Clinical trial results:
A Randomized, Double-Blind, Placebo-Controlled Phase 3 Study to Investigate the Efficacy and Safety of Progesterone in Patients with Severe Traumatic Brain Injury

Summary

EudraCT number	2010-018283-16
Trial protocol	BE HU GB CZ NL AT DE ES IT FI
Global end of trial date	06 March 2014

Results information

Result version number	v1 (current)
This version publication date	22 March 2026
First version publication date	22 March 2026

Trial information

Trial identification

Sponsor protocol code	BHR-100-301

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01143064
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	BHR Pharma, LLC
Sponsor organisation address	607 Herndon Parkway Suite 110, Herndon, VA, United States, 20170
Public contact	Francois Brault, BHR Pharma Belgium, 0032 2629 43 11 N/A, EUclinicaltrials@bhr-pharma.com
Scientific contact	Francois Brault, BHR Pharma Belgium, 0032 2629 43 11 N/A, EUclinicaltrials@bhr-pharma.com

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	06 March 2014
Is this the analysis of the primary completion data?	Yes
Primary completion date	06 March 2014
Global end of trial reached?	Yes
Global end of trial date	06 March 2014
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The aim of the study is to determine the efficacy and safety of BHR-100 i.v. progesterone infusion compared to placebo infusion, utilizing the glasgow outcome scale (GOS) in severe traumatic brain injury patients, glasgow coma scale (GCS 3-8), with the treatment administered continuously over 5 days beginning within 8 hours after the injury. In addition, the safety and clinical benefit of BHR-100 treatment will be assessed through the secondary endpoints.

Protection of trial subjects:

Subjects were managed in accordance with standard guidelines for the treatment of severe TBI (Brain Trauma Foundation, American Brain Injury Consortium, and European Brain Injury Consortium).

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	23 July 2010
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	Argentina: 64
Country: Number of subjects enrolled	China: 35
Country: Number of subjects enrolled	Israel: 62
Country: Number of subjects enrolled	Malaysia: 19
Country: Number of subjects enrolled	Romania: 6
Country: Number of subjects enrolled	Russian Federation: 13
Country: Number of subjects enrolled	Singapore: 15
Country: Number of subjects enrolled	Thailand: 46
Country: Number of subjects enrolled	Taiwan: 5
Country: Number of subjects enrolled	United States: 439
Country: Number of subjects enrolled	Netherlands: 7
Country: Number of subjects enrolled	Spain: 93
Country: Number of subjects enrolled	United Kingdom: 54
Country: Number of subjects enrolled	Austria: 32
Country: Number of subjects enrolled	Belgium: 29
Country: Number of subjects enrolled	Czechia: 58
Country: Number of subjects enrolled	Finland: 6
Country: Number of subjects enrolled	France: 92
Country: Number of subjects enrolled	Germany: 50

Country: Number of subjects enrolled	Hungary: 8
Country: Number of subjects enrolled	Italy: 46
Worldwide total number of subjects	1179
EEA total number of subjects	427

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)	24
Adults (18-64 years)	1089
From 65 to 84 years	66
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

In total, 1195 subjects were randomized, however 16 subjects never received study drug and therefore the 1179 who received study drug were considered enrolled. All tables of the mITT population reflect only subjects who were randomized and received study drug treatment.

Pre-assignment

Screening details:

Inclusion and exclusion

Period 1

Period 1 title	Overall (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Arms

Are arms mutually exclusive?	Yes
Arm title	BHR-100

Arm description:

Progesterone: Intravenous administration of 0.71mg/kg/hr for 1hr followed by 0.5mg/kg/hr administered intravenously for an additional 119 hrs.

Arm type	Experimental
Investigational medicinal product name	Progesterone
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intravenous drip use

Dosage and administration details:

Intravenous administration of 0.71mg/kg/hr for 1hr followed by 0.5mg/kg/hr administered intravenously for an additional 119 hrs

Arm title	Placebo

Arm description:

Lipid emulsion without progesterone: Intravenous administration equal to 0.71mg/kg/hr for 1hr followed by 0.5mg/kg/hr administered intravenously for an additional 119 hrs.

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

Drug: Lipid emulsion without progesterone
Intravenous administration equal to 0.71mg/kg/hr for 1hr followed by 0.5mg/kg/hr administered intravenously for an additional 119 hrs.

Number of subjects in period 1	BHR-100	Placebo
Started	591	588
Completed	458	473
Not completed	133	115
Adverse event, serious fatal	109	91
Consent withdrawn by subject	7	5
Physician decision	-	4
Adverse event, non-fatal	-	1
Lost to follow-up	17	14

Baseline characteristics

Reporting groups	
Reporting group title	BHR-100
Reporting group description:	
Progesterone: Intravenous administration of 0.71mg/kg/hr for 1hr followed by 0.5mg/kg/hr administered intravenously for an additional 119 hrs.	
Reporting group title	Placebo
Reporting group description:	
Lipid emulsion without progesterone: Intravenous administration equal to 0.71mg/kg/hr for 1hr followed by 0.5mg/kg/hr administered intravenously for an additional 119 hrs.	

Reporting group values	BHR-100	Placebo	Total
Number of subjects	591	588	1179
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)	11	13	24
Adults (18-64 years)	545	544	1089
From 65-84 years	35	31	66
85 years and over	0	0	0
Gender categorical Units: Subjects			
Female	127	125	252
Male	464	463	927

Subject analysis sets	
Subject analysis set title	BHR-100
Subject analysis set type	Intention-to-treat
Subject analysis set description:	
Progesterone: Intravenous administration of 0.71mg/kg/hr for 1hr followed by 0.5mg/kg/hr administered intravenously for an additional 119 hrs.	
Subject analysis set title	Placebo
Subject analysis set type	Intention-to-treat
Subject analysis set description:	
Lipid emulsion without progesterone: Intravenous administration equal to 0.71mg/kg/hr for 1hr followed by 0.5mg/kg/hr administered intravenously for an additional 119 hrs.	

Reporting group values	BHR-100	Placebo	
Number of subjects	591	588	
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)	11	13	
Adults (18-64 years)	545	544	
From 65-84 years	35	31	
85 years and over	0	0	
Gender categorical			
Units: Subjects			
Female	127	125	
Male	464	463	

End points

End points reporting groups

Reporting group title	BHR-100
Reporting group description:	
Progesterone: Intravenous administration of 0.71mg/kg/hr for 1hr followed by 0.5mg/kg/hr administered intravenously for an additional 119 hrs.	
Reporting group title	Placebo
Reporting group description:	
Lipid emulsion without progesterone: Intravenous administration equal to 0.71mg/kg/hr for 1hr followed by 0.5mg/kg/hr administered intravenously for an additional 119 hrs.	
Subject analysis set title	BHR-100
Subject analysis set type	Intention-to-treat
Subject analysis set description:	
Progesterone: Intravenous administration of 0.71mg/kg/hr for 1hr followed by 0.5mg/kg/hr administered intravenously for an additional 119 hrs.	
Subject analysis set title	Placebo
Subject analysis set type	Intention-to-treat
Subject analysis set description:	
Lipid emulsion without progesterone: Intravenous administration equal to 0.71mg/kg/hr for 1hr followed by 0.5mg/kg/hr administered intravenously for an additional 119 hrs.	

Primary: Glasgow Outcome Scale (GOS)

End point title	Glasgow Outcome Scale (GOS)
End point description:	
The GOS assesses mortality and disability in traumatic brain injury (TBI) patients according to the designation: Good Recovery, Moderate Disability, Severe Disability, Vegetative State or Dead.	
End point type	Primary
End point timeframe:	
6 months	

End point values	BHR-100	Placebo		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	591	588		
Units: Participants				
Good Recovery	189	183		
Moderate Disability	109	114		
Severe Disability	162	160		
Vegetative State / Dead	131	131		

Statistical analyses

Statistical analysis title	Proportional Odds Model: Summary and Analysis
Statistical analysis description:	
analyzed by the Proportional Odds Model (POM).	
Comparison groups	Placebo v BHR-100

Number of subjects included in analysis	1179
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.0098 [1]
Method	Chi-squared
Parameter estimate	Odds ratio (OR)

Notes:

[1] - The score test is based on the Chi-Square test and the Type 3 analysis of effects is based on the Wald Chi-Square test
from a Logistic Regression analysis.

Secondary: Mortality at Month 1

End point title	Mortality at Month 1

End point description:

The mortality rate at one month will be compared between the two treatment groups.

End point type	Secondary

End point timeframe:

1 month post injury

End point values	BHR-100	Placebo		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	591	588		
Units: Participants				
Lost to Follow Up	0	0		
Consent Withdrawn	0	0		
Alive	500	507		
Dead	87	74		
Other	1	0		
Missing	3	7		

Statistical analyses

No statistical analyses for this end point

Secondary: Mortality at Month 6

End point title	Mortality at Month 6

End point description:

The mortality rate at six months will be compared between the two treatment groups.

End point type	Secondary

End point timeframe:

6 months post injury

End point values	BHR-100	Placebo		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	591	588		
Units: Participants				
Lost to Follow Up	0	2		
Consent Withdrawn	0	0		
Alive	463	472		
Dead	109	95		
Other	0	0		
Missing	19	19		

Statistical analyses

No statistical analyses for this end point

Secondary: Glasgow Outcome Scale at 3 Months

End point title	Glasgow Outcome Scale at 3 Months

End point description:

The GOS assesses the mortality and disability in traumatic brain injury patients according to the designation: Good Recovery, Moderate Disability, Severe Disability, Vegetative State, or Dead.

End point type	Secondary

End point timeframe:

Month 3

End point values	BHR-100	Placebo		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	591	588		
Units: Participants				
Good Recovery	103	101		
Moderate Disability	103	114		
Severe Disability	224	216		
Vegetative State	33	49		
Dead	102	88		
Missing	26	20		

Statistical analyses

No statistical analyses for this end point

Secondary: Glasgow Outcome Scale - Extended (GOS-E)

End point title	Glasgow Outcome Scale - Extended (GOS-E)

End point description:

The GOS-E assessment of mortality and disability in TBI patients extends the original five GOS categories of functional outcome to eight categories:

• Dead
• Vegetative State
• Lower Severe Disability
• Upper Severe Disability
• Lower Moderate Disability
• Upper Moderate Disability
• Lower Good Recovery
• Upper Good Recovery

End point type	Secondary

End point timeframe:

3 months and 6 months post injury

End point values	BHR-100	Placebo		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	565	568		
Units: Participants				
Dead- 3 months	102	88		
Vegetative State- 3 months	33	49		
Lower Severe Disability- 3 months	173	165		
Upper Severe Disability- 3 months	51	51		
Lower Moderate Disability- 3 months	35	34		
Upper Moderate Disability- 3 months	68	80		
Lower Good Recovery- 3months	53	46		
Upper Good Recovery- 3 months	50	55		
Dead- 6 months	109	95		
Vegetative State- 6 months	20	33		
Lower Severe Disability- 6 months	115	109		
Upper Severe Disability- 6 months	37	44		
Lower Moderate Disability- 6 months	36	38		
Upper Moderate Disability- 6 months	70	72		
Lower Good Recovery- 6 months	71	64		
Upper Good Recovery- 6 months	108	109		

Statistical analyses

No statistical analyses for this end point

Secondary: Short Form (36) Health Survey (SF-36)

End point title	Short Form (36) Health Survey (SF-36)

End point description:

The SF-36 is a validated survey of patient health consisting of eight scaled scores. The eight sections are:
• vitality
• physical functioning
• bodily pain
• general health perceptions
• role physical
• role emotional
• role mental

• mental health The 8 scales can also be further summarized to provide a summary score for physical health and a
summary score for mental health.

End point type	Secondary

End point timeframe:

3 months and 6 months post injury

End point values	BHR-100	Placebo		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	354	369		
Units: Score on a Scale				
number (not applicable)				
Physical Composite Summary- Month 3	39.8	40.6		
Physical Composite Summary- Month 6	44.6	45.1		
Mental Composite Summary- Month 3	48.7	48.5		
Mental Composite Summary- Month 6	47.9	46.8		

Statistical analyses

No statistical analyses for this end point

Secondary: Potentially Clinically Important On-Treatment Cerebral Perfusion Pressure (CPP) and Summary of Maximum Therapy Therapeutic Intensity Level (TIL)

End point title	Potentially Clinically Important On-Treatment Cerebral Perfusion Pressure (CPP) and Summary of Maximum Therapy Therapeutic Intensity Level (TIL)

End point description:

Cerebral Perfusion Pressure (CPP) levels are presented according to clinically significant cut-off values. CPP was calculated from intracranial pressures and mean arterial pressures measured from Day through Day 6 after initiation of study medication, if an ICP monitor was in place. Specific therapies received during Days 1-6 are summarized according to the Therapeutic Intensity Level (TIL) by treatment group, as maximum level of therapy administered to the subject.

End point type	Secondary

End point timeframe:

Admission through post-infusion Day 6

End point values	BHR-100	Placebo		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	591	588		
Units: Participants				
Any CPP value <50 mmHg	297	299		
Any CPP value>=50<60 mmHg	448	460		
Any CPP value >=70 mmHg	518	523		
Surgical Decompression (TIL)	192	174		

Barbiturate Induced Coma (TIL)	82	73		
Hypothermia (TIL)	61	69		
Hyperventilation (TIL)	78	68		
Pressor Administered (TIL)	315	343		
Hypertonic Saline (TIL)	225	233		
Mannitol (TIL)	288	285		
Ventricular Drainage (TIL)	198	208		
Paralysis Induction (TIL)	220	231		
Sedation (TIL)	565	565		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events: Screening through end of study	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	13.0

Reporting groups	
Reporting group title	BHR-100
Reporting group description: -	
Reporting group title	Placebo
Reporting group description: -	

Serious adverse events	BHR-100	Placebo	
Total subjects affected by serious adverse events			
subjects affected / exposed	224 / 596 (37.58%)	214 / 583 (36.71%)	
number of deaths (all causes)	109	95	
number of deaths resulting from adverse events			
Injury, poisoning and procedural complications			
Brain contusion			
subjects affected / exposed	5 / 596 (0.84%)	6 / 583 (1.03%)	
occurrences causally related to treatment / all	0 / 5	1 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Brain herniation			
subjects affected / exposed	15 / 596 (2.52%)	13 / 583 (2.23%)	
occurrences causally related to treatment / all	0 / 15	1 / 13	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subdural hematoma			
subjects affected / exposed	10 / 596 (1.68%)	5 / 583 (0.86%)	
occurrences causally related to treatment / all	0 / 10	1 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Traumatic brain injury			
subjects affected / exposed	4 / 596 (0.67%)	10 / 583 (1.72%)	
occurrences causally related to treatment / all	1 / 4	0 / 10	
deaths causally related to treatment / all	0 / 0	0 / 0	

Cardiac disorders			
Cardiac arrest			
subjects affected / exposed	7 / 596 (1.17%)	3 / 583 (0.51%)	
occurrences causally related to treatment / all	0 / 7	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardio-respiratory arrest			
subjects affected / exposed	6 / 596 (1.01%)	5 / 583 (0.86%)	
occurrences causally related to treatment / all	0 / 6	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Multi-organ failure			
subjects affected / exposed	6 / 596 (1.01%)	7 / 583 (1.20%)	
occurrences causally related to treatment / all	1 / 6	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Brain Oedema			
subjects affected / exposed	19 / 596 (3.19%)	17 / 583 (2.92%)	
occurrences causally related to treatment / all	0 / 19	0 / 17	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebral infarction			
subjects affected / exposed	8 / 596 (1.34%)	5 / 583 (0.86%)	
occurrences causally related to treatment / all	1 / 8	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Convulsion			
subjects affected / exposed	9 / 596 (1.51%)	3 / 583 (0.51%)	
occurrences causally related to treatment / all	0 / 9	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hydrocephalus			
subjects affected / exposed	12 / 596 (2.01%)	14 / 583 (2.40%)	
occurrences causally related to treatment / all	0 / 12	0 / 14	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intracranial pressure increased			
subjects affected / exposed	30 / 596 (5.03%)	27 / 583 (4.63%)	
occurrences causally related to treatment / all	1 / 30	1 / 27	
deaths causally related to treatment / all	0 / 0	0 / 0	

Respiratory, thoracic and mediastinal disorders			
Acute respiratory distress disorder			
subjects affected / exposed	6 / 596 (1.01%)	7 / 583 (1.20%)	
occurrences causally related to treatment / all	0 / 6	4 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia aspiration			
subjects affected / exposed	5 / 596 (0.84%)	9 / 583 (1.54%)	
occurrences causally related to treatment / all	0 / 5	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary embolism			
subjects affected / exposed	7 / 596 (1.17%)	6 / 583 (1.03%)	
occurrences causally related to treatment / all	2 / 7	1 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory failure			
subjects affected / exposed	4 / 596 (0.67%)	11 / 583 (1.89%)	
occurrences causally related to treatment / all	0 / 4	1 / 11	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Meningitis			
subjects affected / exposed	7 / 596 (1.17%)	5 / 583 (0.86%)	
occurrences causally related to treatment / all	0 / 7	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia			
subjects affected / exposed	38 / 596 (6.38%)	40 / 583 (6.86%)	
occurrences causally related to treatment / all	0 / 40	0 / 45	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sepsis			
subjects affected / exposed	15 / 596 (2.52%)	14 / 583 (2.40%)	
occurrences causally related to treatment / all	0 / 15	1 / 14	
deaths causally related to treatment / all	0 / 0	0 / 0	
Septic shock			
subjects affected / exposed	11 / 596 (1.85%)	7 / 583 (1.20%)	
occurrences causally related to treatment / all	1 / 11	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	

Frequency threshold for reporting non-serious adverse events: 5 %

Non-serious adverse events	BHR-100	Placebo	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	265 / 596 (44.46%)	286 / 583 (49.06%)	
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	30 / 596 (5.03%)	18 / 583 (3.09%)	
occurrences (all)	30	18	
Gamma-glutamyltransferase increased			
subjects affected / exposed	51 / 596 (8.56%)	35 / 583 (6.00%)	
occurrences (all)	51	35	
Vascular disorders			
Hypertension			
subjects affected / exposed	129 / 596 (21.64%)	127 / 583 (21.78%)	
occurrences (all)	135	143	
Hypotension			
subjects affected / exposed	71 / 596 (11.91%)	80 / 583 (13.72%)	
occurrences (all)	76	88	
Cardiac disorders			
Tachycardia			
subjects affected / exposed	69 / 596 (11.58%)	63 / 583 (10.81%)	
occurrences (all)	73	65	
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	156 / 596 (26.17%)	159 / 583 (27.27%)	
occurrences (all)	173	171	
Thrombocytopenia			
subjects affected / exposed	21 / 596 (3.52%)	32 / 583 (5.49%)	
occurrences (all)	21	32	
Gastrointestinal disorders			
Pyrexia			

subjects affected / exposed	209 / 596 (35.07%)	229 / 583 (39.28%)	
occurrences (all)	223	249	
Constipation			
subjects affected / exposed	97 / 596 (16.28%)	102 / 583 (17.50%)	
occurrences (all)	97	105	
Psychiatric disorders			
Agitation			
subjects affected / exposed	79 / 596 (13.26%)	78 / 583 (13.38%)	
occurrences (all)	81	85	
Endocrine disorders			
Diabetes insipidus			
subjects affected / exposed	33 / 596 (5.54%)	43 / 583 (7.38%)	
occurrences (all)	33	44	
Metabolism and nutrition disorders			
Hyperglycaemia			
subjects affected / exposed	86 / 596 (14.43%)	85 / 583 (14.58%)	
occurrences (all)	87	87	
Hypernatraemia			
subjects affected / exposed	39 / 596 (6.54%)	33 / 583 (5.66%)	
occurrences (all)	42	34	
Hypocalcaemia			
subjects affected / exposed	22 / 596 (3.69%)	29 / 583 (4.97%)	
occurrences (all)	22	30	
Hypokalaemia			
subjects affected / exposed	94 / 596 (15.77%)	126 / 583 (21.61%)	
occurrences (all)	102	132	
Hypomagnesaemia			
subjects affected / exposed	32 / 596 (5.37%)	49 / 583 (8.40%)	
occurrences (all)	32	49	
Hyponatraemia			
subjects affected / exposed	59 / 596 (9.90%)	64 / 583 (10.98%)	
occurrences (all)	64	68	
Hypophosphataemia			
subjects affected / exposed	53 / 596 (8.89%)	52 / 583 (8.92%)	
occurrences (all)	53	53	

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

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

16 pts haven’t received study drugs. 6 BHR-100, 10 placebo.1179 made the mITT population (591+588). Data isn’t available for causality of deaths. Feedback from EudraCT IT on 20-01-2026, we have entered '0' for the deaths values that weren’t reported.

Notes: