



Clinical trial results:

A phase II study evaluating the effect of the addition of lenalidomide to R-CHOP for patients with newly diagnosed MYC positive DLBCL and BCL-U

Summary

EudraCT number	2014-002654-39
Trial protocol	NL BE
Global end of trial date	21 December 2021

Results information

Result version number	v1 (current)
This version publication date	17 December 2022
First version publication date	17 December 2022

Trial information

Trial identification

Sponsor protocol code	HO130
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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	De Boelelaan 1117, Amsterdam, Netherlands,
Public contact	HOVON Data Center, HOVON, +31 0107041560, hdc@erasmusmc.nl
Scientific contact	HOVON Data Center, HOVON, +31 0107041560, hdc@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	26 September 2019
Is this the analysis of the primary completion data?	Yes
Primary completion date	19 June 2019
Global end of trial reached?	Yes
Global end of trial date	21 December 2021
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To evaluate the efficacy of the combination of lenalidomide and R-CHOP in MYC+ DLBCL patients in terms of CR rate by end-of-treatment 18F-FDG PET-CT scan and BM.

Protection of trial subjects:

Monitoring and Insurance

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	25 February 2015
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	Netherlands: 83
Country: Number of subjects enrolled	Belgium: 2
Worldwide total number of subjects	85
EEA total number of subjects	85

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)	1
Adults (18-64 years)	45
From 65 to 84 years	39
85 years and over	0

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 trial (overall period)
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Arm title	Experimental Group
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Arm description: -

Arm type	Experimental
Investigational medicinal product name	Lenalidomide
Investigational medicinal product code	
Other name	Revlimib
Pharmaceutical forms	Capsule, hard
Routes of administration	Oral use

Dosage and administration details:

15mg, day 1 - 14.

Investigational medicinal product name	Cyclophosphamide
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection/infusion
Routes of administration	Intravenous use

Dosage and administration details:

750mg/m2 on day 1.

Investigational medicinal product name	Vincristine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intravenous use

Dosage and administration details:

1.4 mg/m2 (max 2mg) on day 1

Investigational medicinal product name	Doxorubicin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intravenous use

Dosage and administration details:

50mg/m2 on day 1

Investigational medicinal product name	Rituximab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion

Routes of administration	Intravenous use
Dosage and administration details:	
375 mg/m ² on day 1	
Investigational medicinal product name	Prednisone
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details:	
100mg on day 1-5	
Investigational medicinal product name	Pegfilgrastim
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use
Dosage and administration details:	
6mg on day 2	

Number of subjects in period 1	Experimental Group
Started	85
Completed	72
Not completed	13
Adverse reactions	2
Other	3
At patient's request	1
Lack of efficacy	7

Baseline characteristics

Reporting groups

Reporting group title

Overall trial

Reporting group description: -

Reporting group values	Overall trial	Total	
Number of subjects	85	85	
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)	1	1	
Adults (18-64 years)	45	45	
From 65-84 years	39	39	
85 years and over	0	0	
Age continuous			
Units: years			
median	63		
full range (min-max)	29 to 82	-	
Gender categorical			
Units: Subjects			
Female	27	27	
Male	58	58	

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 attached chart/documents for results.

End point values	Experimental Group			
Subject group type	Reporting group			
Number of subjects analysed	82			
Units: Whole	82			

Attachments (see zip file)	Statistical data section from publication/HO130 Statistical data List of reported non-SAE's/nonsaedata130-30Nov2022.pdf List of reported SAE's/saedata130-30Nov2022.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.

Adverse event reporting additional description:

Adverse events occurring after 30 days should also be reported if considered at least possibly related to the investigational medicinal product by the investigator.

Assessment type	Systematic
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Dictionary used

Dictionary name	CTCAE
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Dictionary version	4
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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	37 / 85 (43.53%)		
number of deaths (all causes)	29		
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Additional description: All combined, see SAE chart for details.		
subjects affected / exposed	7 / 85 (8.24%)		
occurrences causally related to treatment / all	4 / 7		
deaths causally related to treatment / all	1 / 1		
Vascular disorders			
Vascular disorders	Additional description: All combined, see SAE chart for details.		
subjects affected / exposed	1 / 85 (1.18%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Surgical and medical procedures			
Surgical and medical procedures	Additional description: All combined, see SAE chart for details.		
subjects affected / exposed	1 / 85 (1.18%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
General disorders and administration			

site conditions			
General disorders and administration site conditions	Additional description: All combined, see SAE chart for details.		
subjects affected / exposed	8 / 85 (9.41%)		
occurrences causally related to treatment / all	5 / 9		
deaths causally related to treatment / all	0 / 1		
Respiratory, thoracic and mediastinal disorders			
Respiratory, thoracic and mediastinal disorders	Additional description: All combined, see SAE chart for details.		
subjects affected / exposed	2 / 85 (2.35%)		
occurrences causally related to treatment / all	2 / 2		
deaths causally related to treatment / all	0 / 0		
Investigations			
Investigations	Additional description: All combined, see SAE chart for details.		
subjects affected / exposed	1 / 85 (1.18%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Injury, poisoning and procedural complications			
Injury, poisoning and procedural complications	Additional description: All combined, see SAE chart for details.		
subjects affected / exposed	1 / 85 (1.18%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cardiac disorders			
Cardiac disorders	Additional description: All combined, see SAE chart for details.		
subjects affected / exposed	4 / 85 (4.71%)		
occurrences causally related to treatment / all	2 / 4		
deaths causally related to treatment / all	0 / 0		
Nervous system disorders			
Nervous system disorders	Additional description: All combined, see SAE chart for details.		
subjects affected / exposed	4 / 85 (4.71%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Blood and lymphatic system disorders			
Blood and lymphatic system disorders	Additional description: All combined, see SAE chart for details.		

subjects affected / exposed	8 / 85 (9.41%)		
occurrences causally related to treatment / all	9 / 9		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Gastrointestinal disorders	Additional description: All combined, see SAE chart for details.		
subjects affected / exposed	11 / 85 (12.94%)		
occurrences causally related to treatment / all	8 / 14		
deaths causally related to treatment / all	0 / 0		
Renal and urinary disorders			
Renal and urinary disorders	Additional description: All combined, see SAE chart for details.		
subjects affected / exposed	2 / 85 (2.35%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Musculoskeletal and connective tissue disorders			
Musculoskeletal and connective tissue disorders	Additional description: All combined, see SAE chart for details.		
subjects affected / exposed	1 / 85 (1.18%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Infections and infestations	Additional description: All combined, see SAE chart for details.		
subjects affected / exposed	12 / 85 (14.12%)		
occurrences causally related to treatment / all	13 / 16		
deaths causally related to treatment / all	0 / 0		
Metabolism and nutrition disorders			
Metabolism and nutrition disorders	Additional description: All combined, see SAE chart for details.		
subjects affected / exposed	1 / 85 (1.18%)		
occurrences causally related to treatment / all	1 / 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	71 / 85 (83.53%)		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Additional description: All combined, see non-SAE chart for details.		
subjects affected / exposed	1 / 85 (1.18%)		
occurrences (all)	1		
Vascular disorders			
Vascular disorders	Additional description: All combined, see non-SAE chart for details.		
subjects affected / exposed	10 / 85 (11.76%)		
occurrences (all)	13		
Surgical and medical procedures			
Surgical and medical procedures	Additional description: All combined, see non-SAE chart for details.		
subjects affected / exposed	1 / 85 (1.18%)		
occurrences (all)	1		
General disorders and administration site conditions			
General disorders and administration site conditions	Additional description: All combined, see non-SAE chart for details.		
subjects affected / exposed	10 / 85 (11.76%)		
occurrences (all)	16		
Reproductive system and breast disorders			
Reproductive system and breast disorders	Additional description: All combined, see non-SAE chart for details.		
subjects affected / exposed	1 / 85 (1.18%)		
occurrences (all)	1		
Respiratory, thoracic and mediastinal disorders			
Respiratory, thoracic and mediastinal disorders	Additional description: All combined, see non-SAE chart for details.		
subjects affected / exposed	8 / 85 (9.41%)		
occurrences (all)	9		
Psychiatric disorders			
Psychiatric disorders	Additional description: All combined, see non-SAE chart for details.		
subjects affected / exposed	1 / 85 (1.18%)		
occurrences (all)	1		
Investigations			
Investigations	Additional description: All combined, see non-SAE chart for details.		
subjects affected / exposed	20 / 85 (23.53%)		
occurrences (all)	63		

Cardiac disorders			
Cardiac disorders	Additional description: All combined, see non-SAE chart for details.		
subjects affected / exposed	7 / 85 (8.24%)		
occurrences (all)	8		
Nervous system disorders			
Nervous system disorders	Additional description: All combined, see non-SAE chart for details.		
subjects affected / exposed	33 / 85 (38.82%)		
occurrences (all)	38		
Blood and lymphatic system disorders			
Blood and lymphatic system disorders	Additional description: All combined, see non-SAE chart for details.		
subjects affected / exposed	11 / 85 (12.94%)		
occurrences (all)	19		
Ear and labyrinth disorders			
Ear and labyrinth disorders	Additional description: All combined, see non-SAE chart for details.		
subjects affected / exposed	5 / 85 (5.88%)		
occurrences (all)	5		
Eye disorders			
Eye disorders	Additional description: All combined, see non-SAE chart for details.		
subjects affected / exposed	3 / 85 (3.53%)		
occurrences (all)	3		
Gastrointestinal disorders			
Gastrointestinal disorders	Additional description: All combined, see non-SAE chart for details.		
subjects affected / exposed	24 / 85 (28.24%)		
occurrences (all)	33		
Hepatobiliary disorders			
Hepatobiliary disorders	Additional description: All combined, see non-SAE chart for details.		
subjects affected / exposed	1 / 85 (1.18%)		
occurrences (all)	1		
Skin and subcutaneous tissue disorders			
Skin and subcutaneous tissue disorders	Additional description: All combined, see non-SAE chart for details.		
subjects affected / exposed	6 / 85 (7.06%)		
occurrences (all)	6		
Renal and urinary disorders			
Renal and urinary disorders	Additional description: All combined, see non-SAE chart for details.		
subjects affected / exposed	5 / 85 (5.88%)		
occurrences (all)	5		
Musculoskeletal and connective tissue disorders			

Musculoskeletal and connective tissue disorders subjects affected / exposed occurrences (all)	Additional description: All combined, see non-SAE chart for details.		
	8 / 85 (9.41%) 10		
Infections and infestations Infections and infestations subjects affected / exposed occurrences (all)	Additional description: All combined, see non-SAE chart for details.		
	24 / 85 (28.24%) 32		
Metabolism and nutrition disorders Metabolism and nutrition disorders subjects affected / exposed occurrences (all)	Additional description: All combined, see non-SAE chart for details.		
	10 / 85 (11.76%) 13		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
23 June 2015	Clarification in sections 9 and 10 in the protocol.
17 August 2016	Updates in section 4 and clarifications in section 8, 10 and 17 of the protocol.
18 July 2017	Target number of patients has been increased. Updates in section 4, 5, 6, clarifications in section 8, 9 , 10 and updates in section 14, 19 appendix B1 and B2.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported