Clinical trial results:
A randomised, open-label, placebo-controlled, single centre study in healthy male volunteers to explore efficacy, safety and tolerability of single doses of low molecular weight dextran sulfate (LMW-DS) in combination with recombinant human granulocyte colony stimulating factor (rhG-CSF, filgrastim) and in comparison with plerixafor treatment and placebo

Summary

EudraCT number	2014-000659-10
Trial protocol	SE
Global end of trial date	13 September 2014

Results information

Result version number	v1 (current)
This version publication date	11 July 2019
First version publication date	11 July 2019

Trial information

Trial identification

Sponsor protocol code	LMW-DS-103

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	TikoMed AB
Sponsor organisation address	P.O. Box 81, 263 03 VIKEN, Sweden,
Public contact	CEO, TikoMed AB, regulatory@tikomed.com
Scientific contact	CEO, TikoMed AB, regulatory@tikomed.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	13 September 2014
Is this the analysis of the primary completion data?	Yes
Primary completion date	13 September 2014
Global end of trial reached?	Yes
Global end of trial date	13 September 2014
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

To determine the blood levels of CD34+ cells at different time points after treatment with filgrastim (for 5 days) in combination with low molecular weight dextran sulfate (LMW-DS) compared to filgrastim treatment (for 5 days) in combination with plerixafor or NaCl.

Protection of trial subjects:

The potential study subject was informed that by signing the ICF he approved that authorized representatives from Sponsor and CTC, the concerned IEC and CA had direct access to his medical records for verification of clinical study procedures. An authorization from the hospital for access to medical records by the Monitor was available, as required by local legislation. The subject had the right to request access to his/her personal data and rectification of any data that was not correct and/or complete.

The Investigator filed a Subject Identification List which included sufficient information to link records, i.e. the CRF and clinical records. This list will be preserved for possible future inspections/audits but has not been made available to the Sponsor except for monitoring or auditing purposes.

As a precaution to minimize any hypersensitivity reactions to LMW-DS, an oral dose of Klemastin (antihistamine), 1 mg, was given to all subjects in Group 1, 2 h before start of the LMW-DS infusion. During the initial 4 days of filgrastim treatment, the subjects came to the clinic in the morning and received a subcutaneous injection of filgrastim. As a safety precaution, the subjects stayed at the clinic for 2 hours after the filgrastim injection. On day 5, the subjects arrived in the morning for filgrastim treatment followed by LMW-DS i.v. infusion (Group 1), plerixafor s.c. injection (Group 2) or 10-min i.v. infusion NaCl (Group 3). Blood samples, vital signs, and electrocardiogram (ECG) were recorded prior to treatment with LMW-DS and at several time points up to 24 h after the day 5 dose administration. Each subject stayed at the clinic until approximately 24 h post start of dose administration of LMW-DS/plerixafor/NaCl.

Background therapy: -	
Evidence for comparator: -	
Actual start date of recruitment	27 May 2014
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: 15
Worldwide total number of subjects	15
EEA total number of subjects	15

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)	15
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

The subjects were recruited from a list of healthy volunteers.

Pre-assignment

Screening details: -

Pre-assignment period milestones

Number of subjects started	15
Number of subjects completed	11

Pre-assignment subject non-completion reasons

Reason: Number of subjects	Adverse event, non-fatal: 2
Reason: Number of subjects	Consent withdrawn by subject: 2

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Group 1 - Experimental Treatment

Arm description:

LMW-DS + Filgrastim

Arm type	Experimental
Investigational medicinal product name	LMW-DS 20 mg/ml
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

20 mg/mL; 18 mg/kg administered by a short-term 10-min intravenous infusion on Day 5.

Investigational medicinal product name	Filgrastim
Investigational medicinal product code	
Other name	Neupogen
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

0.96 mg/mL; 10 µg/kg administered subcutaneously once daily for 5 days.

Arm title	Group 2 - Plerixafor control

Arm description:

Plerixafor + Filgrastim

Arm type	Active comparator

Investigational medicinal product name	Filgrastim
Investigational medicinal product code	
Other name	Neupogen
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

0.96 mg/mL; 10 µg/kg administered subcutaneously once daily for 5 days.

Investigational medicinal product name	Plerixafor
Investigational medicinal product code	
Other name	Mozobil
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

20 mg/mL; 240 µg/kg administered subcutaneously on Day 5.

Arm title	Group 3 - NaCl placebo control

Arm description:

NaCl + Filgrastim

Arm type	Placebo
Investigational medicinal product name	Filgrastim
Investigational medicinal product code	
Other name	Neupogen
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

0.96 mg/mL; 10 µg/kg administered subcutaneously once daily for 5 days.

Investigational medicinal product name	NaCl
Investigational medicinal product code	
Other name	Sodium Chloride
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

9 mg/mL; 0.9 mL/kg administered intravenously on Day 5.

Number of subjects in period 1[1]	Group 1 - Experimental Treatment	Group 2 - Plerixafor control	Group 3 - NaCl placebo control
Started	3	4	4
Completed	3	4	4

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: In total, 15 subjects were enrolled. Two (2) subjects withdrew consent before any treatment and two (2) subjects withdrew from the study due to AEs during the filgrastim pre-assignment treatment. None of these four (4) subjects were included in the overall study period and therefore only 11 subjects are included in the Full / Safety Analysis Set.

Baseline characteristics

Reporting groups

Reporting group title	Overall period

Reporting group description: -

Reporting group values	Overall period	Total	
Number of subjects	11	11	
Age categorical Units: Subjects			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	0	0	
Infants and toddlers (28 days-23 months)	0	0	
Children (2-11 years)	0	0	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	11	11	
From 65-84 years	0	0	
85 years and over	0	0	
Not recorded	0	0	
Age continuous Units: years			
arithmetic mean	30		
full range (min-max)	23 to 44	-	
Gender categorical Units: Subjects			
Female	0	0	
Male	11	11	
Weight Units: kilogram(s)			
arithmetic mean	80.8		
full range (min-max)	67.8 to 90.3	-	

End points

End points reporting groups

Reporting group title	Group 1 - Experimental Treatment
Reporting group description: LMW-DS + Filgrastim	
Reporting group title	Group 2 - Plerixafor control
Reporting group description: Plerixafor + Filgrastim	
Reporting group title	Group 3 - NaCl placebo control
Reporting group description: NaCl + Filgrastim	

Primary: Absolute number of CD34+ cells

End point title	Absolute number of CD34+ cells[1]
End point description:	
End point type	Primary
End point timeframe: From -30 min pre-dose to 24 h after dose	

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: Due to premature termination of the study for efficacy reasons, the statistical analysis was not as extensive as described in the clinical study protocol. Only descriptive statistics have been described in the abbreviated study report.

End point values	Group 1 - Experimental Treatment	Group 2 - Plerixafor control	Group 3 - NaCl placebo control	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	3	4	4	
Units: x 10^6/L				
arithmetic mean (standard deviation)				
Pre-dose (-30 min)	82.0 (± 24.1)	58.3 (± 18.6)	44.3 (± 7.5)	
1 h after dose	107.0 (± 29.5)	123.8 (± 52.7)	63.5 (± 11.0)	
3 h after dose	121.0 (± 33.9)	143.3 (± 49.0)	75.3 (± 16.5)	
6 h after dose	118.3 (± 44.8)	167.3 (± 44.4)	78.0 (± 16.0)	
9 h after dose	123.7 (± 34.0)	203.5 (± 59.7)	90.8 (± 10.5)	
24 h after dose	107.0 (± 30.1)	159.5 (± 66.6)	72.0 (± 10.9)	

Statistical analyses

No statistical analyses for this end point

Secondary: Hepatocyte growth factor

End point title	Hepatocyte growth factor

End point description:

End point type	Secondary

End point timeframe:

From -30 min pre-dose to 24 h after dose.

End point values	Group 1 - Experimental Treatment	Group 2 - Plerixafor control	Group 3 - NaCl placebo control	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	3	4	4	
Units: pg/mL				
arithmetic mean (standard deviation)				
Pre-dose (-30 min)	2057.0 (± 292.9)	1976.8 (± 235.6)	1975.3 (± 402.3)	
1 h	109258.0 (± 21779.9)	6745.3 (± 1176.7)	6920.0 (± 778.1)	
3 h	116479.3 (± 19308.3)	9239.0 (± 3624.3)	7804.0 (± 1534.7)	
6 h	143585.0 (± 44596.1)	8978.5 (± 1578.4)	8519.5 (± 1420.0)	
9 h	93078.7 (± 23685.0)	9715.0 (± 1702.4)	8652.3 (± 793.6)	
24 h	16459.0 (± 7576.8)	8509.8 (± 1854.9)	8086.8 (± 213.9)	

Statistical analyses

No statistical analyses for this end point

Secondary: Stromal cell-derived factor-1

End point title	Stromal cell-derived factor-1

End point description:

End point type	Secondary

End point timeframe:

From -30 min pre-dose until 24 h after dose.

End point values	Group 1 - Experimental Treatment	Group 2 - Plerixafor control	Group 3 - NaCl placebo control	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	3	4	4	
Units: pg/mL				
arithmetic mean (standard deviation)				
Pre-dose (-30 min)	1314.3 (± 124.7)	1437.3 (± 93.7)	1500.5 (± 312.5)	

1 h	3074.0 (± 438.5)	2499.8 (± 300.0)	1541.8 (± 330.1)	
3 h	2135.7 (± 226.7)	2281.8 (± 368.1)	1475.5 (± 320.0)	
6 h	1560.3 (± 250.5)	2238.3 (± 374.2)	1518.8 (± 285.8)	
9 h	1228.0 (± 69.5)	2035.8 (± 235.9)	1512.0 (± 303.4)	
24 h	1208.7 (± 199.2)	1681.0 (± 175.8)	1494.8 (± 199.1)	

Statistical analyses

No statistical analyses for this end point

Secondary: Lymphocytes

End point title	Lymphocytes

End point description:

End point type	Secondary

End point timeframe:

From screening until Follow-up 2 visit (day 19)

End point values	Group 1 - Experimental Treatment	Group 2 - Plerixafor control	Group 3 - NaCl placebo control	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	3	4	4	
Units: x 10^9/L				
arithmetic mean (standard deviation)				
Screening	2.37 (± 0.64)	2.20 (± 0.36)	1.35 (± 0.17)	
Pre-dose (-120 min)	4.67 (± 2.10)	3.95 (± 0.58)	2.68 (± 0.80)	
Pre-dose (-30 min)	4.10 (± 1.51)	3.80 (± 0.80)	2.43 (± 0.38)	
15 min	6.77 (± 2.04)	6.00 (± 1.42)	3.30 (± 0.77)	
30 min	7.17 (± 1.36)	5.68 (± 0.53)	3.43 (± 0.57)	
1 h	8.80 (± 2.29)	6.88 (± 2.01)	2.63 (± 0.33)	
3 h	9.50 (± 3.36)	7.20 (± 0.36)	2.33 (± 0.93)	
6 h	8.03 (± 1.43)	8.85 (± 1.66)	2.47 (± 0.57)	
9 h	6.30 (± 1.85)	7.63 (± 1.07)	3.23 (± 0.81)	
24 h	6.70 (± 3.34)	6.00 (± 0.52)	2.60 (± 0.99)	
Follow-up 2 (day 19)	1.70 (± 0.87)	1.45 (± 0.35)	1.05 (± 0.10)	

Statistical analyses

No statistical analyses for this end point

Secondary: Clinical chemistry - Albumin

End point title	Clinical chemistry - Albumin

End point description:

End point type	Secondary

End point timeframe:

At baseline and Follow-up visit 2 (day 19).

End point values	Group 1 - Experimental Treatment	Group 2 - Plerixafor control	Group 3 - NaCl placebo control	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	3	4	4	
Units: subjects				
Baseline - Normal	3	4	4	
Baseline - NCS	0	0	0	
Baseline - CS	0	0	0	
Baseline - ND/Miss	0	0	0	
Follow-up 2 - Normal	3	4	4	
Follow-up 2 - NCS	0	0	0	
Follow-up 2 - CS	0	0	0	
Follow-up 2 - ND/Miss	0	0	0	

Statistical analyses

No statistical analyses for this end point

Secondary: Clinical chemistry - Alkaline phospatase

End point title	Clinical chemistry - Alkaline phospatase

End point description:

End point type	Secondary

End point timeframe:

At baseline and Follow-up visit 2 (day 19).

End point values	Group 1 - Experimental Treatment	Group 2 - Plerixafor control	Group 3 - NaCl placebo control	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	3	4	4	
Units: subjects				
Baseline - Normal	3	4	4	
Baseline - NCS	0	0	0	
Baseline - CS	0	0	0	

Baseline - ND/Miss	0	0	0	
Follow-up 2 - Normal	3	4	4	
Follow-up 2 - NCS	0	0	0	
Follow-up - CS	0	0	0	
Follow-up - ND/Miss	0	0	0	

Statistical analyses

No statistical analyses for this end point

Secondary: Clinical Chemistry - Alanine Aminotransferase

End point title	Clinical Chemistry - Alanine Aminotransferase

End point description:

End point type	Secondary

End point timeframe:

At baseline and Follow-up visit 2 (day 19).

End point values	Group 1 - Experimental Treatment	Group 2 - Plerixafor control	Group 3 - NaCl placebo control	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	3	4	4	
Units: subjects				
Baseline - Normal	3	4	4	
Baseline - NCS	0	0	0	
Baseline - CS	0	0	0	
Baseline - ND/Miss	0	0	0	
Follow-up 2 - Normal	2	4	4	
Follow-up 2 - NCS	1	0	0	
Follow-up 2 - CS	0	0	0	
Follow-up 2 - ND/Miss	0	0	0	

Statistical analyses

No statistical analyses for this end point

Secondary: Clinical chemistry - Aspartate aminotransferase

End point title	Clinical chemistry - Aspartate aminotransferase

End point description:

End point type	Secondary

End point timeframe:

At baseline and Follow-up visit 2 (day 19).

End point values	Group 1 - Experimental Treatment	Group 2 - Plerixafor control	Group 3 - NaCl placebo control	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	3	4	4	
Units: subjects				
Baseline - Normal	3	4	3	
Baseline - NCS	0	0	1	
Baseline - CS	0	0	0	
Baseline ND/Miss	0	0	0	
Follow-up 2 - Normal	3	4	4	
Follow-up 2 - NCS	0	0	0	
Follow-up 2 - CS	0	0	0	
Follow-up 2 - ND/Miss	0	0	0	

Statistical analyses

No statistical analyses for this end point

Secondary: Clinical chemistry - bilirubin

End point title	Clinical chemistry - bilirubin

End point description:

End point type	Secondary

End point timeframe:

At baseline and Follow-up visit 2 (day 19).

End point values	Group 1 - Experimental Treatment	Group 2 - Plerixafor control	Group 3 - NaCl placebo control	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	3	4	4	
Units: subjects				
Baseline - Normal	3	4	4	
Baseline - NCS	0	0	0	
Baseline - CS	0	0	0	
Baseline - ND/Miss	0	0	0	
Follow-up 2 - Normal	3	4	4	
Follow-up 2 - NCS	0	0	0	
Follow-up 2 - CS	0	0	0	
Follow-up 2 - ND/Miss	0	0	0	

Statistical analyses

No statistical analyses for this end point

Secondary: Clinical chemistry - calcium

End point title	Clinical chemistry - calcium

End point description:

End point type	Secondary

End point timeframe:

At baseline and Follow-up visit 2 (day 19).

End point values	Group 1 - Experimental Treatment	Group 2 - Plerixafor control	Group 3 - NaCl placebo control	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	3	4	4	
Units: subjects				
Baseline - Normal	3	4	3	
Baseline - NCS	0	0	1	
Baseline - CS	0	0	0	
Baseline - ND/Miss	0	0	0	
Follow-up 2 - Normal	3	4	4	
Follow-up 2 - NCS	0	0	0	
Follow-up 2 - CS	0	0	0	
Follow-up 2 ND/Miss	0	0	0	

Statistical analyses

No statistical analyses for this end point

Secondary: Clinical chemistry - chloride

End point title	Clinical chemistry - chloride

End point description:

End point type	Secondary

End point timeframe:

At baseline and Follow-up visit 2 (day 19).

End point values	Group 1 - Experimental Treatment	Group 2 - Plerixafor control	Group 3 - NaCl placebo control	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	3	4	4	
Units: subjects				
Baseline - Normal	3	4	4	
Baseline - NCS	0	0	0	
Baseline - CS	0	0	0	
Baseline - ND/Miss	0	0	0	
Follow-up 2 - Normal	2	3	3	
Follow-up 2 - NCS	1	1	1	
Follow-up 2 - CS	0	0	0	
Follow-up 2 - ND/Miss	0	0	0	

Statistical analyses

No statistical analyses for this end point

Secondary: Clinical chemistry - creatinine

End point title	Clinical chemistry - creatinine

End point description:

End point type	Secondary

End point timeframe:

At baseline and Follow-up visit 2 (day 19).

End point values	Group 1 - Experimental Treatment	Group 2 - Plerixafor control	Group 3 - NaCl placebo control	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	3	4	4	
Units: subjects				
Baseline - Normal	3	4	4	
Baseline - NCS	0	0	0	
Baseline - CS	0	0	0	
Baseline - ND/Miss	0	0	0	
Follow-up 2 - Normal	3	4	3	
Follow-up 2 - NCS	0	0	0	
Follow-up 2 - CS	0	0	1	
Follow-up 2 - ND/Miss	0	0	0	

Statistical analyses

No statistical analyses for this end point

Secondary: Clinical chemistry - C reactive protein

End point title	Clinical chemistry - C reactive protein

End point description:

End point type	Secondary

End point timeframe:

At baseline and Follow-up visit 2 (day 19).

End point values	Group 1 - Experimental Treatment	Group 2 - Plerixafor control	Group 3 - NaCl placebo control	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	3	4	4	
Units: patients				
Baseline - Normal	3	4	4	
Baseline - NCS	0	0	0	
Baseline - CS	0	0	0	
Baseline - ND/Miss	0	0	0	
Follow-up 2 - Normal	3	3	3	
Follow-up 2 - NCS	0	1	1	
Follow-up 2 - CS	0	0	0	
Follow-up 2 - ND/Miss	0	0	0	

Statistical analyses

No statistical analyses for this end point

Secondary: Clinical chemistry - glucose

End point title	Clinical chemistry - glucose

End point description:

End point type	Secondary

End point timeframe:

At baseline and Follow-up visit 2 (day 19).

End point values	Group 1 - Experimental Treatment	Group 2 - Plerixafor control	Group 3 - NaCl placebo control	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	3	4	4	
Units: subjects				
Baseline - Normal	3	4	3	
Baseline - NCS	0	0	1	
Baseline - CS	0	0	0	
Baseline - ND/Miss	0	0	0	
Follow-up 2 - Normal	3	4	4	
Follow-up 2 - NCS	0	0	0	
Follow-up 2 - CS	0	0	0	
Follow-up 2 - ND/Miss	0	0	0	

Statistical analyses

No statistical analyses for this end point

Secondary: Clinical chemistry - potassium

End point title	Clinical chemistry - potassium

End point description:

End point type	Secondary

End point timeframe:

At baseline and Follow-up visit 2 (day 19).

