



Clinical trial results:

The feasibility and efficacy of subcutaneous and intravenous Plerixafor for mobilization of peripheral blood stem cells in allogeneic HLA-identical sibling donors: a randomized phase II study.

Summary

EudraCT number	2010-023436-16
Trial protocol	NL DE
Global end of trial date	28 January 2019

Results information

Result version number	v1 (current)
This version publication date	18 July 2024
First version publication date	18 July 2024
Summary attachment (see zip file)	HO107_End of trial report_17Jun2020 (M2_HO107_End of trial report_17Jun2020.pdf)

Trial information

Trial identification

Sponsor protocol code	HOVON 107
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Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	HOVON
Sponsor organisation address	Dr. Molenwaterplein 40, Rotterdam, Netherlands,
Public contact	HOVON, HOVON, hovan@erasmusmc.nl
Scientific contact	HOVON, HOVON, hovan@erasmusmc.nl

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	14 August 2017
Is this the analysis of the primary completion data?	Yes
Primary completion date	14 June 2017
Global end of trial reached?	Yes
Global end of trial date	28 January 2019
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To determine the feasibility of plerixafor 320 µg/kg subcutaneously and of plerixafor 320 µg/kg intravenously to harvest a sufficient number of CD34+ peripheral blood stem cells/kg recipient body weight.

Feasibility is defined as a minimum of 2.0x10⁶/kg CD34+ cells in one or two phereses in at least 90% of the donors

Protection of trial subjects:

Monitoring and Insurance

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	31 May 2011
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Netherlands: 70
Country: Number of subjects enrolled	Germany: 6
Worldwide total number of subjects	76
EEA total number of subjects	76

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)	75
From 65 to 84 years	1

85 years and over	0
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Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

All subjects gave written informed consent and were screened according to the inclusion- and exclusion criteria.

Period 1

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

Arms

Arm title	Experimental group
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Arm description: -

Arm type	Experimental
Investigational medicinal product name	Plerixafor
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Injection

Dosage and administration details:

Plerixafor 320 µg/kg subcutaneously

Number of subjects in period 1	Experimental group
Started	76
Completed	70
Not completed	6
Adverse events, all combined	1
Other	2
Lack of efficacy	3

Baseline characteristics

Reporting groups

Reporting group title	Overall period
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Reporting group description: -

Reporting group values	Overall period	Total	
Number of subjects	76	76	
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)	75	75	
From 65-84 years	1	1	
85 years and over	0	0	
Age continuous			
Units: years			
median	49		
full range (min-max)	21 to 65	-	
Gender categorical			
Units: Subjects			
Female	28	28	
Male	48	48	

End points

End points reporting groups

Reporting group title	Experimental group
Reporting group description: -	

Primary: Primary endpoint

End point title	Primary endpoint ^[1]
End point description:	

End point type	Primary
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End point timeframe:

See publication

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: See publication

End point values	Experimental group			
Subject group type	Reporting group			
Number of subjects analysed	76			
Units: Whole	76			

Attachments (see zip file)	nonsaedata107-6May2024.pdf saedata107-6May2024.pdf HO107 Statistics (1).pdf
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Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Adverse events will be reported from the first study-related procedure until 30 days following the last dose of any drug from the protocol treatment schedule or until the start of subsequent systemic therapy for the disease under study, if earlier.

Assessment type	Systematic
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Dictionary used

Dictionary name	CTCAE
Dictionary version	4

Reporting groups

Reporting group title	Experimental group
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Reporting group description: -

Serious adverse events	Experimental group		
Total subjects affected by serious adverse events			
subjects affected / exposed	6 / 74 (8.11%)		
number of deaths (all causes)	15		
number of deaths resulting from adverse events			
Blood and lymphatic system disorders			
Clotting during stem cell apheresis			
subjects affected / exposed	2 / 74 (2.70%)		
occurrences causally related to treatment / all	2 / 2		
deaths causally related to treatment / all	0 / 0		
General disorders and administration site conditions			
Fever			
subjects affected / exposed	1 / 74 (1.35%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Renal and urinary disorders			
Renal dysfunction			
subjects affected / exposed	1 / 74 (1.35%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Chronic kidney disease			

subjects affected / exposed	1 / 74 (1.35%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Sepsis			
subjects affected / exposed	1 / 74 (1.35%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Sepsis, acute kidney failure and respiratory failure			
subjects affected / exposed	1 / 74 (1.35%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Metabolism and nutrition disorders			
Hypokalemia			
subjects affected / exposed	1 / 74 (1.35%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	Experimental group		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	45 / 74 (60.81%)		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Neoplasms benign, malignant and unspecified	Additional description: All combined		
subjects affected / exposed	1 / 74 (1.35%)		
occurrences (all)	1		
Vascular disorders			
Vascular disorders	Additional description: All combined		
subjects affected / exposed	8 / 74 (10.81%)		
occurrences (all)	8		
General disorders and administration site conditions			
General disorders and administration site conditions	Additional description: All combined		

subjects affected / exposed	14 / 74 (18.92%)		
occurrences (all)	15		
Immune system disorders			
Immune system disorders	Additional description: All combined		
subjects affected / exposed	2 / 74 (2.70%)		
occurrences (all)	2		
Respiratory, thoracic and mediastinal disorders			
Respiratory, thoracic and mediastinal disorders	Additional description: All combined		
subjects affected / exposed	4 / 74 (5.41%)		
occurrences (all)	4		
Psychiatric disorders			
Psychiatric disorders			
subjects affected / exposed	1 / 74 (1.35%)		
occurrences (all)	1		
Investigations			
Investigations	Additional description: All combined		
subjects affected / exposed	11 / 74 (14.86%)		
occurrences (all)	25		
Injury, poisoning and procedural complications			
Injury, poisoning and procedural complications	Additional description: All combined		
subjects affected / exposed	3 / 74 (4.05%)		
occurrences (all)	5		
Cardiac disorders			
Cardiac disorders	Additional description: All combined		
subjects affected / exposed	1 / 74 (1.35%)		
occurrences (all)	1		
Nervous system disorders			
Nervous system disorders	Additional description: All combined		
subjects affected / exposed	13 / 74 (17.57%)		
occurrences (all)	18		
Blood and lymphatic system disorders			
Blood and lymphatic system disorders	Additional description: All combined		
subjects affected / exposed	6 / 74 (8.11%)		
occurrences (all)	8		
Gastrointestinal disorders			

Gastrointestinal disorders subjects affected / exposed occurrences (all)	Additional description: All combined		
	22 / 74 (29.73%) 31		
Hepatobiliary disorders Hepatobiliary disorders subjects affected / exposed occurrences (all)	Additional description: All combined		
	1 / 74 (1.35%) 2		
Skin and subcutaneous tissue disorders Skin and subcutaneous tissue disorders subjects affected / exposed occurrences (all)	Additional description: All combined		
	2 / 74 (2.70%) 2		
Renal and urinary disorders Renal and urinary disorders subjects affected / exposed occurrences (all)	Additional description: All combined		
	2 / 74 (2.70%) 2		
Musculoskeletal and connective tissue disorders Musculoskeletal and connective tissue disorders subjects affected / exposed occurrences (all)	Additional description: All combined		
	4 / 74 (5.41%) 4		
Infections and infestations Infections and infestations subjects affected / exposed occurrences (all)	Additional description: All combined		
	9 / 74 (12.16%) 10		
Metabolism and nutrition disorders Metabolism and nutrition disorders subjects affected / exposed occurrences (all)	Additional description: All combined		
	3 / 74 (4.05%) 4		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
19 March 2012	adding a new investigational drug; an essential change to the current investigational medicinal product other, namely: Change in protocol inclusion criteria for patients and some typographical errors"
25 September 2013	new document for product information cell therapy product, change type of product information on EudraCT form to SmPC, SmPC plerixafor NL, administrative changes to protocol, change of address of the HDC due to relocation and change of independent doctor VUMC.
14 May 2014	adding safety information about plerixafor and prevention of pregnancy (period of contraceptive use has been extended to 3 months after the last dose of plerixafor), adjustment of patient exclusion criteria, administrative changes to protocol and information letters for test subjects, change to coordinating researcher VUmc.
27 November 2014	clarification of the advice on how to act if the harvest of CD34+ cells is too low.
28 April 2015	modification of the protocol and associated study documents in which the intravenous arm is closed and only the subcutaneous arm is continued. This means that approximately 15 donors/patients still need to be included with an expected duration of 1.5-2 years.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported

Online references

<http://www.ncbi.nlm.nih.gov/pubmed/30548284>