



Clinical trial results:

Consolidation Therapy with Brentuximab Vedotin after Allogeneic Stem Cell Transplantation for Relapsed or Refractory Hodgkin Lymphoma

Summary

EudraCT number	2018-000873-59
Trial protocol	DE
Global end of trial date	12 September 2024

Results information

Result version number	v1 (current)
This version publication date	23 October 2025
First version publication date	23 October 2025

Trial information

Trial identification

Sponsor protocol code	Uni-Koeln-3263
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03652441
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	University of Cologne
Sponsor organisation address	Albertus-Magnus-Platz, Cologne, Germany, 50923
Public contact	Trial Coordination Center, German Hodgkin Study Group (GHSG), 0049 22147888200, ghsg@uk-koeln.de
Scientific contact	Trial Coordination Center, German Hodgkin Study Group (GHSG), 0049 22147888200, ghsg@uk-koeln.de

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	10 January 2025
Is this the analysis of the primary completion data?	Yes
Primary completion date	12 September 2024
Global end of trial reached?	Yes
Global end of trial date	12 September 2024
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

The aim of the trial is to improve disease control after an allogeneic stem cell transplantation (alloSCT) for relapsed or refractory classical Hodgkin lymphoma (rrHL, cHL) with consolidation therapy by Brentuximab Vedotin (BV) for up to one year.

Protection of trial subjects:

Participants give their written informed consent to participate in the trial. They may discontinue trial treatment at their own wish at any time. Protocol treatment can be terminated by the treating physician due to unacceptable toxicity, progressive disease (PD), serious concurrent disease or pregnancy. The trial can be terminated early by the trial chairman if the safety of the trial participants appears to be at risk. The BV-ALLO trial is terminated completely if there is a considerable change in the risk-benefit-ratio for patients, the sponsor considers a termination to be necessary for safety reasons (protocol section 9.6.3), it is no longer justifiable to use trial medication or the trial proves to be not feasible.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	12 November 2019
Long term follow-up planned	Yes
Long term follow-up rationale	Safety, Efficacy
Long term follow-up duration	4 Years
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Germany: 13
Worldwide total number of subjects	13
EEA total number of subjects	13

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)	13
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

The trial aimed to enroll 21 patients over approximately 2 years with 19 patients being eligible. A total of 13 patients were enrolled before the trial was prematurely closed due to feasibility in light of slow recruitment.

Pre-assignment

Screening details:

One participant had a screening failure and could not be included in the trial.

Period 1

Period 1 title	Overall trial - Treatment and Follow-up (overall period)
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Arm title	Single-arm
Arm description: -	
Arm type	Experimental
Investigational medicinal product name	Brentuximab Vedotin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Infusion , Intravenous use

Dosage and administration details:

BV was administered over 30 minutes every 3 weeks at a dose of 1.8 mg/kg body weight intravenously for up to 16 infusions or until day +365 after alloSCT.

Number of subjects in period 1	Single-arm
Started	13
Completed	13

Baseline characteristics

Reporting groups

Reporting group title	Overall trial - Treatment and Follow-up
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Reporting group description:

The reporting group consists of alle patients evaluated in the final analysis. This corresponds to the Full Analysis Set (FAS), which includes all patients who qualified for enrollment and received at least one dose of Brentuximab Vedotin.

Reporting group values	Overall trial - Treatment and Follow-up	Total	
Number of subjects	13	13	
Age categorical			
Units: Subjects			
18-19	1	1	
20-29	4	4	
30-39	3	3	
40-49	3	3	
50-59	1	1	
60-69	0	0	
>70	1	1	
Age continuous			
Patients had to be 18 years or older			
Units: years			
median	33		
full range (min-max)	19 to 61	-	
Gender categorical			
Units: Subjects			
Female	4	4	
Male	9	9	
Performance Status (ECOG)			
Units: Subjects			
ECOG 0	3	3	
ECOG 1	10	10	
Stage (I-IV)			
Units: Subjects			
Stage I	0	0	
Stage II	1	1	
Stage III	3	3	
Stage IV	6	6	
not reported	3	3	
International Prognostic Score (IPS)			
The prognostic score was defined as the number of adverse prognostic factors present at diagnosis. Defined as a serum albumin level of less than 4 g per deciliter, a hemoglobin level of less than 10.5 g per deciliter, male sex, an age of 45 years or older, stage IV disease (according to the Ann Arbor classification), leukocytosis (a white-cell count of at least 15,000 per cubic millimeter), and lymphocytopenia (a lymphocyte count of less than 600 per cubic millimeter, a count that was less than 8 percent of the white-cell count, or both)			
Units: Subjects			
IPS 1	1	1	
IPS 2	2	2	

IPS 3	3	3	
IPS 4	2	2	
IPS 5	0	0	
IPS 6	1	1	
not recorded	4	4	
B-Symptoms			
Units: Subjects			
Yes	6	6	
No	1	1	
not recorded	6	6	
Ann-Arbor Stage of last relapse			
Only relapsed/refractory cHL patients who receive allogeneic stem cell transplantation were included in the trial.			
Units: Subjects			
IA	0	0	
IB	0	0	
IIA	1	1	
IIB	0	0	
IIIA	1	1	
IIIB	1	1	
IVA	4	4	
IVB	0	0	
Not recorded	6	6	
Body height			
Units: cm			
median	177		
full range (min-max)	155 to 186	-	
Body weight			
Units: kg			
median	70		
full range (min-max)	47 to 130	-	
Body Mass Index (BMI)			
Units: numbers			
median	23.3		
full range (min-max)	18.1 to 37.6	-	

Subject analysis sets

Subject analysis set title	Full Analysis Set (FAS)
Subject analysis set type	Full analysis
Subject analysis set description:	
The FAS consists of all patients who received at least one dose of Brentuximab Vedotin (BV).	
Subject analysis set title	Efficacy Analysis Set (EAS)
Subject analysis set type	Per protocol
Subject analysis set description:	
The efficacy analysis set (EAS) consists of all FAS patients who are evaluable for the primary efficacy endpoint.	
Subject analysis set title	Efficacy Analysis Set (EAS) Dummy
Subject analysis set type	Per protocol
Subject analysis set description:	
A duplicate analysis set was created only to satisfy the EudraCT system requirement for at least two comparison groups. Both sets contain the same 10 patients.	

Reporting group values	Full Analysis Set (FAS)	Efficacy Analysis Set (EAS)	Efficacy Analysis Set (EAS) Dummy
Number of subjects	13	10	10
Age categorical			
Units: Subjects			
18-19	1	0	0
20-29	4	4	4
30-39	3	3	3
40-49	3	1	1
50-59	1	1	1
60-69	0	0	0
>70	1	1	1
Age continuous			
Patients had to be 18 years or older			
Units: years			
median	33	33	33
full range (min-max)	19 to 61	20 to 61	20 to 61
Gender categorical			
Units: Subjects			
Female	4	2	2
Male	9	8	8
Performance Status (ECOG)			
Units: Subjects			
ECOG 0	3	1	1
ECOG 1	10	9	9
Stage (I-IV)			
Units: Subjects			
Stage I	0	0	0
Stage II	1	1	1
Stage III	3	3	3
Stage IV	6	6	6
not reported	3	0	0
International Prognostic Score (IPS)			
The prognostic score was defined as the number of adverse prognostic factors present at diagnosis. Defined as a serum albumin level of less than 4 g per deciliter, a hemoglobin level of less than 10.5 g per deciliter, male sex, an age of 45 years or older, stage IV disease (according to the Ann Arbor classification), leukocytosis (a white-cell count of at least 15,000 per cubic millimeter), and lymphocytopenia (a lymphocyte count of less than 600 per cubic millimeter, a count that was less than 8 percent of the white-cell count, or both)			
Units: Subjects			
IPS 1	1	1	1
IPS 2	2	2	2
IPS 3	3	3	3
IPS 4	2	2	2
IPS 5	0	0	0
IPS 6	1	1	1
not recorded	4	1	1
B-Symptoms			
Units: Subjects			
Yes	6	6	6
No	1	1	1
not recorded	6	3	3