End point values	Group 1 - Experimental Treatment	Group 2 - Plerixafor control	Group 3 - NaCl placebo control	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	3	4	4	
Units: subjects				
Baseline - Normal	3	4	4	
Baseline - NCS	0	0	0	
Baseline - CS	0	0	0	
Baseline - ND/Miss	0	0	0	
Follow-up 2 - Normal	3	4	4	
Follow-up 2 - NCS	0	0	0	
Follow-up 2 - CS	0	0	0	
Follow-up 2 - ND/Miss	0	0	0	

Statistical analyses

No statistical analyses for this end point

Secondary: Clinical chemistry - sodium

End point title	Clinical chemistry - sodium

End point description:

End point type	Secondary

End point timeframe:

At baseline and Follow-up visit 2 (day 19).

End point values	Group 1 - Experimental Treatment	Group 2 - Plerixafor control	Group 3 - NaCl placebo control	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	3	4	4	
Units: subjects				
Baseline - Normal	2	2	3	
Baseline - NCS	1	2	1	
Baseline - CS	0	0	0	
Baseline - ND/Miss	0	0	0	
Follow-up 2 - Normal	3	4	3	
Follow-up 2 - NCS	0	0	1	
Follow-up 2 - CS	0	0	0	
Follow-up 2 - ND/Miss	0	0	0	

Statistical analyses

No statistical analyses for this end point

Secondary: Haematology - Basophils

End point title	Haematology - Basophils

End point description:

End point type	Secondary

End point timeframe:

From Screening until Follow-up visit 2.

End point values	Group 1 - Experimental Treatment	Group 2 - Plerixafor control	Group 3 - NaCl placebo control	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	3	4	4	
Units: x10^9/L				
arithmetic mean (standard deviation)				
Screening	0.10 (± 0)	0.10 (± 0)	0.10 (± 0)	
Pre-dose (-120 min)	0.23 (± 0.15)	0.18 (± 0.05)	0.23 (± 0.13)	
Pre-dose (-30 min)	0.20 (± 0.10)	0.10 (± 0)	0.15 (± 0.06)	
15 min	0.10 (± 0)	0.10 (± 0)	0.13 (± 0.05)	
30 min	0.17 (± 0.12)	0.18 (± 0.10)	0.15 (± 0.10)	
1 h	0.13 (± 0.06)	0.18 (± 0.10)	0.13 (± 0.05)	
3 h	0.27 (± 0.06)	0.28 (± 0.29)	0.13 (± 0.05)	
6 h	0.20 (± 0.10)	0.25 (± 0.24)	0.10 (± 0)	
9 h	0.17 (± 0.12)	0.28 (± 0.21)	0.20 (± 0.14)	
24 h	0.13 (± 0.06)	0.18 (± 0.10)	0.23 (± 0.13)	
Follow-up 2 (day 19)	0.10 (± 0)	0.10 (± 0)	0.10 (± 0)	

Statistical analyses

No statistical analyses for this end point

Secondary: Haematology - eosinophils

End point title	Haematology - eosinophils

End point description:

End point type	Secondary

End point timeframe:

From Screening until Follow-up visit 2.

End point values	Group 1 - Experimental Treatment	Group 2 - Plerixafor control	Group 3 - NaCl placebo control	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	3	4	4	
Units: x10^9/L				
arithmetic mean (standard deviation)				
Screening	0.17 (± 0.06)	0.33 (± 0.26)	0.15 (± 0.06)	
Pre-dose (-120 min)	0.60 (± 0.10)	0.70 (± 0.29)	0.90 (± 0.24)	
Pre-dose (-30 min)	0.63 (± 0.23)	0.90 (± 0.34)	0.63 (± 0.10)	
15 min	0.77 (± 0.40)	0.83 (± 0.26)	0.60 (± 0.24)	
30 min	1.13 (± 0.74)	0.70 (± 0.53)	0.70 (± 0.18)	
1 h	1.10 (± 0.70)	0.95 (± 0.44)	0.65 (± 0.31)	

3 h	1.03 (± 0.15)	1.40 (± 0.61)	0.55 (± 0.29)	
6 h	1.23 (± 0.90)	1.55 (± 0.31)	0.55 (± 0.34)	
9 h	1.20 (± 0.30)	2.05 (± 0.54)	0.33 (± 0.21)	
24 h	0.83 (± 0.64)	0.83 (± 0.48)	0.30 (± 0.14)	
Follow-up 2 (day 19)	0.20 (± 0.10)	0.23 (± 0.19)	0.15 (± 0.06)	

Statistical analyses

No statistical analyses for this end point

Secondary: Haematology - haematocrit

End point title	Haematology - haematocrit

End point description:

End point type	Secondary

End point timeframe:

From Screening until Follow-up visit 2.

End point values	Group 1 - Experimental Treatment	Group 2 - Plerixafor control	Group 3 - NaCl placebo control	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	3	4	4	
Units: (no unit)				
arithmetic mean (standard deviation)				
Screening	0.430 (± 0.010)	0.435 (± 0.025)	0.415 (± 0.029)	
Day 2	0.427 (± 0.012)	0.443 (± 0.026)	0.428 (± 0.022)	
Day 3	0.430 (± 0.010)	0.440 (± 0.022)	0.413 (± 0.026)	
Day 4	0.430 (± 0.017)	0.428 (± 0.026)	0.413 (± 0.019)	
Day 5 Pre-dose (-120 min)	0.427 (± 0.012)	0.433 (± 0.033)	0.420 (± 0.022)	
Pre-dose (-30 min)	0.420 (± 0.01)	0.423 (± 0.033)	0.420 (± 0.032)	
15 min	0.427 (± 0.012)	0.425 (± 0.026)	0.413 (± 0.028)	
30 min	0.430 (± 0.010)	0.425 (± 0.031)	0.413 (± 0.028)	
1 h	0.430 (± 0.017)	0.423 (± 0.033)	0.413 (± 0.030)	
3 h	0.430 (± 0.017)	0.428 (± 0.039)	0.415 (± 0.031)	
6 h	0.437 (± 0.012)	0.430 (± 0.038)	0.420 (± 0.022)	
9 h	0.433 (± 0.006)	0.433 (± 0.039)	0.420 (± 0.018)	
24 h	0.430 (± 0.010)	0.438 (± 0.030)	0.437 (± 0.021)	

Follow-up 2 (day 19)	0.370 (± 0.010)	0.398 (± 0.036)	0.375 (± 0.021)	

Statistical analyses

No statistical analyses for this end point

Secondary: Haematology - haemoglobin

End point title	Haematology - haemoglobin

End point description:

End point type	Secondary

End point timeframe:

From Screening until Follow-up visit 2.

End point values	Group 1 - Experimental Treatment	Group 2 - Plerixafor control	Group 3 - NaCl placebo control	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	3	4	4	
Units: gram(s)/litre				
arithmetic mean (standard deviation)				
Screening	150.3 (± 2.1)	152.3 (± 10.4)	145.3 (± 6.9)	
Day 2	147.0 (± 2.0)	151.5 (± 9.9)	146.0 (± 3.6)	
Day 3	148.3 (± 2.1)	150.3 (± 10.2)	141.8 (± 7.5)	
Day 4	147.7 (± 4.7)	147.3 (± 11.3)	139.8 (± 4.6)	
Day 5 - Pre-dose (-120 min)	146.0 (± 3.6)	145.3 (± 14.0)	143.0 (± 4.2)	
Pre-dose (-30 min)	144.7 (± 1.5)	145.3 (± 14.0)	142.3 (± 9.9)	
15 min	144.3 (± 2.3)	144.0 (± 12.5)	140.3 (± 7.9)	
30 min	145.7 (± 1.2)	145.3 (± 13.2)	140.3 (± 8.7)	
1 h	148.0 (± 5.0)	144.5 (± 12.4)	141.5 (± 9.0)	
3 h	148.0 (± 1.7)	146.8 (± 15.8)	141.0 (± 8.0)	
6 h	150.0 (± 3.0)	146.3 (± 13.5)	143.3 (± 8.2)	
9 h	149.7 (± 3.8)	149.5 (± 14.9)	144.0 (± 7.1)	
24 h	146.7 (± 2.9)	149.8 (± 9.3)	148.7 (± 5.5)	
Follow-up 2 (day 19)	130.0 (± 3.5)	139.5 (± 12.8)	130.3 (± 8.2)	

Statistical analyses

No statistical analyses for this end point

Secondary: Haematology - monocytes

End point title	Haematology - monocytes

End point description:

End point type	Secondary

End point timeframe:

From Screening until Follow-up visit 2.

End point values	Group 1 - Experimental Treatment	Group 2 - Plerixafor control	Group 3 - NaCl placebo control	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	3	4	4	
Units: x10^9/L				
arithmetic mean (standard deviation)				
Screening	0.50 (± 0.10)	0.78 (± 0.13)	0.48 (± 0.05)	
Pre-dose (-120 min)	1.73 (± 0.60)	3.25 (± 0.70)	2.30 (± 0.67)	
Pre-dose (-30 min)	1.43 (± 0.60)	1.38 (± 0.56)	0.93 (± 0.22)	
15 min	2.53 (± 0.67)	2.43 (± 0.98)	1.30 (± 0.67)	
30 min	1.63 (± 0.75)	2.80 (± 1.03)	1.73 (± 0.39)	
1 h	1.80 (± 0.17)	3.00 (± 1.12)	1.45 (± 0.26)	
3 h	2.13 (± 0.64)	4.68 (± 2.26)	1.40 (± 0.23)	
6 h	3.10 (± 1.57)	5.63 (± 3.01)	2.72 (± 0.59)	
9 h	2.77 (± 1.96)	4.98 (± 1.02)	2.75 (± 1.23)	
24 h	1.50 (± 1.15)	4.60 (± 1.54)	2.00 (± 1.05)	
Follow-up 2 (day 19)	0.37 (± 0.12)	0.55 (± 0.24)	0.40 (± 0.08)	

Statistical analyses

No statistical analyses for this end point

Secondary: Haematology - neutrophils

End point title	Haematology - neutrophils

End point description:

End point type	Secondary

End point timeframe:

From Screening until Follow-up visit 2.

End point values	Group 1 - Experimental Treatment	Group 2 - Plerixafor control	Group 3 - NaCl placebo control	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	3	4	4	
Units: x10^9/L				
arithmetic mean (standard deviation)				
Screening	3.93 (± 0.51)	4.03 (± 0.92)	3.40 (± 1.27)	

Pre-dose (-120 min)	32.83 (± 0.76)	28.35 (± 5.63)	25.80 (± 8.92)	
Pre-dose (-30 min)	18.30 (± 6.67)	12.70 (± 4.31)	8.08 (± 4.83)	
15 min	23.17 (± 1.95)	19.10 (± 3.88)	12.80 (± 5.70)	
30 min	26.93 (± 1.66)	22.88 (± 4.50)	13.28 (± 5.51)	
1 h	30.93 (± 2.86)	24.35 (± 6.28)	15.88 (± 5.19)	
3 h	42.93 (± 2.59)	35.15 (± 8.33)	23.85 (± 6.88)	
6 h	50.93 (± 1.66)	42.85 (± 7.40)	30.58 (± 9.41)	
9 h	51.47 (± 5.93)	47.35 (± 9.34)	34.10 (± 10.53)	
24 h	39.23 (± 6.78)	43.38 (± 10.43)	26.28 (± 7.74)	
Follow-up 2 (day 19)	2.17 (± 0.74)	2.63 (± 0.74)	1.73 (± 0.78)	

Statistical analyses

No statistical analyses for this end point

Secondary: Haematology - platelets

End point title	Haematology - platelets

End point description:

End point type	Secondary

End point timeframe:

From Screening until Follow-up visit 2.

End point values	Group 1 - Experimental Treatment	Group 2 - Plerixafor control	Group 3 - NaCl placebo control	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	3	4	4	
Units: x10^9/L				
arithmetic mean (standard deviation)				
Screening	213.0 (± 24.6)	260.0 (± 26.0)	194.3 (± 27.0)	
Day 2	190.3 (± 34.7)	246.0 (± 31.4)	191.0 (± 38.9)	
Day 3	192.0 (± 37.0)	237.5 (± 27.4)	180.8 (± 26.7)	
Day 4	189.0 (± 33.0)	223.8 (± 43.1)	176.3 (± 22.1)	
Day 5 - Pre-dose (-120 min)	171.0 (± 25.1)	221.8 (± 37.6)	175.8 (± 17.7)	
Pre-dose (-30 min)	165.3 (± 24.9)	207.5 (± 34.7)	162.3 (± 19.4)	
15 min	182.7 (± 35.5)	215.3 (± 28.8)	168.3 (± 15.9)	
30 min	185.3 (± 37.1)	219.0 (± 32.8)	165.3 (± 21.8)	
1 h	181.0 (± 29.1)	207.8 (± 31.1)	165.5 (± 24.5)	
3 h	175.3 (± 25.5)	211.0 (± 33.3)	165.5 (± 13.5)	
6 h	187.0 (± 27.6)	229.8 (± 39.4)	174.3 (± 20.4)	
9 h	175.7 (± 22.1)	222.3 (± 31.4)	173.5 (± 15.5)	
24 h	142.3 (± 11.6)	217.0 (± 34.8)	166.7 (± 24.2)	
Follow-up 2 (day 19)	273.0 (± 5.2)	268.5 (± 77.0)	240.8 (± 85.9)	

Statistical analyses

No statistical analyses for this end point

Secondary: Haematology - erythrocytes

End point title	Haematology - erythrocytes

End point description:

End point type	Secondary

End point timeframe:

From Screening until Follow-up visit 2.

End point values	Group 1 - Experimental Treatment	Group 2 - Plerixafor control	Group 3 - NaCl placebo control	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	3	4	4	
Units: x10^12/L				
arithmetic mean (standard deviation)				
Screening	5.10 (± 0)	5.10 (± 0.43)	4.80 (± 0.34)	
Day 2	4.93 (± 0.06)	5.08 (± 0.44)	4.90 (± 0.22)	
Day 3	5.00 (± 0.10)	5.00 (± 0.42)	4.73 (± 0.30)	
Day 4	4.97 (± 0.12)	4.88 (± 0.50)	4.68 (± 0.25)	
Day 5 - Pre-dose (-120 min)	4.90 (± 0.10)	4.90 (± 0.54)	4.78 (± 0.21)	
Pre-dose (-30 min)	4.87 (± 0.06)	4.83 (± 0.50)	4.78 (± 0.40)	
15 min	4.87 (± 0.06)	4.88 (± 0.51)	4.68 (± 0.34)	
30 min	4.93 (± 0.12)	4.85 (± 0.55)	4.70 (± 0.36)	
1 h	4.93 (± 0.12)	4.83 (± 0.57)	4.70 (± 0.34)	
3 h	4.93 (± 0.06)	4.90 (± 0.61)	4.73 (± 0.36)	
6 h	4.97 (± 0.06)	4.93 (± 0.56)	4.73 (± 0.29)	
9 h	4.93 (± 0.06)	4.93 (± 0.59)	4.78 (± 0.26)	
24 h	4.93 (± 0.06)	5.03 (± 0.46)	5.00 (± 0)	
Follow-up 2 (day 19)	4.40 (± 0.10)	4.68 (± 0.52)	4.35 (± 0.31)	

Statistical analyses

No statistical analyses for this end point

Secondary: White blood cells / leukocytes

End point title	White blood cells / leukocytes

End point description:

End point type	Secondary

End point timeframe:

From Screening until Follow-up visit 2.

End point values	Group 1 - Experimental Treatment	Group 2 - Plerixafor control	Group 3 - NaCl placebo control	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	3	4	4	
Units: x10^9/L				
arithmetic mean (standard deviation)				
Screening	7.03 (± 0.71)	7.33 (± 0.94)	5.43 (± 1.09)	
Day 2	28.90 (± 2.36)	30.25 (± 2.89)	25.28 (± 8.39)	
Day 3	34.90 (± 4.43)	32.05 (± 3.14)	27.00 (± 8.72)	
Day 4	38.17 (± 4.32)	37.05 (± 7.55)	30.80 (± 9.85)	
Day 5 - Pre-dose (-120 min)	41.90 (± 2.97)	37.53 (± 7.20)	33.08 (± 9.24)	
Pre-dose (-30 min)	25.70 (± 9.09)	19.65 (± 4.98)	12.78 (± 4.34)	
15 min	34.30 (± 4.13)	30.30 (± 4.97)	19.23 (± 5.85)	
30 min	38.50 (± 4.31)	34.18 (± 4.35)	20.25 (± 6.40)	
1 h	44.47 (± 4.97)	37.15 (± 5.96)	21.78 (± 5.21)	
3 h	57.53 (± 6.26)	51.08 (± 9.35)	29.58 (± 7.65)	
6 h	65.87 (± 3.93)	63.33 (± 12.47)	38.48 (± 10.50)	
9 h	64.73 (± 3.19)	65.85 (± 11.70)	42.48 (± 9.42)	
24 h	49.90 (± 10.58)	57.05 (± 12.90)	33.08 (± 5.31)	
Follow-up 2 (day 19)	4.47 (± 1.11)	4.98 (± 0.97)	3.38 (± 0.94)	

Statistical analyses

No statistical analyses for this end point

Secondary: APTT

End point title	APTT[2]

End point description:

End point type	Secondary

End point timeframe:

From Screening until 24 hours after dose (Group 1)

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: The study drug administered in Group 1 (Experimental Arm, LMW-DS) has a specific property of prolonging the APTT significantly, which the drugs in the control Arms (Group 2, Group 3) do not have, which is why the APTT parameter was relevant to study only for Group 1.

End point values	Group 1 - Experimental Treatment			
Subject group type	Reporting group			
Number of subjects analysed	3			
Units: second				
arithmetic mean (standard deviation)				
Screening	33.7 (± 0.6)			
Pre-dose (-30 min)	30.7 (± 0.6)			
6 h	104.0 (± 11.4)			
9 h	73.7 (± 5.7)			
24 h	38.7 (± 2.1)			

Statistical analyses

No statistical analyses for this end point

Secondary: Systolic blood pressure

End point title	Systolic blood pressure

End point description:

End point type	Secondary

End point timeframe:

From Screening until Follow-up visit 2.

End point values	Group 1 - Experimental Treatment	Group 2 - Plerixafor control	Group 3 - NaCl placebo control	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	3	4	4	
Units: mmHg				
arithmetic mean (standard deviation)				
Screening	127.3 (± 4.6)	131.8 (± 6.7)	134.5 (± 5.2)	
Pre-dose (-30 min)	118.3 (± 8.7)	126.3 (± 1.5)	123.8 (± 11.9)	
15 min	121.7 (± 6.5)	126.8 (± 5.5)	127.5 (± 3.9)	
30 min	126.0 (± 3.0)	123.8 (± 3.5)	117.3 (± 6.6)	
1 h	129.3 (± 4.2)	125.0 (± 8.5)	125.5 (± 12.1)	
2 h	125.3 (± 7.2)	123.5 (± 4.5)	126.3 (± 10.9)	
3 h	125.0 (± 7.2)	134.8 (± 5.1)	131.0 (± 12.9)	
4 h	127.0 (± 5.3)	128.3 (± 5.9)	126.0 (± 5.0)	
5 h	124.7 (± 14.5)	126.0 (± 9.3)	125.3 (± 5.1)	
6 h	131.5 (± 0.7)	123.5 (± 9.5)	125.3 (± 6.8)	
7 h	127.7 (± 4.2)	127.5 (± 7.2)	129.0 (± 11.2)	
8 h	130.7 (± 1.2)	131.3 (± 11.0)	127.5 (± 3.9)	
Follow-up 2 (day 19)	124.7 (± 5.1)	128.5 (± 4.2)	130.3 (± 7.4)	

Statistical analyses

No statistical analyses for this end point

Secondary: Diastolic blood pressure

End point title	Diastolic blood pressure

End point description:

End point type	Secondary

End point timeframe:

From Screening until Follow-up visit 2.

End point values	Group 1 - Experimental Treatment	Group 2 - Plerixafor control	Group 3 - NaCl placebo control	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	3	4	4	
Units: mmHg				
arithmetic mean (standard deviation)				
Screening	73.0 (± 5.0)	81.3 (± 3.3)	76.0 (± 4.3)	
Pre-dose (-30 min)	72.0 (± 5.0)	77.5 (± 3.9)	73.5 (± 7.9)	
15 min	72.7 (± 5.9)	77.0 (± 3.6)	72.8 (± 1.9)	
30 min	75.3 (± 8.1)	74.3 (± 4.9)	70.8 (± 5.1)	
1 h	74.0 (± 7.5)	73.0 (± 6.4)	75.0 (± 9.1)	
2 h	72.3 (± 5.0)	75.0 (± 5.9)	71.8 (± 8.2)	
3 h	74.3 (± 7.6)	73.0 (± 10.6)	71.8 (± 7.6)	
4 h	70.0 (± 5.3)	73.8 (± 7.4)	69.0 (± 2.9)	
5 h	73.3 (± 9.9)	75.5 (± 5.6)	73.8 (± 2.8)	
6 h	78.5 (± 2.1)	72.0 (± 5.0)	73.3 (± 7.5)	
7 h	77.0 (± 4.0)	77.0 (± 7.1)	76.8 (± 5.6)	
8 h	78.0 (± 7.9)	77.0 (± 4.2)	73.8 (± 4.5)	
Follow-up 2 (day 19)	73.0 (± 10.1)	78.5 (± 5.3)	72.5 (± 4.5)	

Statistical analyses

No statistical analyses for this end point

Secondary: Pulse rate

End point title	Pulse rate

End point description:

End point type	Secondary

End point timeframe:

From Screening until Follow-up visit 2.

End point values	Group 1 - Experimental Treatment	Group 2 - Plerixafor control	Group 3 - NaCl placebo control	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	3	4	4	
Units: bpm				
arithmetic mean (standard deviation)				
Screening	51.7 (± 5.5)	55.0 (± 7.5)	60.5 (± 2.6)	
Pre-dose (-30 min)	55.3 (± 7.2)	57.3 (± 13.0)	56.0 (± 4.7)	
15 min	60.7 (± 11.5)	58.0 (± 13.7)	52.5 (± 2.6)	
30 min	57.0 (± 7.5)	55.8 (± 12.7)	53.5 (± 6.0)	
1 h	59.7 (± 3.5)	57.3 (± 16.0)	56.8 (± 12.3)	
2 h	62.3 (± 11.0)	59.3 (± 14.7)	61.5 (± 11.4)	
3 h	71.7 (± 8.1)	68.5 (± 20.8)	67.5 (± 4.7)	
4 h	67.0 (± 3.5)	64.5 (± 18.6)	64.5 (± 6.6)	
5 h	67.0 (± 11.3)	69.0 (± 18.5)	63.3 (± 9.0)	
6 h	63.3 (± 3.2)	69.5 (± 20.6)	62.0 (± 10.0)	
7 h	70.0 (± 12.2)	64.8 (± 19.1)	65.3 (± 6.7)	
8 h	62.3 (± 6.7)	65.3 (± 16.0)	65.5 (± 11.4)	
Follow-up 2 (day 19)	56.7 (± 8.4)	66.0 (± 8.7)	66.5 (± 3.5)	

Statistical analyses

No statistical analyses for this end point

Secondary: Tympanic body temperature

End point title	Tympanic body temperature

End point description:

End point type	Secondary

End point timeframe:

From Screening until Follow-up visit 2.

End point values	Group 1 - Experimental Treatment	Group 2 - Plerixafor control	Group 3 - NaCl placebo control	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	3	4	4	
Units: celsius temperature				
arithmetic mean (standard deviation)				
Screening	36.30 (± 0.20)	36.28 (± 0.31)	36.83 (± 0.47)	
Pre-dose (-30 min)	36.43 (± 0.49)	36.60 (± 0.14)	36.68 (± 0.55)	
15 min	36.43 (± 0.50)	36.55 (± 0.30)	36.65 (± 0.29)	
30 min	36.47 (± 0.32)	36.63 (± 0.37)	36.53 (± 0.46)	
1 h	36.47 (± 0.23)	36.43 (± 0.34)	36.60 (± 0.24)	
2 h	36.63 (± 0.31)	36.78 (± 0.37)	36.70 (± 0.55)	
3 h	36.93 (± 0.21)	37.03 (± 0.33)	36.78 (± 0.21)	
4 h	37.13 (± 0.32)	36.80 (± 0.08)	36.93 (± 0.36)	
5 h	36.93 (± 0.40)	36.63 (± 0.73)	37.05 (± 0.53)	
6 h	36.97 (± 0.29)	37.08 (± 0.22)	37.08 (± 0.33)	
7 h	36.90 (± 0.50)	36.95 (± 0.52)	37.03 (± 0.36)	
8 h	36.87 (± 0.35)	37.13 (± 0.15)	37.05 (± 0.17)	
Follow-up 2 (day 19)	36.33 (± 0.12)	36.50 (± 0.32)	36.48 (± 0.29)	

Statistical analyses

No statistical analyses for this end point

Secondary: ECG

End point title	ECG

End point description:

End point type	Secondary

End point timeframe:

At baseline and Follow-up visit 2 (day 19).

End point values	Group 1 - Experimental Treatment	Group 2 - Plerixafor control	Group 3 - NaCl placebo control	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	3	4	4	
Units: subjects				
Baseline - Normal	2	4	4	
Baseline - NCS	1	0	0	
Baseline - CS	0	0	0	
Follow-up 2 - Normal	2	4	4	
Follow-up 2 - NCS	1	0	0	
Follow-up 2 - CS	0	0	0	

Statistical analyses

No statistical analyses for this end point

Secondary: Physical exam

End point title	Physical exam

End point description:

End point type	Secondary

End point timeframe:

At baseline and Follow-up visit 2 (day 19).

End point values	Group 1 - Experimental Treatment	Group 2 - Plerixafor control	Group 3 - NaCl placebo control	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	3	4	4	
Units: subjects				
Baseline - Normal	2	2	2	
Baseline - NCS	1	2	2	
Baseline - CS	0	0	0	
Follow-up 2 - Normal	3	3	4	
Follow-up 2 - NCS	0	0	0	
Follow-up 2 - CS	0	1	0	

Statistical analyses

No statistical analyses for this end point

Secondary: Clinical Chemistry - creatinine kinase

End point title	Clinical Chemistry - creatinine kinase

End point description:

End point type	Secondary

End point timeframe:

At baseline and Follow-up visit 2 (day 19).

End point values	Group 1 - Experimental Treatment	Group 2 - Plerixafor control	Group 3 - NaCl placebo control	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	3	4	4	
Units: subjects				
Baseline - Normal	2	4	4	
Baseline - NCS	1	0	0	
Baseline - CS	0	0	0	
Baseline - ND/Miss	0	0	0	
Follow-up 2 - Normal	3	4	4	
Follow-up 2 - NCS	0	0	0	
Follow-up 2 - CS	0	0	0	
Follow-up 2 - ND/Miss	0	0	0	

Statistical analyses

No statistical analyses for this end point

Secondary: Spirometry - FEV1, FVC, PEF, VC

End point title	Spirometry - FEV1, FVC, PEF, VC

End point description:

FEV1 = Forced Expiratory Volume in 1 Second (L)
FVC = Forced Vital Capacity (L)
PEF = Peak Expiratory Flow (L)
VC = Vital Capacity (L)

End point type	Secondary

End point timeframe:

At baseline and Follow-up visit 2 (day 19).

End point values	Group 1 - Experimental Treatment	Group 2 - Plerixafor control	Group 3 - NaCl placebo control	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	3	4	4	
Units: subjects				
Baseline FEV1 - Normal	2	4	4	
Baseline FEV1 - NCS	1	0	0	
Baseline FEV1 - CS	0	0	0	
Baseline FVC - Normal	3	3	4	
Baseline FVC - NCS	0	1	0	
Baseline FVC - CS	0	0	0	
Baseline PEF - Normal	2	4	4	
Baseline PEF - NCS	1	0	0	
Baseline PEF - CS	0	0	0	
Baseline VC - Normal	2	3	4	
Baseline VC - NCS	1	1	0	
Baseline VC - CS	0	0	0	

Follow-up 2 FEV1 - Normal	2	4	4	
Follow-up 2 FEV1 - NCS	1	0	0	
Follow-up 2 FEV1 - CS	0	0	0	
Follow-up 2 FVC - Normal	3	3	4	
Follow-up 2 FVC -NCS	0	1	0	
Follow-up 2 FVC - CS	0	0	0	
Follow-up 2 PEF - Normal	3	3	3	
Follow-up 2 PEF - NCS	0	1	1	
Follow-up 2 PEF - CS	0	0	0	
Follow-up 2 VC - Normal	2	1	4	
Follow-up 2 VC - NCS	1	3	0	
Follow-up 2 VC - CS	0	0	0	

Statistical analyses

No statistical analyses for this end point

Secondary: Spirometry - PP FEV1/FVC

End point title	Spirometry - PP FEV1/FVC

End point description:

Percent Predicted Forced Expiratory Volume in 1 Second / Forced Vital Capacity (%)

End point type	Secondary

End point timeframe:

At baseline and Follow-up visit 2 (day 19).

End point values	Group 1 - Experimental Treatment	Group 2 - Plerixafor control	Group 3 - NaCl placebo control	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	3	4	4	
Units: percent				
arithmetic mean (standard deviation)				
Baseline	78.64 (± 9.39)	76.66 (± 5.98)	75.85 (± 5.53)	
Follow-up 2	77.69 (± 8.64)	74.17 (± 4.79)	75.89 (± 7.58)	

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events: After administration of LMW-DS/Plerixafor/NaCl	
Assessment type	Systematic
Dictionary used	
Dictionary name	MedDRA
Dictionary version	17.0
Reporting groups	
Reporting group title	Group 1 - Experimental Treatment
Reporting group description: LMW-DS + Filgrastim	
Reporting group title	Group 2 - Plerixafor control
Reporting group description: Plerixafor + Filgrastim	
Reporting group title	Group 3 - NaCl placebo control
Reporting group description: NaCl + Filgrastim	

Serious adverse events	Group 1 - Experimental Treatment	Group 2 - Plerixafor control	Group 3 - NaCl placebo control
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0

Frequency threshold for reporting non-serious adverse events: 5 %

Non-serious adverse events	Group 1 - Experimental Treatment	Group 2 - Plerixafor control	Group 3 - NaCl placebo control
Total subjects affected by non-serious adverse events			
subjects affected / exposed	3 / 3 (100.00%)	4 / 4 (100.00%)	4 / 4 (100.00%)
Investigations			
Activated partial thromboplastin time prolonged			
subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Injury, poisoning and procedural complications			

Contusion			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Vascular disorders			
Hot flush			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Nervous system disorders			
Headache			
subjects affected / exposed	2 / 3 (66.67%)	1 / 4 (25.00%)	1 / 4 (25.00%)
occurrences (all)	2	1	1
Dizziness			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Hypoaesthesia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Blood and lymphatic system disorders			
Leukopenia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (0.00%)	3 / 4 (75.00%)
occurrences (all)	1	0	3
Neutropenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	2 / 4 (50.00%)
occurrences (all)	0	0	2
Thrombocytopenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
Feeling hot			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Influenza like illness			

subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	0 / 3 (0.00%)	2 / 4 (50.00%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
Abdominal tenderness			
subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Dyspepsia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Flatulence			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Hypoaesthesia oral			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Skin and subcutaneous tissue disorders			
Hyperhidrosis			
subjects affected / exposed	1 / 3 (33.33%)	1 / 4 (25.00%)	0 / 4 (0.00%)
occurrences (all)	1	1	0
Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	1 / 3 (33.33%)	1 / 4 (25.00%)	1 / 4 (25.00%)
occurrences (all)	1	1	1

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

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.

The study was terminated early due to lack of effect on the primary endpoint, mobilization of CD34+ cells, in the experimental group. Only 3 subjects received the experimental treatment and the statistical analysis was not as extensive as planned.

Notes: