Clinical trial results:
Efficacy and safety of a single dose of 14.8 MBq/kg (0.4 mCi/kg) 90Y-ibritumomab tiuxetan ("Zevalin") in elderly patients with diffuse large B-cell lymphoma and FDG-PET positive partial remission following first-line R-CHOP therapy. A Phase II clinical trial (HOVON 77)

Summary

EudraCT number	2005-003796-20
Trial protocol	BE
Global end of trial date	12 January 2017

Results information

Result version number	v1 (current)
This version publication date	29 January 2023
First version publication date	29 January 2023

Trial information

Trial identification

Sponsor protocol code	HOVON 77

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, hdc@erasmusmc.nl
Scientific contact	HOVON Data Center, HOVON, 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	31 January 2013
Is this the analysis of the primary completion data?	Yes
Primary completion date	13 January 2013
Global end of trial reached?	Yes
Global end of trial date	12 January 2017
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

The primary objective of this study is to evaluate the conversion rate from PET-positive to PET-negative residual masses after 90Y-ibritumomab tiuxetan treatment in patients with PET-positive partial remission following first-line R-CHOP chemotherapy.

Protection of trial subjects:

Monitoring and Insurance

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	12 May 2006
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: 19
Worldwide total number of subjects	19
EEA total number of subjects	19

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)	1
From 65 to 84 years	17
85 years and over	1

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
Arm description: -	
Arm type	Experimental
Investigational medicinal product name	Rituximab
Investigational medicinal product code	
Other name	Mabthera
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use
Dosage and administration details: 250mg/m2, day -7 and 0	
Investigational medicinal product name	90Y-ibritumomab tiuxetan
Investigational medicinal product code	
Other name	Zevalin
Pharmaceutical forms	Kit for radiopharmaceutical preparation
Routes of administration	Intravenous use

Dosage and administration details:

14.8MBq/kg (max dose 1184 MBq or 31mCi), day 0.

Number of subjects in period 1	Experimental Group
Started	19
Completed	9
Not completed	10
Lack of efficacy	10

Baseline characteristics

Reporting groups

Reporting group title	Overall trial

Reporting group description: -

Reporting group values	Overall trial	Total	
Number of subjects	19	19	
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)	1	1	
From 65-84 years	17	17	
85 years and over	1	1	
Age continuous Units: years			
median	73		
full range (min-max)	63 to 88	-	
Gender categorical Units: Subjects			
Female	7	7	
Male	12	12	

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

End point timeframe:

Primary endopoint is dan complete response on FDG-PET (i.e. PET-negative residual masses) at 3 and 6 months after radioimmunotherapy.

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: No article has been published for this trial.

End point values	Experimental Group			
Subject group type	Reporting group			
Number of subjects analysed	17			
Units: Whole	17			

Attachments (see zip file)	List of reported non-SAE's/nonsaedata77-21Dec2022.pdf List of reported SAE's/saedata77-21Dec2022.pdf

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

AEs will be reported on the CRF. All adverse events of Grade 2 or higher, with the exception of progression of disease, occurring during the protocol treatment period will be reported.

Adverse event reporting additional description:

Adverse events occurring after that period should also be reported if considered related to protocol treatment.

Assessment type	Systematic

Dictionary used

Dictionary name	CTCAE
Dictionary version	3

Reporting groups

Reporting group title	Experimental Group

Reporting group description: -

Serious adverse events	Experimental Group		
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 19 (15.79%)		
number of deaths (all causes)	12		
number of deaths resulting from adverse events			
General disorders and administration site conditions			
General disorders and administration site conditions	Additional description: All combined, see SAE chart for details.		
subjects affected / exposed	2 / 19 (10.53%)		
occurrences causally related to treatment / all	1 / 3		
deaths causally related to treatment / all	0 / 2		
Infections and infestations			
Infections and infestations	Additional description: All combined, see SAE chart for details.		
subjects affected / exposed	1 / 19 (5.26%)		
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	8 / 19 (42.11%)		
Nervous system disorders			
Neurology	Additional description: All combined, see non-SAE chart for details		
subjects affected / exposed	1 / 19 (5.26%)		
occurrences (all)	2		
Blood and lymphatic system disorders			
Blood/bone marrow	Additional description: All combined, see non-SAE chart for details		
subjects affected / exposed	2 / 19 (10.53%)		
occurrences (all)	5		
General disorders and administration site conditions			
Constitutional symptoms	Additional description: All combined, see non-SAE chart for details		
subjects affected / exposed	2 / 19 (10.53%)		
occurrences (all)	2		
Pain	Additional description: All combined, see non-SAE chart for details		
subjects affected / exposed	2 / 19 (10.53%)		
occurrences (all)	2		
Gastrointestinal disorders			
GI	Additional description: All combined, see non-SAE chart for details		
subjects affected / exposed	3 / 19 (15.79%)		
occurrences (all)	4		
Skin and subcutaneous tissue disorders			
Dermatology/skin	Additional description: All combined, see non-SAE chart for details		
subjects affected / exposed	2 / 19 (10.53%)		
occurrences (all)	2		

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

None reported