



## Clinical trial results:

### BRENTUXIMAB VEDOTIN ASSOCIATED WITH CHEMOTHERAPY IN UNTREATED PATIENTS WITH STAGE I/II UNFAVOURABLE HODGKIN LYMPHOMA - A RANDOMIZED PHASE II LYSA-FIL-EORTC INTERGROUP STUDY

#### Summary

EudraCT number	2013-000182-37
Trial protocol	FR BE IT DK NL HR
Global end of trial date	02 June 2022

#### Results information

Result version number	v1 (current)
This version publication date	20 October 2022
First version publication date	20 October 2022

#### Trial information

##### Trial identification

Sponsor protocol code	BREACH
-----------------------	--------

##### Additional study identifiers

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

Notes:

#### Sponsors

Sponsor organisation name	LYSARC
Sponsor organisation address	Centre Hospitalier Lyon-Sud Bâtiment 2D , Pierre Benite Cedex, France,
Public contact	Co-coordinating Investigator, Dr Luc-Matthieu Fornecker, 33 388127676, luc-matthieu.fornecker@chru-strasbourg.fr
Scientific contact	Co-coordinating Investigator, Dr Luc-Matthieu Fornecker, 33 388127676, luc-matthieu.fornecker@chru-strasbourg.fr

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	08 December 2020
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	02 June 2022
Was the trial ended prematurely?	No

Notes:

## General information about the trial

Main objective of the trial:

To assess the efficacy of the combination AVD+brentuximab vedotin in untreated patients with stage I/II unfavourable Hodgkin lymphoma, as measured by the rate of PET negativity after two cycles of immuno chemotherapy, PET assessment based on central review.

Protection of trial subjects:

Appropriate precautions should be taken during infusion of the drug, with regular monitoring of vital signs, drugs available for the treatment of anaphylactic reaction, and a physician in attendance. Patients treated with brentuximab vedotin should be monitored closely during the infusion and be advised of the potential to develop allergy-like symptoms post-infusion.

Infusion-related reactions may occur during the infusion of study treatment. The infusion is to be administered at a site properly equipped and staffed to manage anaphylaxis should it occur. The patient should be observed for at least 60 minutes following the first infusion of study treatment. During this observation period, the IV line should remain open for at least 1 hour to allow administration of IV drugs if necessary. All supportive measures consistent with optimal patient care will be given throughout the study according to institutional standards. This includes adjusting the infusion time if necessary.

Medications for infusion-related reactions should be available for immediate use.

Routine premedication should not be administered prior to the first dose of study treatment. But, patients who experience an infusion-related reaction (any grade) may receive subsequent study treatment infusions with premedication consisting of paracetamol, an antihistaminic (e.g. diphenhydramine 25–50 mg orally or 10–25 mg IV), epinephrine and corticosteroids or according to institutional standards, administered 30–60 minutes prior to each 30-minute infusion.

The use of prophylactic hydrocortisone or other steroids is also allowed.

Background therapy: -

Evidence for comparator:

ABVD is used as a reference group to confirm study hypothesis and not as a comparator arm.

Actual start date of recruitment	01 September 2014
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: 3
Country: Number of subjects enrolled	Croatia: 9
Country: Number of subjects enrolled	Belgium: 17
Country: Number of subjects enrolled	Denmark: 5
Country: Number of subjects enrolled	France: 132
Country: Number of subjects enrolled	Italy: 4
Worldwide total number of subjects	170
EEA total number of subjects	170

Notes:

<b>Subjects enrolled per age group</b>	
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)	170
From 65 to 84 years	0
85 years and over	0

## Subject disposition

### Recruitment

Recruitment details:

First randomized patient: 23Mar2015

Last patient enrolled: 15Sep2016

### Pre-assignment

Screening details:

Number of patients included and randomised: 170

### Pre-assignment period milestones

Number of subjects started	170
Number of subjects completed	

### Period 1

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

### Arms

Are arms mutually exclusive?	Yes
<b>Arm title</b>	Experimental

Arm description:

Arm B: 4 cycles of AVD/Brentuximab vedotin

Arm type	Experimental
Investigational medicinal product name	Brentuximab vedotin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection/infusion
Routes of administration	Intravenous use

Dosage and administration details:

1.2 mg/kg Day 1 and Day 15

<b>Arm title</b>	Standard
------------------	----------

Arm description:

Arm A: 4 cycles of ABVD

Arm type	reference
No investigational medicinal product assigned in this arm	

Number of subjects in period 1	Experimental	Standard
Started	113	57
Completed	102	49
Not completed	11	8
Consent withdrawn by subject	1	2
Physician decision	-	1

Adverse event, non-fatal	6	-
Lack of efficacy	2	5
Protocol deviation	2	-

## Baseline characteristics

### Reporting groups

Reporting group title	Experimental
-----------------------	--------------

Reporting group description:

Arm B: 4 cycles of AVD/Brentuximab vedotin

Reporting group title	Standard
-----------------------	----------

Reporting group description:

Arm A: 4 cycles of ABVD

Reporting group values	Experimental	Standard	Total
Number of subjects	113	57	170
Age categorical			
Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	113	57	170
From 65-84 years	0	0	0
85 years and over	0	0	0
Gender categorical			
Units: Subjects			
Female	60	26	86
Male	53	31	84

## End points

### End points reporting groups

Reporting group title	Experimental
Reporting group description:	
Arm B: 4 cycles of AVD/Brentuximab vedotin	
Reporting group title	Standard
Reporting group description:	
Arm A: 4 cycles of ABVD	

### Primary: PET response according to Deauville criteria

End point title	PET response according to Deauville criteria
End point description:	
The primary endpoint is the PET response rate according to the Deauville criteria (Appendix 10 "Deauville criteria for PET analysis") based on central review assessed after 2 cycles of chemotherapy or immunochemotherapy (ABVD or AVD/ Brentuximab vedotin).	
The categorization of the patients according to PET results will be performed as follows:	
- 1, 2 or 3: PET negative = Responder	
- 4 – 5: PET positive =Non-responder.	
- Missing PET evaluation (for whatever reason) : Non-responder	
End point type	Primary
End point timeframe:	
after 2 cycles of chemotherapy	

End point values	Experimental	Standard		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	113	57		
Units: number of patients				
Responder	93	43		
Non responder	20	14		

### Statistical analyses

Statistical analysis title	Complete Response Rate
Statistical analysis description:	
PET response analysis: will be expressed with 90% confidence limits (to be consistent with one sided 5% level of significance) according to Pearson-Clopper method.	
Response rates: will be expressed with 90% confidence limits (to be consistent with one sided 5% level of significance) according to Pearson-Clopper method.	
Comparison groups	Experimental v Standard

Number of subjects included in analysis	170
Analysis specification	Pre-specified
Analysis type	other <sup>[1]</sup>
P-value	< 0.05
Method	Fisher exact
Parameter estimate	Response Rate
Point estimate	82.3
Confidence interval	
level	90 %
sides	2-sided
lower limit	75.3
upper limit	88

Notes:

[1] - test against null hypothesis response rate less or equal to 75%

### Secondary: Progression Free Survival at 3 years

End point title	Progression Free Survival at 3 years
End point description:	
End point type	Secondary
End point timeframe:	
PFS at 3 years	

End point values	Experimental	Standard		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	113	57		
Units: percentage of patients	97	93		

### Statistical analyses

No statistical analyses for this end point

### Secondary: Overall Survival at 3 years

End point title	Overall Survival at 3 years
End point description:	
End point type	Secondary
End point timeframe:	
OS at 3 years	



<b>End point values</b>	Experimental	Standard		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	113	57		
Units: percentage of patients	113	57		

### Statistical analyses

---

No statistical analyses for this end point

## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

to Informed consent signature to the end of treatment evaluation (10 to 12 weeks after the last radiotherapy)

Assessment type	Systematic
-----------------	------------

### Dictionary used

Dictionary name	MedDRA
-----------------	--------

Dictionary version	25.0
--------------------	------

### Reporting groups

Reporting group title	Experimental group
-----------------------	--------------------

Reporting group description: -

Reporting group title	Standard group
-----------------------	----------------

Reporting group description: -

Serious adverse events	Experimental group	Standard group	
Total subjects affected by serious adverse events			
subjects affected / exposed	29 / 113 (25.66%)	7 / 55 (12.73%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events			
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	1 / 113 (0.88%)	1 / 55 (1.82%)	
occurrences causally related to treatment / all	1 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Jugular vein thrombosis			
subjects affected / exposed	0 / 113 (0.00%)	1 / 55 (1.82%)	
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	3 / 113 (2.65%)	1 / 55 (1.82%)	
occurrences causally related to treatment / all	2 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chest pain			

subjects affected / exposed	1 / 113 (0.88%)	0 / 55 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mucosal inflammation			
subjects affected / exposed	1 / 113 (0.88%)	0 / 55 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Pneumonitis			
subjects affected / exposed	1 / 113 (0.88%)	0 / 55 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary embolism			
subjects affected / exposed	1 / 113 (0.88%)	0 / 55 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			
Dissociative amnesia			
subjects affected / exposed	1 / 113 (0.88%)	0 / 55 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Investigations			
Weight decreased			
subjects affected / exposed	1 / 113 (0.88%)	0 / 55 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Congenital, familial and genetic disorders			
Congenital anomaly			
subjects affected / exposed	1 / 113 (0.88%)	0 / 55 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Neuropathy peripheral			

subjects affected / exposed	2 / 113 (1.77%)	0 / 55 (0.00%)	
occurrences causally related to treatment / all	2 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Epilepsy			
subjects affected / exposed	1 / 113 (0.88%)	0 / 55 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Headache			
subjects affected / exposed	1 / 113 (0.88%)	0 / 55 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neuralgia			
subjects affected / exposed	1 / 113 (0.88%)	0 / 55 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Paraesthesia			
subjects affected / exposed	0 / 113 (0.00%)	1 / 55 (1.82%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood and lymphatic system disorders			
Febrile neutropenia			
subjects affected / exposed	5 / 113 (4.42%)	1 / 55 (1.82%)	
occurrences causally related to treatment / all	6 / 6	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Febrile bone marrow aplasia			
subjects affected / exposed	2 / 113 (1.77%)	0 / 55 (0.00%)	
occurrences causally related to treatment / all	4 / 5	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anaemia			
subjects affected / exposed	1 / 113 (0.88%)	0 / 55 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neutropenia			

subjects affected / exposed	1 / 113 (0.88%)	0 / 55 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Nausea			
subjects affected / exposed	3 / 113 (2.65%)	0 / 55 (0.00%)	
occurrences causally related to treatment / all	1 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal pain			
subjects affected / exposed	2 / 113 (1.77%)	0 / 55 (0.00%)	
occurrences causally related to treatment / all	1 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Constipation			
subjects affected / exposed	2 / 113 (1.77%)	0 / 55 (0.00%)	
occurrences causally related to treatment / all	1 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vomiting			
subjects affected / exposed	2 / 113 (1.77%)	1 / 55 (1.82%)	
occurrences causally related to treatment / all	2 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colitis			
subjects affected / exposed	1 / 113 (0.88%)	0 / 55 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrooesophageal reflux disease			
subjects affected / exposed	1 / 113 (0.88%)	0 / 55 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Irritable bowel syndrome			
subjects affected / exposed	1 / 113 (0.88%)	0 / 55 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatitis acute			

subjects affected / exposed	1 / 113 (0.88%)	0 / 55 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Hepatitis			
subjects affected / exposed	1 / 113 (0.88%)	1 / 55 (1.82%)	
occurrences causally related to treatment / all	1 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatitis cholestatic			
subjects affected / exposed	0 / 113 (0.00%)	1 / 55 (1.82%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertransaminasaemia			
subjects affected / exposed	1 / 113 (0.88%)	0 / 55 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin and subcutaneous tissue disorders			
Dermatitis			
subjects affected / exposed	1 / 113 (0.88%)	0 / 55 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rash			
subjects affected / exposed	1 / 113 (0.88%)	0 / 55 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
Renal colic			
subjects affected / exposed	0 / 113 (0.00%)	1 / 55 (1.82%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
Muscle haemorrhage			

subjects affected / exposed	0 / 113 (0.00%)	1 / 55 (1.82%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Infections and infestations</b>			
<b>Appendicitis</b>			
subjects affected / exposed	0 / 113 (0.00%)	1 / 55 (1.82%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Bacterial infection</b>			
subjects affected / exposed	1 / 113 (0.88%)	0 / 55 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Device related infection</b>			
subjects affected / exposed	1 / 113 (0.88%)	0 / 55 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Gastrointestinal infection</b>			
subjects affected / exposed	1 / 113 (0.88%)	0 / 55 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Influenza</b>			
subjects affected / exposed	1 / 113 (0.88%)	0 / 55 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Liver abscess</b>			
subjects affected / exposed	1 / 113 (0.88%)	0 / 55 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Meningitis</b>			
subjects affected / exposed	1 / 113 (0.88%)	0 / 55 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Neonatal infection</b>			

subjects affected / exposed	1 / 113 (0.88%)	0 / 55 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural infection			
subjects affected / exposed	0 / 113 (0.00%)	1 / 55 (1.82%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Septic shock			
subjects affected / exposed	1 / 113 (0.88%)	0 / 55 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sinusitis			
subjects affected / exposed	0 / 113 (0.00%)	1 / 55 (1.82%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tooth infection			
subjects affected / exposed	1 / 113 (0.88%)	0 / 55 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Upper respiratory tract infection			
subjects affected / exposed	1 / 113 (0.88%)	0 / 55 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Viral infection			
subjects affected / exposed	1 / 113 (0.88%)	0 / 55 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Hyponatraemia			
subjects affected / exposed	1 / 113 (0.88%)	0 / 55 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	



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

<b>Non-serious adverse events</b>	Experimental group	Standard group	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	113 / 113 (100.00%)	55 / 55 (100.00%)	
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	60 / 113 (53.10%)	21 / 55 (38.18%)	
occurrences (all)	0	0	
Creatinine urine increased			
subjects affected / exposed	4 / 113 (3.54%)	0 / 55 (0.00%)	
occurrences (all)	0	0	
Nervous system disorders			
Neuropathy peripheral			
subjects affected / exposed	53 / 113 (46.90%)	9 / 55 (16.36%)	
occurrences (all)	2	0	
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	98 / 113 (86.73%)	35 / 55 (63.64%)	
occurrences (all)	1	0	
Neutrophil count decreased			
subjects affected / exposed	93 / 113 (82.30%)	46 / 55 (83.64%)	
occurrences (all)	1	0	
White blood cell count decreased			
subjects affected / exposed	86 / 113 (76.11%)	40 / 55 (72.73%)	
occurrences (all)	1	0	
Platelet count decreased			
subjects affected / exposed	26 / 113 (23.01%)	11 / 55 (20.00%)	
occurrences (all)	0	0	
Febrile neutropenia			
subjects affected / exposed	9 / 113 (7.96%)	3 / 55 (5.45%)	
occurrences (all)	6	1	
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	69 / 113 (61.06%)	31 / 55 (56.36%)	
occurrences (all)	0	0	

Pyrexia subjects affected / exposed occurrences (all)	20 / 113 (17.70%) 3	6 / 55 (10.91%) 1	
Gastrointestinal disorders Vomiting subjects affected / exposed occurrences (all)	54 / 113 (47.79%) 2	19 / 55 (34.55%) 0	
Diarrhoea subjects affected / exposed occurrences (all)	27 / 113 (23.89%) 0	14 / 55 (25.45%) 0	
Mucositis management subjects affected / exposed occurrences (all)	42 / 113 (37.17%) 1	12 / 55 (21.82%) 0	
Respiratory, thoracic and mediastinal disorders Pneumonitis subjects affected / exposed occurrences (all)	4 / 113 (3.54%) 1	0 / 55 (0.00%) 0	
Infections and infestations Sepsis subjects affected / exposed occurrences (all)	1 / 113 (0.88%) 1	0 / 55 (0.00%) 0	

## More information

### Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
09 April 2015	Protocol V2.0 09Feb2015 = adding the collection of biological samples
04 September 2015	Protocol V3.0 22JUL2015: G-CSF administration is now part of prophylactic measures due to the risk of neutropenia after treatment with Brentuximab Vedotin

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/35867960>