Ann-Arbor Stage of last relapse			
Only relapsed/refractory cHL patients who receive allogeneic stem cell transplantation were included in the trial.			
Units: Subjects			
IA	0	0	0
IB	0	0	0
IIA	1	1	1
IIB	0	0	0
IIIA	1	1	1
IIIB	1	1	1
IVA	4	4	4
IVB	0	0	0
Not recorded	6	3	3
Body height			
Units: cm			
median	177	181.5	181.5
full range (min-max)	155 to 186	156 to 186	156 to 186
Body weight			
Units: kg			
median	70	71.5	71.5
full range (min-max)	47 to 130	56 to 130	56 to 130
Body Mass Index (BMI)			
Units: numbers			
median	23.3	24.2	24.2
full range (min-max)	18.1 to 37.6	18.1 to 37.6	18.1 to 37.6

End points

End points reporting groups

Reporting group title	Single-arm
Reporting group description: -	
Subject analysis set title	Full Analysis Set (FAS)
Subject analysis set type	Full analysis
Subject analysis set description: The FAS consists of all patients who received at least one dose of Brentuximab Vedotin (BV).	
Subject analysis set title	Efficacy Analysis Set (EAS)
Subject analysis set type	Per protocol
Subject analysis set description: The efficacy analysis set (EAS) consists of all FAS patients who are evaluable for the primary efficacy endpoint.	
Subject analysis set title	Efficacy Analysis Set (EAS) Dummy
Subject analysis set type	Per protocol
Subject analysis set description: A duplicate analysis set was created only to satisfy the EudraCT system requirement for at least two comparison groups. Both sets contain the same 10 patients.	

Primary: Cumulative Incidence of Relapse (CIR)

End point title	Cumulative Incidence of Relapse (CIR)
End point description: The tumor status was determined at the final restgng (RE-365).	
End point type	Primary
End point timeframe: Efficacy was determined using the CIR within the first year after aSCT.	

End point values	Efficacy Analysis Set (EAS)	Efficacy Analysis Set (EAS) Dummy		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	10	10		
Units: percent				
number (confidence interval 95%)	50 (18.7 to 81.3)	50 (18.7 to 81.3)		

Statistical analyses

Statistical analysis title	Primary endpoint analysis: 12-month CIR
Statistical analysis description: The statistical analysis originally planned in the trial protocol was not done due to insufficient patient numbers for the test. Instead, an exact one-sided 95% confidence interval for the CIR was calculated for the enpoint. A duplicate analysis set was created just to satisfy technical requirements; both sets contain the same 10 patients.	
Comparison groups	Efficacy Analysis Set (EAS) v Efficacy Analysis Set (EAS) Dummy

Number of subjects included in analysis	20
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	12-month Cumulative Incidence of Relapse
Point estimate	50
Confidence interval	
level	95 %
sides	2-sided
lower limit	18.7
upper limit	81.3

Secondary: Progression-free survival (PFS)

End point title	Progression-free survival (PFS)
End point description:	
PFS was calculated as time between the date of aSCT and the date of first progression, relapse or death or, in case of continuing response, the date of the last documented follow-up. Patients were censored at the date of the last documented follow-up if no progression/relapse or death was registered before the trial end.	
End point type	Secondary
End point timeframe:	
1-year progression-free survival will be reported	

End point values	Single-arm	Full Analysis Set (FAS)		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	13	13		
Units: percentage				
number (confidence interval 95%)	76.9 (54 to 99.8)	76.9 (54 to 99.8)		

Statistical analyses

No statistical analyses for this end point

Secondary: Overall survival (OS)

End point title	Overall survival (OS)
End point description:	
Overall survival was calculated as time between the date of aSCT and the date of death or the date of last documented follow-up. Patients were censored at the date of last documented follow-up if no death was registered before trial end.	
End point type	Secondary
End point timeframe:	
1-year overall survival will be reported.	

End point values	Single-arm	Full Analysis Set (FAS)		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	13	13		
Units: percentage				
number (confidence interval 95%)	76.9 (54 to 99.8)	76.9 (54 to 99.8)		

Statistical analyses

No statistical analyses for this end point

Secondary: Remission status (RE-100)

End point title	Remission status (RE-100)
End point description:	
In case, BV treatment ended before RE-365 and no data of end of treatment restaging was available, the last documented restaging was used.	
End point type	Secondary
End point timeframe:	
Remission status (CR, PR, NC, PD) was summarized at the end of the BV treatment (RE-365).	

End point values	Single-arm	Full Analysis Set (FAS)		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	13			
Units: subjects				
Complete remission (CR)	10	10		
Partial remission (PR)	0	0		
No change (NC)	0	0		
Progressive disease (PD)	2	1		
RE not done	1	2		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

All events up to 30 days after end of treatment (EOT) had to be reported. Events that occurred later than 30 days after EOT had to be reported if causality was rated as at least "possible".

Adverse event reporting additional description:

AEs were assessed on therapy administration CRFs. SAEs were additionally assessed on specific forms. SAEs may thus be reported twice; non-serious AEs might contain SAEs; non-serious and SAEs might not add up to a total number of AEs. All AEs of CTCAE grade ≥ 1 were reported.

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	10.1
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Reporting groups

Reporting group title	Single-arm
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Reporting group description: -

Serious adverse events	Single-arm		
Total subjects affected by serious adverse events			
subjects affected / exposed	9 / 13 (69.23%)		
number of deaths (all causes)	3		
number of deaths resulting from adverse events	0		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Urinary bladder adenoma			
subjects affected / exposed	1 / 13 (7.69%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	1 / 13 (7.69%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	1 / 13 (7.69%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal ulcer			

subjects affected / exposed	1 / 13 (7.69%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			
Pneumonitis			
subjects affected / exposed	1 / 13 (7.69%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Cystitis			
subjects affected / exposed	1 / 13 (7.69%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Pneumonia	Additional description: Patient had a lung infection (fungal pneumonia) after allogeneic stem cell transplantation. The event is not related to treatment with BV.		
subjects affected / exposed	1 / 13 (7.69%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Sepsis	Additional description: 1 patient had a sepsis with fulminant development of pneumonia with palliative procedure at patient's request. . 1 patient had a sepsis due to phlegmon left upper thigh (Myositis). In both cases, sepsis was possibly related to allogeneic SCT.		
subjects affected / exposed	2 / 13 (15.38%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Streptococcal infection			
subjects affected / exposed	1 / 13 (7.69%)		
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	Single-arm		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	13 / 13 (100.00%)		
Nervous system disorders			

Sensory polyneuropathy subjects affected / exposed occurrences (all)	10 / 13 (76.92%) 10		
General disorders and administration site conditions			
Alopecia subjects affected / exposed occurrences (all)	1 / 13 (7.69%) 2		
Anaphylactic reaction subjects affected / exposed occurrences (all)	2 / 13 (15.38%) 2		
Bleeding subjects affected / exposed occurrences (all)	1 / 13 (7.69%) 1		
Impairment of organ function subjects affected / exposed occurrences (all)	5 / 13 (38.46%) 5		
Blood and lymphatic system disorders			
Anemia subjects affected / exposed occurrences (all)	9 / 13 (69.23%) 38		
Febrile neutropenia subjects affected / exposed occurrences (all)	1 / 13 (7.69%) 1		
haemorrhagic cystitis subjects affected / exposed occurrences (all)	1 / 13 (7.69%) 2		
Leukopenia subjects affected / exposed occurrences (all)	8 / 13 (61.54%) 24		
Neutropenia subjects affected / exposed occurrences (all)	8 / 13 (61.54%) 18		
Thrombocytopenia subjects affected / exposed occurrences (all)	8 / 13 (61.54%) 28		
Gastrointestinal disorders			

Gastrointestinal disorder subjects affected / exposed occurrences (all)	4 / 13 (30.77%) 7		
Mucositis subjects affected / exposed occurrences (all)	1 / 13 (7.69%) 1		
Nausea / vomiting subjects affected / exposed occurrences (all)	7 / 13 (53.85%) 13		
Hepatobiliary disorders Hepatobiliary disorder subjects affected / exposed occurrences (all)	6 / 13 (46.15%) 10		
Infections and infestations Infection subjects affected / exposed occurrences (all)	7 / 13 (53.85%) 8		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
17 July 2020	Update of SmPC
16 June 2021	Update of SmPC
26 October 2021	Update of SmPC

Notes:

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 recruitment of the BV-Allo trial was prematurely closed on 31.08.2022 due to feasibility in light of slow recruitment. Therefore, the planned statistical analyses were not done.

Notes: