0	
Nasopharyngitis			
subjects affected / exposed	7 / 87 (8.05%)	10 / 90 (11.11%)	
occurrences (all)	10	11	
Gastrointestinal disorders			
Constipation			
subjects affected / exposed	2 / 87 (2.30%)	5 / 90 (5.56%)	
occurrences (all)	2	5	
Abdominal pain			
subjects affected / exposed	2 / 87 (2.30%)	4 / 90 (4.44%)	
occurrences (all)	2	4	
Vomiting			
subjects affected / exposed	1 / 87 (1.15%)	3 / 90 (3.33%)	
occurrences (all)	1	3	
Reproductive system and breast disorders			
Genital pain			
subjects affected / exposed	0 / 87 (0.00%)	0 / 90 (0.00%)	
occurrences (all)	0	0	
Renal and urinary disorders			
Dysuria			
subjects affected / exposed	0 / 87 (0.00%)	1 / 90 (1.11%)	
occurrences (all)	0	1	
Urinary retention			
subjects affected / exposed	0 / 87 (0.00%)	0 / 90 (0.00%)	
occurrences (all)	0	0	
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	0 / 87 (0.00%)	0 / 90 (0.00%)	
occurrences (all)	0	0	
Infections and infestations			
Influenza			
subjects affected / exposed	1 / 87 (1.15%)	2 / 90 (2.22%)	
occurrences (all)	1	2	
Vaginal laceration			

subjects affected / exposed occurrences (all)	0 / 87 (0.00%) 0	0 / 90 (0.00%) 0	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
20 February 2017	Only applicable for Sweden and Finland: - Added spontaneous rupture of membranes (SROM) are required to definitions of indication. - Exclusion criteria Fetal macrosomia and Intrauterine growth retardation updated. - Exclusion criteria Previous uterine scar and Labor induction added. - Safety blood samples specified for Biochemistry (plasma) and Hematology. - Infant requires emergency treatment (e.g., Neonatal Intensive Care Unit (NICU) admission) is always recorded as a SAE. - Wording of hypercontractility changed. - Added "Primary" to all sections in the text with Labor Arrest including the study title. - Urine analysis deleted - The dosing of Oxytocin is updated. "Oxytocin will be given as 8.3 µg oxytocin in 500 ml NaCl. The starting dose is 20 ml per hour and increase by 20 ml every 20 minute until progress." is changed to; "Oxytocin will be given as 8.3 µg oxytocin in 500ml saline (NaCl). The starting dose rate is 20 ml per hour and increased by 20 ml per hour every 20 minutes until 5 contractions per 10 minutes is observed." - Partogram shows duplicate of temperature measurements. Point "temperature when indicated" changed to "use of epidural analgesia (EDA)"
05 April 2017	Only applicable for Sweden and Finland: - Definitions of indications changed for Primary Slow progress of Labor, Prolonged latent phase and Labor arrest.
24 January 2018	- Definitions of indications updated for Primary Slow progress of Labor, Prolonged latent phase and Primary Labor arrest. - Exclusion criterion added; Inability to understand local language. - Objectives and endpoints have been clarified and numbers of instrumental deliveries has been deleted. - Wording of exclusion criteria LGA (Large for Gestational Age) and Small for gestational age (SGA) changed. - Clarification that iron, mineral, and vitamin supplements does not have to be reported as and concomitant medications has been implemented.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported