Clinical trial results:
A Retrospective and Prospective, Open-label, Long-term Safety and Efficacy Study of Teduglutide in Pediatric Subjects with Short Bowel Syndrome Who Completed TED-C13-003

Summary

EudraCT number	2016-000863-17
Trial protocol	GB
Global end of trial date	14 July 2020

Results information

Result version number	v1 (current)
This version publication date	29 January 2021
First version publication date	29 January 2021

Trial information

Trial identification

Sponsor protocol code	SHP633-303

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02949362
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Shire
Sponsor organisation address	300 ShireWay, Lexington, United States, MA 02421
Public contact	Study Director, Shire, +1 866 842 5335, ClinicalTransparency@shire.com
Scientific contact	Study Director, Shire, +1 866 842 5335, ClinicalTransparency@shire.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	Yes
EMA paediatric investigation plan number(s)	EMEA-000482-PIP01-08
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?	Yes

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	14 July 2020
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	14 July 2020
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objective of the study is to evaluate the long-term safety and tolerability of teduglutide treatment in pediatric subjects with short bowel syndrome (SBS) who completed TED-C13-003 (2013-004588-30).

Protection of trial subjects:

The study was conducted in accordance with the ethical principles that have their origins in the Declaration of Helsinki and in compliance with all applicable industry regulations, International Council For Harmonisation Good Clinical Practice Guideline E6 (1996), European Union Directive 2001/20/EC, as well as all applicable national and local laws and regulations.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	09 December 2016
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	United States: 26
Country: Number of subjects enrolled	United Kingdom: 3
Worldwide total number of subjects	29
EEA total number of subjects	0

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)	3
Children (2-11 years)	23
Adolescents (12-17 years)	3
Adults (18-64 years)	0
From 65 to 84 years	0

85 years and over	0

Subject disposition

Recruitment

Recruitment details:

The study was conducted at 11 sites in United Kingdom and United States between 09 December 2016 (first subject first visit) and 14 July 2020 (last subject last visit).

Pre-assignment

Screening details:

Of the 40 subjects who completed TED-C13-003, 29 subjects consented to retrospective period. Of these, 24 enrolled into Retro TED/NTT (didn’t receive teduglutide) and 5 into Retro TED/TED (received teduglutide). Out of 29 subjects of retrospective period, 24 enrolled into prospective period (ANY TED group), including 19 in TED/TED and 5 in TED/NTT.

Period 1

Period 1 title	Period 1: Retrospective Period
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Retrospective TED/NTT Group

Arm description:

Subjects who received teduglutide 0.05 milligrams per kilogram (mg/kg) subcutaneous (SC) injection once daily in TED-C13-003 (2013-004588-30) and didn't received teduglutide in retrospective period of current study SHP633-303 (2016-000863-17).

Arm type	Experimental
Investigational medicinal product name	Teduglutide
Investigational medicinal product code	ALX-0600
Other name	Revestive
Pharmaceutical forms	Powder and solvent for solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Subjects received teduglutide 0.05 mg/kg SC injection once daily in TED-C13-003 (2013-004588-30) and didn't received in retrospective period of current study SHP633-303 (2016-000863-17).

Arm title	Retrospective TED/TED Group

Arm description:

Subjects who received teduglutide 0.05 mg/kg SC injection once daily in TED-C13-003 (2013-004588-30) and received teduglutide in retrospective period of current study SHP633-303 (2016-000863-17).

Arm type	Experimental
Investigational medicinal product name	Teduglutide
Investigational medicinal product code	ALX-0600
Other name	Revestive
Pharmaceutical forms	Powder and solvent for solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Subjects received teduglutide 0.05 mg/kg SC injection once daily in TED-C13-003 (2013-004588-30) and received in retrospective period of current study SHP633-303 (2016-000863-17).

Number of subjects in period 1	Retrospective TED/NTT Group	Retrospective TED/TED Group
Started	24	5
Completed	20	4
Not completed	4	1
Inform consent is not signed	4	1

Period 2

Period 2 title	Period 2: Prospective Data
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Prospective TED/NTT Group

Arm description:

Subjects who received teduglutide 0.05 mg/kg SC injection once daily in TED-C13-003 (2013-004588-30) and didn't received teduglutide in prospective period of current study SHP633-303 (2016-000863-17) up to 24 weeks.

Arm type	Experimental
Investigational medicinal product name	Teduglutide
Investigational medicinal product code	ALX-0600
Other name	Revestive
Pharmaceutical forms	Powder and solvent for solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Subjects received teduglutide 0.05 mg/kg SC injection once daily in TED-C13-003 (2013-004588-30) and didn't received in prospective period of current study SHP633-303 (2016-000863-17) up to 24 weeks.

Arm title	Prospective TED/TED Group

Arm description:

Subjects who received teduglutide 0.05 mg/kg SC injection once daily in TED-C13-003 (2013-004588-30) and also received teduglutide in prospective period of current study SHP633-303 (2016-000863-17) up to 24 weeks.

Arm type	Experimental
Investigational medicinal product name	Teduglutide
Investigational medicinal product code	ALX-0600
Other name	Revestive
Pharmaceutical forms	Powder and solvent for solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Subjects received teduglutide 0.05 mg/kg SC injection once daily in TED-C13-003 (2013-004588-30) and received in prospective period of current study SHP633-303 (2016-000863-17) up to 24 weeks.

Number of subjects in period 2	Prospective TED/NTT Group	Prospective TED/TED Group
Started	5	19
Completed	4	15
Not completed	1	4
subject didn't complete an early termination visit	1	-
Unspecified	-	4

Baseline characteristics

Reporting groups	
Reporting group title	Retrospective TED/NTT Group
Reporting group description:	
Subjects who received teduglutide 0.05 milligrams per kilogram (mg/kg) subcutaneous (SC) injection once daily in TED-C13-003 (2013-004588-30) and didn't received teduglutide in retrospective period of current study SHP633-303 (2016-000863-17).	
Reporting group title	Retrospective TED/TED Group
Reporting group description:	
Subjects who received teduglutide 0.05 mg/kg SC injection once daily in TED-C13-003 (2013-004588-30) and received teduglutide in retrospective period of current study SHP633-303 (2016-000863-17).	

Reporting group values	Retrospective TED/NTT Group	Retrospective TED/TED Group	Total
Number of subjects	24	5	29
Age Categorical Units: Subjects			
Age Continuous Units: years			
arithmetic mean	4.0	8.2	
standard deviation	± 2.88	± 5.50	-
Gender Categorical Units: Subjects			
Female	9	0	9
Male	15	5	20
Race (NIH/OMB) Units: Subjects			
White	20	3	23
Black or African American	2	1	3
Asian	0	1	1
Other	2	0	2
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	9	1	10
Not Hispanic or Latino	15	3	18
Not allowed based on local regulations	0	1	1

End points

End points reporting groups

Reporting group title	Retrospective TED/NTT Group
Reporting group description:	
Subjects who received teduglutide 0.05 milligrams per kilogram (mg/kg) subcutaneous (SC) injection once daily in TED-C13-003 (2013-004588-30) and didn't received teduglutide in retrospective period of current study SHP633-303 (2016-000863-17).	
Reporting group title	Retrospective TED/TED Group
Reporting group description:	
Subjects who received teduglutide 0.05 mg/kg SC injection once daily in TED-C13-003 (2013-004588-30) and received teduglutide in retrospective period of current study SHP633-303 (2016-000863-17).	
Reporting group title	Prospective TED/NTT Group
Reporting group description:	
Subjects who received teduglutide 0.05 mg/kg SC injection once daily in TED-C13-003 (2013-004588-30) and didn't received teduglutide in prospective period of current study SHP633-303 (2016-000863-17) up to 24 weeks.	
Reporting group title	Prospective TED/TED Group
Reporting group description:	
Subjects who received teduglutide 0.05 mg/kg SC injection once daily in TED-C13-003 (2013-004588-30) and also received teduglutide in prospective period of current study SHP633-303 (2016-000863-17) up to 24 weeks.	

Primary: Number of Subjects With Adverse Events (AEs), Related AEs, Serious Adverse Events (SAEs) and Related SAEs of Retrospective Observation Period

End point title	Number of Subjects With Adverse Events (AEs), Related AEs, Serious Adverse Events (SAEs) and Related SAEs of Retrospective Observation Period[1]
End point description:	
An Adverse Event (AE) was any untoward medical occurrence in a clinical investigation participant administered a pharmaceutical product and that does not necessarily have a causal relationship with this treatment. A SAE was any untoward medical occurrence (whether considered to be related to investigational product or not) that at any dose: results in death, was life-threatening, requires inpatient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability/incapacity, was a congenital abnormality/birth defect, was an important medical event. Retrospective subjects (RETRO) are all subjects who consented to participation in this extension study and provided data for the retrospective period of the protocol.	
End point type	Primary
End point timeframe:	
From end of the core study (TED-C13-003 [2013-004588-30]) up to end of the current study (up to 168 weeks)	

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 statistical and comparison analyses were performed for this endpoint.

End point values	Retrospective TED/NTT Group	Retrospective TED/TED Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	24	5		
Units: Subjects				
Subjects with AEs	23	4		
Subjects with Related AEs	23	4		

Subjects with SAEs	23	4		
Subjects with Related SAEs	0	0		

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in Height for Age Z-score at Week 168 of Retrospective Observation Period

End point title	Change From Baseline in Height for Age Z-score at Week 168 of Retrospective Observation Period[2]

End point description:

Height was measured using age Z-score. Z-score was calculated as (observed value - median value of the reference population) / standard deviation value of reference population. Centers for Disease Control and Prevention (age greater than or equal to [>=] 2 years old) and World Health Organization (age less than [<] 2 years old) Z-score calculation charts are used for calculation. A negative Z-score indicates values lower than the mean while a positive Z-score indicates values higher than the mean. Change from baseline in height for age Z-score at Week 168 of retrospective observation period was reported. Retrospective subjects (RETRO) are all subjects who consented to participation in this extension study and provided data for the retrospective period of the protocol. Here, the number of subjects analysed refer to the subjects evaluable for this timepoint.

End point type	Primary

End point timeframe:

Baseline: From end of the core study (TED-C13-003 [2013-004588-30]), Week 168

Notes:

[2] - 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 statistical and comparison analyses were performed for this endpoint.

End point values	Retrospective TED/NTT Group	Retrospective TED/TED Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2	0[3]		
Units: Z-score				
arithmetic mean (standard deviation)	0.128 (± 0.0505)	()		

Notes:

[3] - Data for this end point was not planned to be collected and analysed in retrospective TED/TED group.

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in Body Weight for age Z-score at Week 168 of Retrospective Observation Period

End point title	Change From Baseline in Body Weight for age Z-score at Week 168 of Retrospective Observation Period[4]

End point description:

Body weight was measured using age Z-score. Z-score was calculated as (observed value - median value of the reference population) / standard deviation value of reference population. Centers for Disease Control and Prevention (age >= 2 years old) and World Health Organization (age < 2 years old) Z-score calculation charts are used for calculation. A negative Z-score indicates values lower than the

mean while a positive Z-score indicates values higher than the mean. Change from baseline in body weight for age Z-score at Week 168 was reported. Retrospective subjects (RETRO) are all subjects who consented to participation in this extension study and provided data for the retrospective period of the protocol. Here, the number of subjects analysed refer to the subjects evaluable for this timepoint.

End point type	Primary

End point timeframe:

Baseline: From end of the core study (TED-C13-003 [2013-004588-30]), Week 168

Notes:

[4] - 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 statistical and comparison analyses were performed for this endpoint.

End point values	Retrospective TED/NTT Group	Retrospective TED/TED Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2	0[5]		
Units: Z-score				
arithmetic mean (standard deviation)	-0.181 (± 0.0601)	()		

Notes:

[5] - Data for this end point was not planned to be collected and analysed in retrospective TED/TED group.

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in Head Circumference for Age Z-score at Week 12 of Retrospective Observation Period

End point title	Change From Baseline in Head Circumference for Age Z-score at Week 12 of Retrospective Observation Period[6]

End point description:

Head circumference was measured using age Z-score. Z-score was calculated as (observed value - median value of the reference population) / standard deviation value of reference population. Centers for Disease Control and Prevention (age >= 2 years old) and World Health Organization (age < 2 years old) Z-score calculation charts are used for calculation. A negative Z-score indicates values lower than the mean while a positive Z-score indicates values higher than the mean. Change from baseline in head circumference for age Z-score at Week 12 of retrospective observation period was reported. Retrospective subjects (RETRO) are all subjects who consented to participation in this extension study and provided data for the retrospective period of the protocol. Here, the number of subjects analysed refer to the subjects evaluable for this timepoint. Here, '99999' indicates that standard deviation was not estimated as only single subject was analysed for the specified arm.

End point type	Primary

End point timeframe:

Baseline: From end of the core study (TED-C13-003 [2013-004588-30]), Week 12

Notes:

[6] - 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 statistical and comparison analyses were performed for this endpoint.

End point values	Retrospective TED/NTT Group	Retrospective TED/TED Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[7]	1		
Units: Z-score				
arithmetic mean (standard deviation)	()	-0.260 (±		

	99999)

Notes:

[7] - Data for this end point was not planned to be collected and analysed in retrospective TED/NTT group.

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in Body Mass Index (BMI) for Age Z-score at Week 168 of Retrospective Observation Period

End point title	Change From Baseline in Body Mass Index (BMI) for Age Z-score at Week 168 of Retrospective Observation Period[8]

End point description:

BMI z-score was calculated by using the retrospective height and weight data. Z-score was calculated as (observed value - median value of the reference population) / standard deviation value of reference population. Centers for Disease Control and Prevention (age >= 2 years old) and World Health Organization (age < 2 years old) Z-score calculation charts are used for calculation. A negative Z-score indicates values lower than the mean while a positive Z-score indicates values higher than the mean. Change from baseline in height for age Z-score at Week 168 of retrospective observation period was reported. Retrospective subjects (RETRO) are all subjects who consented to participation in this extension study and provided data for the retrospective period of the protocol. Here, the number of subjects analysed refer to the subjects evaluable for this timepoint.

End point type	Primary

End point timeframe:

Baseline: From end of the core study (TED-C13-003 [2013-004588-30]), Week 168

Notes:

[8] - 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 statistical and comparison analyses were performed for this endpoint.

End point values	Retrospective TED/NTT Group	Retrospective TED/TED Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2	0[9]		
Units: Z-score				
arithmetic mean (standard deviation)	-0.283 (± 0.0646)	()		

Notes:

[9] - Data for this end point was not planned to be collected and analysed in retrospective TED/TED group.

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects With Treatment Emergent Adverse Events (TEAEs), Treatment Emergent Serious Adverse Events (TESAEs) and Adverse Events of Special Interest (AESI) of Prospective Study Period

End point title	Number of Subjects With Treatment Emergent Adverse Events (TEAEs), Treatment Emergent Serious Adverse Events (TESAEs) and Adverse Events of Special Interest (AESI) of Prospective Study Period[10]

End point description:

TEAEs are defined as AEs that started or worsened on or after the first dose of teduglutide treatment in

the core study. A SAE was any untoward medical occurrence (whether considered to be related to investigational product or not) that at any dose: results in death, was life-threatening, required inpatient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability/incapacity, was a congenital abnormality/birth defect, was an important medical event. AESI was an TEAE or TESAE of scientific and medical concern specific to the sponsor's product or program and for which ongoing monitoring and immediate notification by the investigator to the sponsor. Safety population included all enrolled subjects who provided informed consent for the prospective portion and met all the inclusion criteria.

End point type	Primary

End point timeframe:

Baseline: From end of retrospective study period up to follow-up (Week 28)

Notes:

[10] - 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 statistical and comparison analyses were performed for this endpoint.

End point values	Prospective TED/NTT Group	Prospective TED/TED Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	5	19		
Units: Subjects				
Subjects with TEAEs	4	19		
Subjects with TESAEs	3	17		
Subjects with AESI	0	0		

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in Height for Age Z-score at Cycle 6 Week 12 During the End of Each Teduglutide Treatment Period of Prospective Study Period

End point title	Change From Baseline in Height for Age Z-score at Cycle 6 Week 12 During the End of Each Teduglutide Treatment Period of Prospective Study Period[11]

End point description:

Height was measured using age Z-score. Z-score was calculated as (observed value - median value of the reference population) / standard deviation value of reference population. Centers for Disease Control and Prevention (age >= 2 years old) and World Health Organization (age < 2 years old) Z-score calculation charts are used for calculation. A negative Z-score indicates values lower than the mean while a positive Z-score indicates values higher than the mean. Change from baseline in height for age Z-score at Cycle 6 Week 12 during the end of each teduglutide treatment period in prospective study period was reported. Safety population included all enrolled subjects who provided informed consent for the prospective portion and met all the inclusion criteria. Here, the number of subjects analysed refer to the subjects evaluable for this timepoint. Since baseline scores were unavailable for TED/NTT group, data was not analysed for this arm.

End point type	Primary

End point timeframe:

Baseline: From end of retrospective study period, Cycle 6 Week 12

Notes:

[11] - 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 statistical and comparison analyses were performed for this endpoint.

End point values	Prospective TED/TED Group			
Subject group type	Reporting group			
Number of subjects analysed	3			
Units: Z-score				
arithmetic mean (standard deviation)	0.05 (± 1.068)			

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in Body Weight for Age Z-score at Cycle 6 Week 24 During the End of Each Teduglutide Treatment Period of Prospective Study Period

End point title	Change From Baseline in Body Weight for Age Z-score at Cycle 6 Week 24 During the End of Each Teduglutide Treatment Period of Prospective Study Period[12]

End point description:

Body weight was measured using age Z-score. Z-score was calculated as (observed value - median value of the reference population) / standard deviation value of reference population. Centers for Disease Control and Prevention (age >= 2 years old) and World Health Organization (age < 2 years old) Z-score calculation charts are used for calculation. A negative Z-score indicates values lower than the mean while a positive Z-score indicates values higher than the mean. Change from baseline in body weight for age Z-score at Cycle 6 Week 24 during the end of each teduglutide treatment period of prospective study period was reported. Safety population analysis. Here, the number of subjects analysed refer to the subjects evaluable for this timepoint. Here, '99999' indicates that standard deviation was not estimated as only single subject was analysed for the specified arm. Since baseline scores were unavailable for TED/NTT group, data was not analysed for this arm.

End point type	Primary

End point timeframe:

Baseline: From end of retrospective study period, Cycle 6 Week 24

Notes:

[12] - 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 statistical and comparison analyses were performed for this endpoint.

End point values	Prospective TED/TED Group			
Subject group type	Reporting group			
Number of subjects analysed	1			
Units: Z-score				
arithmetic mean (standard deviation)	-0.66 (± 99999)			

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in Body Mass Index (BMI) for Age Z-score at Cycle 6 Week 12 During the End of Each Teduglutide Treatment Period of Prospective Study Period

End point title	Change From Baseline in Body Mass Index (BMI) for Age Z-score at Cycle 6 Week 12 During the End of Each Teduglutide Treatment Period of Prospective Study Period[13]

End point description:

BMI z-score was calculated by using the height and weight data. Z-score was calculated as (observed value - median value of the reference population) / standard deviation value of reference population. Centers for Disease Control and Prevention (age >= 2 years old) and World Health Organization (age < 2 years old) Z-score calculation charts are used for calculation. A negative Z-score indicates values lower than the mean while a positive Z-score indicates values higher than the mean. Change from baseline in BMI for age Z-score at Cycle 6 Week 12 during the end of each teduglutide treatment period of prospective study period was reported. Safety population included all enrolled subjects who provided informed consent for the prospective portion and met all the inclusion criteria. Here, the number of subjects analysed refer to the subjects evaluable for this timepoint. Since baseline scores were unavailable for TED/NTT group, data was not analysed for this arm.

End point type	Primary

End point timeframe:

Baseline: From end of retrospective study period, Cycle 6 Week 12

Notes:

[13] - 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 statistical and comparison analyses were performed for this endpoint.

End point values	Prospective TED/TED Group			
Subject group type	Reporting group			
Number of subjects analysed	3			
Units: Z-score				
arithmetic mean (standard deviation)	-0.68 (± 0.349)			

Statistical analyses

No statistical analyses for this end point

Primary: Average Total 48-Hour Urine Output at Cycle 6 Week 12 During the End of Each Teduglutide Treatment Period of Prospective Study Period

End point title	Average Total 48-Hour Urine Output at Cycle 6 Week 12 During the End of Each Teduglutide Treatment Period of Prospective Study Period[14]

End point description:

Average total urine output was calculated based on the daily data recorded in subjects' diaries over a 48-hour period of nutritional stability prior to each scheduled visit. Average total 48-Hour urine output at cycle 6 week 12 during the end of each teduglutide treatment period of prospective study period was reported. Safety population included all enrolled subjects who provided informed consent for the prospective portion and met all the inclusion criteria. Here, mL/kg/day is abbreviated as milliliter per kilogram per day. Here, the number of subjects analysed refer to the subjects evaluable for this time point. Since baseline scores were unavailable for TED/NTT group, data was not analysed for this arm.

End point type	Primary

End point timeframe:

Baseline: From end of retrospective study period, Cycle 6 Week 12

Notes:

[14] - 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 statistical and comparison analyses were performed for this endpoint.

End point values	Prospective TED/TED Group			
Subject group type	Reporting group			
Number of subjects analysed	3			
Units: mL/kg/day				
arithmetic mean (standard deviation)	14.38 (± 12.712)			

Statistical analyses

No statistical analyses for this end point

Primary: Average Total 48-Hour Urine Output at End of Study (EOS) During the End of Non-Teduglutide Treatment (NTT) Period of Prospective Study Period

End point title	Average Total 48-Hour Urine Output at End of Study (EOS) During the End of Non-Teduglutide Treatment (NTT) Period of Prospective Study Period[15]

End point description:

Average total urine output was calculated based on the daily data recorded in subjects' diaries over a 48-hour period of nutritional stability prior to each scheduled visit. Average total 48-Hour urine output at EOS during the end of NTT period in prospective study period was reported. Safety population included all enrolled subjects who provided informed consent for the prospective portion and met all the inclusion criteria. Here, the number of subjects analysed refer to the subjects evaluable for this timepoint.

End point type	Primary

End point timeframe:

Baseline: From end of retrospective study period, EOS (up to Week 28)

Notes:

[15] - 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 statistical and comparison analyses were performed for this endpoint.

End point values	Prospective TED/NTT Group	Prospective TED/TED Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2	0[16]		
Units: mL/kg/day				
arithmetic mean (standard deviation)	22.86 (± 9.956)	()		

Notes:

[16] - Data for this end point was not planned to be collected and analysed in prospective TED/TED group.

Statistical analyses

No statistical analyses for this end point

Primary: Average Number of Stools per Day at Cycle 6 Week 24 During the End of Each Teduglutide Treatment Period of Prospective Study Period

End point title	Average Number of Stools per Day at Cycle 6 Week 24 During the End of Each Teduglutide Treatment Period of Prospective Study Period[17]

End point description:

Average number of stools per day was calculated based on the daily data recorded in subjects' diaries over a 48-hour period of nutritional stability prior to each scheduled visit. Average number of stools per day at cycle 6 week 24 during the end of each teduglutide treatment period in prospective study period was reported. Safety population included all enrolled subjects who provided informed consent for the prospective portion and met all the inclusion criteria. Here, the number of subjects analysed refer to the subjects evaluable for this timepoint. Here, '99999' indicates that standard deviation was not estimated as only single subject was analysed for the specified arm. Since baseline scores were unavailable for TED/NTT group, data was not analysed for this arm.

End point type	Primary

End point timeframe:

Baseline: From end of retrospective study period, Cycle 6 Week 24

Notes:

[17] - 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 statistical and comparison analyses were performed for this endpoint.

End point values	Prospective TED/TED Group			
Subject group type	Reporting group			
Number of subjects analysed	1			
Units: Stools per day				
arithmetic mean (standard deviation)	5.50 (± 99999)			

Statistical analyses

No statistical analyses for this end point

Primary: Average Number of Stools per Day at End of Study (EOS) During the End of Non-Teduglutide Treatment (NTT) Period of Prospective Study Period

End point title	Average Number of Stools per Day at End of Study (EOS) During the End of Non-Teduglutide Treatment (NTT) Period of Prospective Study Period[18]

End point description:

Average number of stools per day was calculated based on the daily data recorded in subjects' diaries over a 48-hour period of nutritional stability prior to each scheduled visit. Average number of stools per day at EOS during the end of each teduglutide treatment period in prospective study period was reported. Safety population included all enrolled subjects who provided informed consent for the prospective portion and met all the inclusion criteria. Here, the number of subjects analysed refer to the subjects evaluable for this timepoint.

End point type	Primary

End point timeframe:

Baseline: From end of retrospective study period, EOS (up to Week 28)

Notes:

[18] - 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 statistical and comparison analyses were performed for this endpoint.

End point values	Prospective TED/NTT Group	Prospective TED/TED Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2	0[19]		
Units: Stools per day				
arithmetic mean (standard deviation)	3.75 (± 3.182)	()		

Notes:

[19] - Data for this end point was not planned to be collected and analysed in prospective TED/TED group.

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects With Positive Specific Antibodies at End of Study (EOS) During the End of Each Teduglutide Treatment Period of Prospective Study Period

End point title	Number of Subjects With Positive Specific Antibodies at End of Study (EOS) During the End of Each Teduglutide Treatment Period of Prospective Study Period[20]

End point description:

Number of subjects with positive specific antibodies to teduglutide were used to summarize the presence of antibodies. Safety population included all enrolled subjects who provided informed consent for the prospective portion and met all the inclusion criteria. Here, the number of subjects analysed refer to the subjects evaluable for this timepoint. Since baseline scores were unavailable for TED/NTT group, data was not analysed for this arm.

End point type	Primary

End point timeframe:

Baseline: From end of retrospective study period, EOS (up to Week 28)

Notes:

[20] - 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 statistical and comparison analyses were performed for this endpoint.

End point values	Prospective TED/TED Group			
Subject group type	Reporting group			
Number of subjects analysed	7			
Units: Subjects	1			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants Achieved At least 20 Percent (%) Reduction in Parenteral Support (PS) Volume at 12 Weeks Interval up to Week 156 of Retrospective Observation Period

End point title	Number of Participants Achieved At least 20 Percent (%) Reduction in Parenteral Support (PS) Volume at 12 Weeks Interval up to Week 156 of Retrospective Observation Period

End point description:

Number of participants achieved at least 20% reduction in PS volume at 12 weeks interval up to Week 156 in retrospective observation period was reported. Retrospective subjects (RETRO) are all subjects who consented to participation in this extension study and provided data for the retrospective portion of

the protocol. Here, n=number of subjects analysed refer to the subjects evaluable for this timepoints.

End point type	Secondary

End point timeframe:

Baseline: From end of the core study (TED-C13-003 [2013-004588-30]) at 12 weeks interval up to Week 156

End point values	Retrospective TED/NTT Group	Retrospective TED/TED Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	24	5		
Units: Subjects				
at 12 weeks (n=24, 5)	12	2		
at 24 weeks (n=23, 5)	9	2		
at 36 weeks (n=24, 4)	9	4		
at 48 weeks (n=23, 4)	9	4		
at 60 weeks (n=23, 5)	9	4		
at 72 weeks (n=22, 5)	6	2		
at 84 weeks (n=22, 5)	7	2		
at 96 weeks (n=24, 5)	10	5		
at 108 weeks (n=24, 5)	9	5		
at 120 weeks (n=22, 5)	10	4		
at 132 weeks (n=14, 4)	7	4		
at 144 weeks (n=8, 1)	3	1		
at 156 weeks (n=2, 1)	0	1		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Parenteral Support (PS) Volume at 12 Weeks Interval up to Week 156 of Retrospective Observation Period

End point title	Change From Baseline in Parenteral Support (PS) Volume at 12 Weeks Interval up to Week 156 of Retrospective Observation Period

End point description:

Change from baseline in PS volume at 12 weeks interval up to Week 156 in retrospective observation period was reported. Here, milliliter per kilogram per day is abbreviated as mL/kg/day. Retrospective subjects (RETRO) are all subjects who consented to participation in this extension study and provided data for the retrospective portion of the protocol. Here, n=number of subjects analysed refer to the subjects evaluable for this timepoints. Here, '99999' indicates that standard deviation was not estimated as only single subject was analysed for the specified arm.

End point type	Secondary

End point timeframe:

Baseline: From end of the core study (TED-C13-003 [2013-004588-30]) at 12 weeks interval up to Week 156

End point values	Retrospective TED/NTT Group	Retrospective TED/TED Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	24	5		
Units: mL/kg/day				
arithmetic mean (standard deviation)				
Change at 12 weeks (n=23, 5)	-14.45 (± 17.770)	-12.84 (± 17.694)		
Change at 24 weeks (n=24, 4)	-9.27 (± 21.642)	-13.49 (± 14.530)		
Change at 36 weeks (n=23, 5)	-10.65 (± 20.877)	-17.91 (± 17.069)		
Change at 48 weeks (n=23, 4)	-12.24 (± 29.646)	-26.12 (± 8.044)		
Change at 60 weeks (n=23, 5)	-13.85 (± 30.219)	-21.35 (± 12.285)		
Change at 72 weeks (n=22, 5)	-13.65 (± 30.577)	-11.41 (± 22.030)		
Change at 84 weeks (n=22, 5)	-8.74 (± 36.078)	-15.65 (± 19.603)		
Change at 96 weeks (n=24, 5)	-12.87 (± 37.996)	-27.34 (± 16.531)		
Change at 108 weeks (n=24, 5)	-10.35 (± 29.370)	-31.83 (± 14.872)		
Change at 120 weeks (n=22, 5)	-12.21 (± 27.480)	-30.48 (± 19.043)		
Change at 132 weeks (n=14, 4)	-19.20 (± 26.171)	-37.70 (± 12.296)		
Change at 144 weeks (n=8, 1)	-16.79 (± 29.620)	-34.32 (± 99999)		
Change at 156 weeks (n=2, 1)	-7.46 (± 1.931)	-34.43 (± 99999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percent Change From Baseline in Parenteral Support (PS) Volume at 12 Weeks Interval up to Week 156 of Retrospective Observation Period

End point title	Percent Change From Baseline in Parenteral Support (PS) Volume at 12 Weeks Interval up to Week 156 of Retrospective Observation Period

End point description:

Percent change from baseline in PS volume at 12 weeks interval up to Week 156 of retrospective observation period was reported. Retrospective subjects (RETRO) are all subjects who consented to participation in this extension study and provided data for the retrospective portion of the protocol. Here, n=number of subjects analysed refer to the subjects evaluable for this timepoints. Here, '99999' indicates that standard deviation was not estimated as only single subject was analysed for the specified arm.

End point type	Secondary

End point timeframe:

Baseline: From end of the core study (TED-C13-003 [2013-004588-30]) at 12 weeks interval up to Week 156

End point values	Retrospective TED/NTT Group	Retrospective TED/TED Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	24	5		
Units: Percent change				
arithmetic mean (standard deviation)				
Percent change at 12 weeks (n=23, 5)	-24.50 (± 27.853)	-24.88 (± 35.649)		
Percent change at 24 weeks (n=24, 4)	-10.72 (± 33.081)	-32.10 (± 31.645)		
Percent change at 36 weeks (n=23, 5)	-13.21 (± 34.172)	-43.09 (± 42.753)		
Percent change at 48 weeks (n=23, 4)	-14.04 (± 39.390)	-65.18 (± 31.650)		
Percent change at 60 weeks (n=23, 5)	-16.15 (± 39.491)	-53.61 (± 37.141)		
Percent change at 72 weeks (n=22, 5)	-14.19 (± 40.558)	-14.11 (± 58.452)		
Percent change at 84 weeks (n=22, 5)	-8.67 (± 47.108)	-30.25 (± 39.598)		
Percent change at 96 weeks (n=24, 5)	-12.04 (± 51.631)	-61.19 (± 29.335)		
Percent change at 108 weeks (n=24, 5)	-10.62 (± 48.820)	-73.43 (± 29.298)		
Percent change at 120 weeks (n=22, 5)	-12.89 (± 49.366)	-69.61 (± 39.194)		
Percent change at 132 weeks (n=14, 4)	-20.24 (± 47.431)	-85.92 (± 17.457)		
Percent change at 144 weeks (n=8, 1)	-7.70 (± 44.170)	-65.20 (± 99999)		
Percent change at 156 weeks (n=2, 1)	-17.21 (± 3.164)	-65.42 (± 99999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Parenteral Support (PS) Caloric Intake at 12 Weeks Interval up to Week 156 of Retrospective Observation Period

End point title	Change From Baseline in Parenteral Support (PS) Caloric Intake at 12 Weeks Interval up to Week 156 of Retrospective Observation Period

End point description:

Change from baseline in PS caloric intake at 12 weeks interval up to Week 156 of retrospective observation period was reported. Here, kilo-calories per kilogram per day was abbreviated as (kcal/kg/day). Retrospective subjects (RETRO) are all subjects who consented to participation in this extension study and provided data for the retrospective portion of the protocol. Here, n=number of subjects analysed refer to the subjects evaluable for this timepoints. Here, '99999' indicates that standard deviation was not estimated as only single subject was analysed for the specified arm.

End point type	Secondary

End point timeframe:

Baseline: From end of the core study (TED-C13-003 [2013-004588-30]) at 12 weeks interval up to Week 156

End point values	Retrospective TED/NTT Group	Retrospective TED/TED Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	24	5		
Units: kcal/kg/day				
arithmetic mean (standard deviation)				
Change at 12 weeks (n=23, 5)	-10.15 (± 13.026)	-2.64 (± 18.739)		
Change at 24 weeks (n=23, 4)	-3.96 (± 16.970)	-7.25 (± 11.916)		
Change at 36 weeks (n=22, 5)	-8.38 (± 17.148)	-6.42 (± 24.547)		
Change at 48 weeks (n=22, 4)	-9.84 (± 22.144)	-18.11 (± 7.896)		
Change at 60 weeks (n=22, 5)	-10.55 (± 23.136)	-10.53 (± 18.538)		
Change at 72 weeks (n=21, 5)	-12.64 (± 23.642)	-0.05 (± 23.552)		
Change at 84 weeks (n=21, 5)	-9.70 (± 24.860)	-5.24 (± 23.064)		
Change at 96 weeks (n=23, 5)	-10.08 (± 23.998)	-15.09 (± 18.604)		
Change at 108 weeks (n=23, 5)	-7.20 (± 22.875)	-19.05 (± 18.229)		
Change at 120 weeks (n=21, 5)	-7.98 (± 21.425)	-17.18 (± 23.169)		
Change at 132 weeks (n=13, 4)	-12.93 (± 18.744)	-27.59 (± 5.114)		
Change at 144 weeks (n=8, 1)	-11.97 (± 17.977)	-25.53 (± 99999)		
Change at 156 weeks (n=2, 1)	-6.55 (± 4.708)	-25.67 (± 99999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percent Change From Baseline in Parenteral Support (PS) Caloric Intake at 12 Weeks Interval up to Week 156 of Retrospective Observation Period

End point title	Percent Change From Baseline in Parenteral Support (PS) Caloric Intake at 12 Weeks Interval up to Week 156 of Retrospective Observation Period

End point description:

Percent change from baseline in PS caloric intake at 12 weeks interval up to Week 156 of retrospective observation period was reported. Retrospective subjects (RETRO) are all subjects who consented to participation in this extension study and provided data for the retrospective portion of the protocol. Here, n=number of subjects analysed refer to the subjects evaluable for this timepoints. Here, '99999' indicates that standard deviation was not estimated as only single subject was analysed for the specified arm.

End point type	Secondary

End point timeframe:

Baseline: From end of the core study (TED-C13-003 [2013-004588-30]) at 12 weeks interval up to Week 156

End point values	Retrospective TED/NTT Group	Retrospective TED/TED Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	24	5		
Units: Percent change				
arithmetic mean (standard deviation)				
Percent change at 12 weeks (n=23, 5)	-24.91 (± 29.001)	7.64 (± 82.061)		
Percent change at 24 weeks (n=23, 4)	-10.12 (± 42.431)	-21.29 (± 37.759)		
Percent change at 36 weeks (n=22, 5)	-18.29 (± 41.070)	-3.38 (± 118.167)		
Percent change at 48 weeks (n=22, 4)	-21.03 (± 43.924)	-59.31 (± 38.042)		
Percent change at 60 weeks (n=22, 5)	-20.63 (± 44.903)	-25.65 (± 83.470)		
Percent change at 72 weeks (n=21, 5)	-25.48 (± 45.035)	23.26 (± 99.380)		
Percent change at 84 weeks (n=21, 5)	-20.42 (± 45.287)	4.41 (± 102.162)		
Percent change at 96 weeks (n=23, 5)	-21.12 (± 46.005)	-36.49 (± 72.357)		
Percent change at 108 weeks (n=23, 5)	-16.41 (± 46.034)	-50.24 (± 70.513)		
Percent change at 120 weeks (n=21, 5)	-18.79 (± 45.774)	-38.58 (± 97.750)		
Percent change at 132 weeks (n=13, 4	-29.37 (± 40.170)	-82.01 (± 21.165)		
Percent change at 144 weeks (n=8, 1)	-25.25 (± 33.618)	-60.36 (± 99999)		
Percent change at 156 weeks (n=2, 1)	-15.66 (± 7.700)	-60.69 (± 99999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Number of Hours per Day of Parenteral Support (PS) Usage at 12 Weeks Interval up to Week 156 of Retrospective Observation Period

End point title	Change From Baseline in Number of Hours per Day of Parenteral Support (PS) Usage at 12 Weeks Interval up to Week 156 of Retrospective Observation Period

End point description:

Change from baseline were not presented as prescribed hours per day were not collected at baseline in the core study.

End point type	Secondary

End point timeframe:

Baseline: From end of the core study (TED-C13-003 [2013-004588-30]) up to Week 156

End point values	Retrospective TED/NTT Group	Retrospective TED/TED Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[21]	0[22]		
Units: Hours per day				
arithmetic mean (standard deviation)	()	()		

Notes:

[21] - Data was not collected at baseline in the core study.
[22] - Data was not collected at baseline in the core study.

Statistical analyses

No statistical analyses for this end point

Secondary: Percent Change From Baseline in Number of Hours per Day of Parenteral Support (PS) Usage at 12 Weeks Interval up to Week 156 of Retrospective Observation Period

End point title	Percent Change From Baseline in Number of Hours per Day of Parenteral Support (PS) Usage at 12 Weeks Interval up to Week 156 of Retrospective Observation Period

End point description:

Percent changes from baseline was not presented as prescribed hours per day were not collected at baseline in the core study.

End point type	Secondary

End point timeframe:

Baseline: From end of the core study (TED-C13-003 [2013-004588-30]) up to Week 156

End point values	Retrospective TED/NTT Group	Retrospective TED/TED Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[23]	0[24]		
Units: Percent Change				
arithmetic mean (standard deviation)	()	()		

Notes:

[23] - Data was not collected at baseline in the core study.
[24] - Data was not collected at baseline in the core study.

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Number of Days per Week of Parenteral

Support (PS) Usage at 12 Weeks Interval up to Week 156 of Retrospective Observation Period

End point title	Change From Baseline in Number of Days per Week of Parenteral Support (PS) Usage at 12 Weeks Interval up to Week 156 of Retrospective Observation Period

End point description:

Change from baseline in number of days per Week of PS usage at 12 weeks interval up to Week 156 in retrospective observation period was reported. Retrospective subjects (RETRO) are all subjects who consented to participation in this extension study and provided data for the retrospective portion of the protocol. Here, n=number of subjects analysed refer to the subjects evaluable for this timepoints. Here, '99999' indicates that standard deviation was not estimated as only single subject was analysed for the specified arm.

End point type	Secondary

End point timeframe:

Baseline: From end of the core study (TED-C13-003 [2013-004588-30]) at 12 weeks interval up to Week 156

End point values	Retrospective TED/NTT Group	Retrospective TED/TED Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	24	5		
Units: Days per week				
arithmetic mean (standard deviation)				
Change at 12 weeks (n=24, 5)	-0.38 (± 1.469)	-1.20 (± 2.683)		
Change at 24 weeks (n=24, 4)	-0.29 (± 1.429)	-1.00 (± 2.000)		
Change at 36 weeks (n=23, 5)	-0.43 (± 1.562)	-2.60 (± 2.793)		
Change at 48 weeks (n=23, 4)	-0.61 (± 2.017)	-4.50 (± 2.082)		
Change at 60 weeks (n=23, 5)	-0.61 (± 2.017)	-3.00 (± 3.536)		
Change at 72 weeks (n=22, 5)	-0.64 (± 2.060)	-1.40 (± 2.966)		
Change at 84 weeks (n=22, 5)	-0.64 (± 2.060)	-1.40 (± 2.966)		
Change at 96 weeks (n=24, 5)	-1.17 (± 2.665)	-2.00 (± 3.536)		
Change at 108 weeks (n=24, 5)	-0.88 (± 2.365)	-3.80 (± 3.701)		
Change at 120 weeks (n=22, 5)	-0.95 (± 2.459)	-3.80 (± 3.701)		
Change at 132 weeks (n=14, 4)	-1.00 (± 2.542)	-5.25 (± 2.062)		
Change at 144 weeks (n=8, 1)	0.00 (± 0.000)	-3.00 (± 99999)		
Change at 156 weeks (n=2, 1)	0.00 (± 0.000)	-3.00 (± 99999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percent Change From Baseline in Number of Days per Week of Parenteral Support (PS) Usage at 12 Weeks Interval up to Week 156 of Retrospective Observation Period

End point title	Percent Change From Baseline in Number of Days per Week of Parenteral Support (PS) Usage at 12 Weeks Interval up to Week 156 of Retrospective Observation Period

End point description:

Percent change from baseline in number of days per Week of PS usage at 12 weeks interval up to Week 156 in retrospective observation period was reported. Retrospective subjects (RETRO) are all subjects who consented to participation in this extension study and provided data for the retrospective portion of the protocol. Here, n=number of subjects analysed refer to the subjects evaluable for this timepoints. Here, '99999' indicates that standard deviation was not estimated as only single subject was analysed for the specified arm.

End point type	Secondary

End point timeframe:

Baseline: From end of the core study (TED-C13-003 [2013-004588-30]) at 12 weeks interval up to Week 156

End point values	Retrospective TED/NTT Group	Retrospective TED/TED Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	24	5		
Units: Percent change				
arithmetic mean (standard deviation)				
Percent change at 12 weeks (n=24, 5)	-6.25 (± 22.421)	-14.86 (± 41.913)		
Percent change at 24 weeks (n=24, 4)	-4.17 (± 20.412)	-14.29 (± 28.571)		
Percent change at 36 weeks (n=23, 5)	-6.21 (± 22.309)	-34.86 (± 44.648)		
Percent change at 48 weeks (n=23, 4)	-8.70 (± 28.810)	-64.29 (± 29.738)		
Percent change at 60 weeks (n=23, 5)	-8.70 (± 28.810)	-40.57 (± 54.638)		
Percent change at 72 weeks (n=22, 5)	-9.09 (± 29.424)	-17.71 (± 45.821)		
Percent change at 84 weeks (n=22, 5)	-9.09 (± 29.424)	-17.71 (± 45.821)		
Percent change at 96 weeks (n=24, 5)	-16.67 (± 38.069)	-26.29 (± 53.886)		
Percent change at 108 weeks (n=24, 5)	-12.50 (± 33.783)	-52.00 (± 57.407)		
Percent change at 120 weeks (n=22, 5)	-13.64 (± 35.125)	-52.00 (± 57.407)		
Percent change at 132 weeks (n=14, 4)	-14.29 (± 36.314)	-75.00 (± 29.451)		
Percent change at 144 weeks (n=8, 1)	0.00 (± 0.000)	-42.86 (± 99999)		
Percent change at 156 weeks (n=2, 1)	0.00 (± 0.000)	-42.86 (± 99999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants Who Achieved At least 20, 50 and 75 Percent (%) Reduction in Parenteral Support (PS) Volume at End of Treatment (EOT) of Each Cycle During the End of Each Teduglutide Treatment Period of Prospective Study Period

End point title	Number of Participants Who Achieved At least 20, 50 and 75 Percent (%) Reduction in Parenteral Support (PS) Volume at End of Treatment (EOT) of Each Cycle During the End of Each Teduglutide Treatment Period of Prospective Study Period

End point description:

Number of participants who achieved at least 20, 50 and 75% reduction in PS volume at EOT of each cycle during the end of each teduglutide treatment period in prospective study period was reported. Safety population included all enrolled subjects who provided informed consent for the prospective portion and met all the inclusion criteria. Here, n=number of subjects analysed refer to the subjects evaluable for this endpoint at specific categories.

End point type	Secondary

End point timeframe:

Baseline: From end of retrospective study period, EOT of each cycle (up to Week 24)

End point values	Prospective TED/TED Group			
Subject group type	Reporting group			
Number of subjects analysed	19			
Units: Subjects				
Cycle 1: EOT at >= 20% (n=19)	13			
Cycle 2: EOT at >= 20% (n=17)	12			
Cycle 3: EOT at >= 20% (n=14)	10			
Cycle 4: EOT at >= 20% (n=13)	9			
Cycle 5: EOT at >= 20% (n=8)	7			
Cycle 6: EOT at >= 20% (n=5)	5			
Cycle 1: EOT at >= 50% (n=19)	5			
Cycle 2: EOT at >= 50% (n=17)	10			
Cycle 3: EOT at >= 50% (n=14)	9			
Cycle 4: EOT at >= 50% (n=13)	9			
Cycle 5: EOT at >= 50% (n=8)	5			
Cycle 6: EOT at >= 50% (n=5)	4			
Cycle 1: EOT at >= 75% (n=19)	2			
Cycle 2: EOT at >= 75% (n=17)	4			
Cycle 3: EOT at >= 75% (n=14)	6			
Cycle 4: EOT at >= 75% (n=13)	5			
Cycle 5: EOT at >= 75% (n=8)	4			

Cycle 6: EOT at >= 75% (n=5)	3			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Parenteral Support (PS) Volume at End of Treatment (EOT) of Each Cycle During the End of Each Teduglutide Treatment Period of Prospective Study Period

End point title	Change From Baseline in Parenteral Support (PS) Volume at End of Treatment (EOT) of Each Cycle During the End of Each Teduglutide Treatment Period of Prospective Study Period

End point description:

Change from baseline in PS volume at EOT of each cycle during the end of each teduglutide treatment period in prospective study period was reported. Safety population included all enrolled subjects who provided informed consent for the prospective portion and met all the inclusion criteria. Here, n=number of subjects analysed refer to the subjects evaluable for this endpoint at specific categories.

End point type	Secondary

End point timeframe:

Baseline: From end of retrospective study period, EOT of each cycle (up to Week 24)

End point values	Prospective TED/TED Group			
Subject group type	Reporting group			
Number of subjects analysed	19			
Units: mL/kg/day				
arithmetic mean (standard deviation)				
Cycle 1: EOT (n=18)	-25.18 (± 19.915)			
Cycle 2: EOT (n=16)	-28.59 (± 29.856)			
Cycle 3: EOT (n=13)	-40.05 (± 29.711)			
Cycle 4: EOT (n=12)	-40.10 (± 30.359)			
Cycle 5: EOT (n=7)	-40.49 (± 24.259)			
Cycle 6: EOT (n=5)	-47.57 (± 26.243)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percent Change From Baseline in Parenteral Support (PS) Volume at End

of Treatment (EOT) of Each Cycle During the End of Each Teduglutide Treatment Period of Prospective Study Period

End point title	Percent Change From Baseline in Parenteral Support (PS) Volume at End of Treatment (EOT) of Each Cycle During the End of Each Teduglutide Treatment Period of Prospective Study Period

End point description:

Percent change from baseline in PS volume at EOT of each cycle during the end of each teduglutide treatment period in prospective study period. Safety population included all enrolled subjects who provided informed consent for the prospective portion and met all the inclusion criteria. Here, n=number of subjects analysed refer to the subjects evaluable for this endpoint at specific categories.

End point type	Secondary

End point timeframe:

Baseline: From end of retrospective study period, EOT of each cycle (up to Week 24)

End point values	Prospective TED/TED Group			
Subject group type	Reporting group			
Number of subjects analysed	19			
Units: Percent Change				
arithmetic mean (standard deviation)				
Cycle 1: EOT (n=18)	-38.02 (± 28.611)			
Cycle 2: EOT (n=16)	-45.58 (± 48.150)			
Cycle 3: EOT (n=13)	-62.16 (± 41.805)			
Cycle 4: EOT (n=12)	-62.92 (± 38.466)			
Cycle 5: EOT (n=7)	-73.49 (± 34.593)			
Cycle 6: EOT (n=5)	-78.75 (± 33.949)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Parenteral Support (PS) Caloric Intake at End of Treatment (EOT) of Each Cycle During the End of Each Teduglutide Treatment Period of Prospective Study Period

End point title	Change From Baseline in Parenteral Support (PS) Caloric Intake at End of Treatment (EOT) of Each Cycle During the End of Each Teduglutide Treatment Period of Prospective Study Period

End point description:

Change from baseline in PS caloric intake at EOT of each cycle during the end of each teduglutide treatment period in prospective study period was reported. Safety population included all enrolled subjects who provided informed consent for the prospective portion and met all the inclusion criteria. Here, n=number of subjects analysed refer to the subjects evaluable for this endpoint at specific categories.

End point type	Secondary

End point timeframe:

Baseline: From end of retrospective study period, EOT of each cycle (up to Week 24)

End point values	Prospective TED/TED Group			
Subject group type	Reporting group			
Number of subjects analysed	19			
Units: kcal/kg/day				
arithmetic mean (standard deviation)				
Cycle 1: EOT (N= 19)	-17.66 (± 17.649)			
Cycle 2: EOT (n=17)	-19.95 (± 23.402)			
Cycle 3: EOT (n=14)	-27.66 (± 19.668)			
Cycle 4: EOT (n=13)	-24.05 (± 22.746)			
Cycle 5: EOT (n=8)	-26.98 (± 27.465)			
Cycle 6: EOT (n=5)	-27.53 (± 32.486)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percent Change From Baseline in Parenteral Support (PS) Caloric Intake at End of Treatment (EOT) of Each Cycle During the End of Each Teduglutide Treatment Period of Prospective Study Period

End point title	Percent Change From Baseline in Parenteral Support (PS) Caloric Intake at End of Treatment (EOT) of Each Cycle During the End of Each Teduglutide Treatment Period of Prospective Study Period

End point description:

Percent change from baseline in PS caloric intake at EOT of each cycle during the end of each teduglutide treatment period in prospective study period was reported. Safety population included all enrolled subjects who provided informed consent for the prospective portion and met all the inclusion criteria. Here, n=number of subjects analysed refer to the subjects evaluable for this endpoint at specific categories.

End point type	Secondary

End point timeframe:

Baseline: From end of retrospective study period, EOT of each cycle (up to Week 24)

End point values	Prospective TED/TED Group			
Subject group type	Reporting group			
Number of subjects analysed	19			
Units: Percent change				
arithmetic mean (standard deviation)				
Cycle 1: EOT (n=19)	-33.50 (± 40.439)			
Cycle 2: EOT (n=17)	-42.06 (± 44.077)			
Cycle 3: EOT (n=14)	-62.47 (± 37.677)			
Cycle 4: EOT (n=13)	-49.51 (± 54.041)			
Cycle 5: EOT (n=8)	-54.08 (± 64.002)			
Cycle 6: EOT (n=5)	-59.00 (± 57.267)			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects Who Achieved 100 Percent (%) Reduction in Complete Weaning of Parenteral Support (PS) Volume at End of Treatment (EOT) of Each Cycle During the End of Each Teduglutide Treatment Period of Prospective Study Period

End point title	Number of Subjects Who Achieved 100 Percent (%) Reduction in Complete Weaning of Parenteral Support (PS) Volume at End of Treatment (EOT) of Each Cycle During the End of Each Teduglutide Treatment Period of Prospective Study Period

End point description:

Number of subjects who achieved at least 100% reduction in complete weaning of PS volume at EOT of each cycle during the end of each teduglutide treatment period in prospective study period was reported. Safety population included all enrolled subjects who provided informed consent for the prospective portion and met all the inclusion criteria. Here, n=number of subjects analysed refer to the subjects evaluable for this endpoint at specific categories.

End point type	Secondary

End point timeframe:

Baseline: From end of retrospective study period, EOT of each cycle (up to Week 24)

End point values	Prospective TED/TED Group			
Subject group type	Reporting group			
Number of subjects analysed	19			
Units: Subjects				
Cycle 1: EOT (n=19)	1			
Cycle 2: EOT (n=17)	3			
Cycle 3: EOT (n=14)	6			
Cycle 4: EOT (n=13)	5			

Cycle 5: EOT (n=8)	4			
Cycle 6: EOT (n=5)	3			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Number of Hours per Day of Parenteral Support (PS) Usage at End of Treatment (EOT) of Each Cycle During the End of Each Teduglutide Treatment Period of Prospective Study Period

End point title	Change From Baseline in Number of Hours per Day of Parenteral Support (PS) Usage at End of Treatment (EOT) of Each Cycle During the End of Each Teduglutide Treatment Period of Prospective Study Period

End point description:

Change from baseline in number of hours per day of PS usage at EOT of each cycle during the end of each teduglutide treatment period in prospective study period was reported. Safety population included all enrolled subjects who provided informed consent for the prospective portion and met all the inclusion criteria. Here, n=number of subjects analysed refer to the subjects evaluable for this endpoint at specific categories.

End point type	Secondary

End point timeframe:

Baseline: From end of retrospective study period, EOT of each cycle (up to Week 24)

End point values	Prospective TED/TED Group			
Subject group type	Reporting group			
Number of subjects analysed	19			
Units: Hours per day				
arithmetic mean (standard deviation)				
Cycle 1: EOT (n=18)	-3.40 (± 3.752)			
Cycle 2: EOT (n=16)	-4.80 (± 5.360)			
Cycle 3: EOT (n=13)	-6.69 (± 4.247)			
Cycle 4: EOT (n=12)	-6.48 (± 4.881)			
Cycle 5: EOT (n=7)	-6.71 (± 6.175)			
Cycle 6: EOT (n=5)	-8.08 (± 6.075)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percent Change From Baseline in Number of Hours per Day of Parenteral Support (PS) Usage at End of Treatment (EOT) of Each Cycle During the End of Each Teduglutide Treatment Period of Prospective Study Period

End point title	Percent Change From Baseline in Number of Hours per Day of Parenteral Support (PS) Usage at End of Treatment (EOT) of Each Cycle During the End of Each Teduglutide Treatment Period of Prospective Study Period

End point description:

Percent change from baseline in number of hours per day of PS usage at EOT of each cycle during the end of each teduglutide treatment period in prospective study period was reported. Safety population included all enrolled subjects who provided informed consent for the prospective portion and met all the inclusion criteria. Here, n=number of subjects analysed refer to the subjects evaluable for this endpoint at specific categories.

End point type	Secondary

End point timeframe:

Baseline: From end of retrospective study period, EOT of each cycle (up to Week 24)

End point values	Prospective TED/TED Group			
Subject group type	Reporting group			
Number of subjects analysed	19			
Units: Percent change				
arithmetic mean (standard deviation)				
Cycle 1: EOT (n=18)	-26.32 (± 29.732)			
Cycle 2: EOT (n=16)	-40.47 (± 40.476)			
Cycle 3: EOT (n=13)	-57.61 (± 36.973)			
Cycle 4: EOT (n=12)	-55.87 (± 42.693)			
Cycle 5: EOT (n=7)	-58.85 (± 52.717)			
Cycle 6: EOT (n=5)	-66.39 (± 46.042)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Number of Days per Week of Parenteral Support (PS) Usage at End of Treatment (EOT) of Each Cycle During the End of Each Teduglutide Treatment Period of Prospective Study Period

End point title	Change From Baseline in Number of Days per Week of Parenteral Support (PS) Usage at End of Treatment (EOT) of Each Cycle During the End of Each Teduglutide Treatment Period of Prospective Study Period

End point description:

Change from baseline in number of days per week of PS usage at EOT of each cycle during the end of each teduglutide treatment period in prospective study period was reported. Safety population included all enrolled subjects who provided informed consent for the prospective portion and met all the inclusion criteria. Here, n=number of subjects analysed refer to the subjects evaluable for this endpoint at specific

categories.

End point type	Secondary

End point timeframe:

Baseline: From end of retrospective study period, EOT of each cycle (up to Week 24)

End point values	Prospective TED/TED Group			
Subject group type	Reporting group			
Number of subjects analysed	19			
Units: Days per week				
arithmetic mean (standard deviation)				
Cycle 1: EOT (n=18)	-0.60 (± 1.892)			
Cycle 2: EOT (n=16)	-1.93 (± 2.840)			
Cycle 3: EOT (n=13)	-3.03 (± 3.257)			
Cycle 4: EOT (n=12)	-2.99 (± 3.610)			
Cycle 5: EOT (n=7)	-3.83 (± 3.969)			
Cycle 6: EOT (n=5)	-4.37 (± 3.618)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percent Change From Baseline in Number of Days per Week of Parenteral Support (PS) Usage at End of Treatment (EOT) of Each Cycle During the End of Each Teduglutide Treatment Period of Prospective Study Period

End point title	Percent Change From Baseline in Number of Days per Week of Parenteral Support (PS) Usage at End of Treatment (EOT) of Each Cycle During the End of Each Teduglutide Treatment Period of Prospective Study Period

End point description:

Percent change from baseline in number of days per week of PS usage at EOT of each cycle during the end of each teduglutide treatment period in prospective study period was reported. Safety population included all enrolled subjects who provided informed consent for the prospective portion and met all the inclusion criteria. Here, n=number of subjects analysed refer to the subjects evaluable for this endpoint at specific categories.

End point type	Secondary

End point timeframe:

Baseline: From end of retrospective study period, EOT of each cycle (up to Week 24)

End point values	Prospective TED/TED Group			
Subject group type	Reporting group			
Number of subjects analysed	19			
Units: Percent change				
arithmetic mean (standard deviation)				
Cycle 1: EOT (n=18)	-9.01 (± 27.472)			
Cycle 2: EOT (n=16)	-29.24 (± 40.525)			
Cycle 3: EOT (n=13)	-44.51 (± 47.929)			
Cycle 4: EOT (n=12)	-42.38 (± 51.929)			
Cycle 5: EOT (n=7)	-54.29 (± 57.404)			
Cycle 6: EOT (n=5)	-62.86 (± 51.110)			

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Change From Baseline In Pediatric Quality of Life Inventory (PedsQL) Generic Core Scale (GCS) Score at Week 12 and 24 of Each Treatment Cycle During the End of Each Teduglutide Treatment Period of Prospective Study Period

End point title	Change From Baseline In Pediatric Quality of Life Inventory (PedsQL) Generic Core Scale (GCS) Score at Week 12 and 24 of Each Treatment Cycle During the End of Each Teduglutide Treatment Period of Prospective Study Period

End point description:

PedsQL GCS was used for quality of life assessment. It encompasses 4 dimensions of functioning (physical, emotional, social, school). Age groups are: Toddler (2-4 years), Young child (5-7 years), Child (8-12 years), and Teens (13-18 years). Depending on the subject's age, the questionnaire may be completed by either the subject or the parent/caregiver as appropriate. For the Toddler group, the PedsQL GCS consists of 21 items, using a 5-point Likert scale (0 to 4); for all other groups, the PedsQL GCS consists of 23 items, with a 3-point Likert scale (0, 2, 4) for the young child, and a 5-point Likert scale for the child and teens groups. Scores are transformed on a scale from 0 to 100 where 0=100, 1=75, 2=50, 3=25, and 4=0. Higher scores indicate improved quality of life. Safety population analysis. Here, n=number of subjects analysed refer to subjects evaluable for this category. Here, '99999' indicates that standard deviation was not estimated as only single subject was analysed.

End point type	Other pre-specified

End point timeframe:

Baseline: From end of retrospective study period, Week 12 and 24 of each treatment cycle

End point values	Prospective TED/TED Group			
Subject group type	Reporting group			
Number of subjects analysed	19			
Units: Score on a scale				
arithmetic mean (standard deviation)				
Physical Functioning: Cycle1 Week12 (n=15)	-0.39 (± 24.326)			
Physical Functioning: Cycle1 Week24 (n=15)	-0.83 (± 10.726)			
Physical Functioning: Cycle2 Week12 (n=12)	2.34 (± 15.717)			
Physical Functioning: Cycle2 Week24 (n=13)	2.40 (± 16.296)			
Physical Functioning: Cycle3 Week12 (n=11)	-0.57 (± 16.167)			
Physical Functioning: Cycle3 Week24 (n=9)	-1.74 (± 25.963)			
Physical Functioning: Cycle4 Week12 (n=9)	-1.74 (± 22.378)			
Physical Functioning: Cycle4 Week24 (n=7)	1.79 (± 19.998)			
Physical Functioning: Cycle5 Week12 (n=5)	-7.50 (± 19.961)			
Physical Functioning: Cycle5 Week24 (n=4)	-2.34 (± 14.292)			
Physical Functioning: Cycle6 Week12 (n=4)	-6.25 (± 22.244)			
Physical Functioning: Cycle6 Week24 (n=1)	3.13 (± 99999)			
Emotional Functioning: Cycle1 Week12 (n=15)	4.17 (± 18.843)			
Emotional Functioning: Cycle1 Week24 (n=15)	-4.67 (± 24.511)			
Emotional Functioning: Cycle2 Week12 (n=12)	-3.33 (± 28.591)			
Emotional Functioning: Cycle2 Week24 (n=13)	-0.38 (± 21.454)			
Emotional Functioning: Cycle3 Week12 (n=11)	7.05 (± 29.661)			
Emotional Functioning: Cycle3 Week24 (n=9)	-8.33 (± 36.120)			
Emotional Functioning: Cycle4 Week12 (n=9)	2.78 (± 33.481)			
Emotional Functioning: Cycle4 Week24 (n=7)	-0.71 (± 35.786)			
Emotional Functioning: Cycle5 Week12 (n=5)	-11.00 (± 40.566)			
Emotional Functioning: Cycle5 Week24 (n=4)	-17.50 (± 37.804)			
Emotional Functioning: Cycle6 Week12 (n=4)	-5.63 (± 56.065)			
Emotional Functioning: Cycle6 Week24 (n=1)	17.50 (± 99999)			
Social Functioning: Cycle1 Week12 (n=1)	-15.00 (± 99999)			
Social Functioning: Cycle1 Week24 (n=1)	-10.00 (± 99999)			
Social Functioning: Cycle2 Week12 (n=1)	-5.00 (± 99999)			

Social Functioning: Cycle2 Week24 (n=1)	0.00 (± 99999)			
Social Functioning: Cycle3 Week12 (n=1)	10.00 (± 99999)			
Social Functioning: Cycle3 Week24 (n=1)	0.00 (± 99999)			
Social Functioning: Cycle4 Week12 (n=1)	10.00 (± 99999)			
Social Functioning: Cycle4 Week24 (n=1)	10.00 (± 99999)			
Social Functioning: Cycle5 Week12 (n=1)	10.00 (± 99999)			
Social Functioning: Cycle5 Week24 (n=1)	10.00 (± 99999)			
Social Functioning: Cycle6 Week12 (n=1)	10.00 (± 99999)			
Social Functioning: Cycle6 Week24 (n=0)	88888 (± 88888)			
School Functioning: Cycle1 Week12 (n=15)	5.67 (± 19.445)			
School Functioning: Cycle1 Week24 (n=15)	2.00 (± 20.160)			
School Functioning: Cycle2 Week12 (n=12)	-5.00 (± 24.027)			
School Functioning: Cycle2 Week24 (n=12)	8.75 (± 16.394)			
School Functioning: Cycle3 Week12 (n=11)	3.64 (± 23.355)			
School Functioning: Cycle3 Week24 (n=9)	-3.33 (± 22.500)			
School Functioning: Cycle4 Week12 (n=9)	0.00 (± 15.000)			
School Functioning: Cycle4 Week24 (n=7)	13.57 (± 8.018)			
School Functioning: Cycle5 Week12 (n=5)	15.00 (± 11.180)			
School Functioning: Cycle5 Week24 (n=4)	18.75 (± 8.539)			
School Functioning: Cycle6 Week12 (n=4)	13.75 (± 4.787)			
School Functioning: Cycle6 Week24 (n=1)	20.00 (± 99999)			

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Change From Baseline In Pediatric Quality of Life Inventory (PedsQL) Generic Core Scale (GCS) Score at End of Study (EOS) During the End of Non-Teduglutide Treatment (NTT) Periods in Prospective Study Period

End point title	Change From Baseline In Pediatric Quality of Life Inventory (PedsQL) Generic Core Scale (GCS) Score at End of Study (EOS) During the End of Non-Teduglutide Treatment (NTT) Periods in Prospective Study Period

End point description:

PedsQL GCS was used for quality of life assessment. It encompasses 4 dimensions of functioning (physical, emotional, social, school). Age groups are: Toddler (2-4 years), Young child (5-7 years), Child (8-12 years), and Teens (13-18 years). Depending on the subject's age, the questionnaire may be

completed by either the participant or the parent/caregiver as appropriate. For the Toddler group, the PedsQL GCS consists of 21 items, using a 5-point Likert scale (0 to 4); for all other groups, the PedsQL GCS consists of 23 items, with a 3-point Likert scale (0, 2, 4) for the young child, and a 5-point Likert scale for the child and teens groups. Scores are transformed on a scale from 0 to 100 were 0=100, 1=75, 2=50, 3=25, and 4=0. Higher scores indicate improved quality of life. Safety population analysis.

End point type	Other pre-specified

End point timeframe:

Baseline: From end of retrospective study period, EOS (up to Week 28)

End point values	Prospective TED/NTT Group	Prospective TED/TED Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[25]	0[26]		
Units: Scale on a score				
arithmetic mean (standard deviation)				
Physical Functioning: EOS	()	()		
Emotional Functioning: EOS	()	()		
Social Functioning: EOS	()	()		
School Functioning: EOS	()	()		

Notes:

[25] - No subjects were analysed at EOS.

[26] - No subjects were analysed at EOS.

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Change From Baseline In Pediatric Quality of Life Inventory (PedsQL) Family Impact Module Total Score at Week 12 and 24 of Each Treatment Cycle During the End of Each Teduglutide Treatment Period in Prospective Study Period

End point title	Change From Baseline In Pediatric Quality of Life Inventory (PedsQL) Family Impact Module Total Score at Week 12 and 24 of Each Treatment Cycle During the End of Each Teduglutide Treatment Period in Prospective Study Period

End point description:

PedsQL Family Impact Module was composed of 36 items comprising Physical Functioning (6 items), Emotional Functioning (5 items), Social Functioning (4 items), Cognitive Functioning (5 items), Communication (3 items), Worry (5 items), Daily Activities (3 items) and Family Relationships (5 items). Total score was calculated as the sum of all the items over the number of items answered on all the scales. Scores are transformed on a scale from 0 to 100 were 0=100, 1=75, 2=50, 3=25, and 4=0. Higher scores indicate improved quality of life. Safety population analysis. Here, n=number of subjects analysed refer to subjects evaluable for this category. Here, '99999' indicates standard deviation was not estimated as only single subject was analysed. Since baseline scores were unavailable for TED/NTT group, data was not analysed for this arm.

End point type	Other pre-specified

End point timeframe:

Baseline: From end of retrospective study period, Week 12 and 24 of each treatment cycle

End point values	Prospective TED/TED Group			
Subject group type	Reporting group			
Number of subjects analysed	19			
Units: Score on a Scale				
arithmetic mean (standard deviation)				
Total Score: Cycle1 Week12 (n=18)	1.39 (± 15.742)			
Total Score: Cycle1 Week24 (n=19)	1.56 (± 13.372)			
Total Score: Cycle2 Week12 (n=15)	0.10 (± 13.622)			
Total Score: Cycle2 Week24 (n=16)	1.90 (± 11.664)			
Total Score: Cycle3 Week12 (n=13)	2.72 (± 15.051)			
Total Score: Cycle3 Week24 (n=11)	3.90 (± 16.018)			
Total Score: Cycle4 Week12 (n=10)	2.14 (± 20.762)			
Total Score: Cycle4 Week24 (n=9)	4.66 (± 23.546)			
Total Score: Cycle5 Week12 (n=8)	0.11 (± 14.105)			
Total Score: Cycle5 Week24 (n=6)	2.23 (± 16.099)			
Total Score: Cycle6 Week12 (n=4)	5.13 (± 18.084)			
Total Score: Cycle6 Week24 (n=1)	-17.86 (± 99999)			

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Change From Baseline In Pediatric Quality of Life Inventory (PedsQL) Family Impact Module Total Score at End of Study (EOS) During the End of Non-Teduglutide Treatment (NTT) Periods of Prospective Study Period

End point title	Change From Baseline In Pediatric Quality of Life Inventory (PedsQL) Family Impact Module Total Score at End of Study (EOS) During the End of Non-Teduglutide Treatment (NTT) Periods of Prospective Study Period

End point description:

PedsQL Family Impact Module was composed of 36 items comprising Physical Functioning (6 items), Emotional Functioning (5 items), Social Functioning (4 items), Cognitive Functioning (5 items), Communication (3 items), Worry (5 items), Daily Activities (3 items) and Family Relationships (5 items). Total score was calculated as the sum of all the items over the number of items answered on all the scales. Scores are transformed on a scale from 0 to 100 were 0=100, 1=75, 2=50, 3=25, and 4=0. Higher scores indicate improved quality of life. Safety population analysis. Here, n=number of subjects analysed refer to subjects evaluable for this category. Here, '99999' indicates standard deviation was not estimated as only single subject was analysed.

End point type	Other pre-specified

End point timeframe:

Baseline: From end of retrospective study period, EOS (up to Week 28)

End point values	Prospective TED/NTT Group	Prospective TED/TED Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[27]	0[28]		
Units: Score on a scale				
arithmetic mean (standard deviation)				
Total score: EOS	()	()		

Notes:

[27] - No subjects were analysed at EOS.

[28] - No subjects were analysed at EOS.

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Change From Baseline In Pediatric Quality of Life Inventory (PedsQL) Gastrointestinal Symptoms Module at Week 12 and 24 of Each Treatment Cycle During the End of Each Teduglutide Treatment Period of Prospective Study Period

End point title	Change From Baseline In Pediatric Quality of Life Inventory (PedsQL) Gastrointestinal Symptoms Module at Week 12 and 24 of Each Treatment Cycle During the End of Each Teduglutide Treatment Period of Prospective Study Period

End point description:

PedsQL GI symptoms module was composed of 58 items, comprised of 10 different symptom scales that assess gastrointestinal symptom-related quality of life: food and drink limits, trouble swallowing, heartburn and reflux, nausea and vomiting, gas and bloating, constipation, blood in poop, and diarrhea. Only the scales of food and drink limits (6 items) and diarrhea (7 items) was used in this study. Subscale score was calculated as the sum of the items over the number of items answered in the scale. Scores are transformed on a scale from 0 to 100 were 0=100, 1=75, 2=50, 3=25, and 4=0. Higher scores indicate improved quality of life. Safety population analysis. Here, n=number of subjects analysed refer to subjects evaluable for this category. Here, '99999' indicates that standard deviation was not estimated as only single subject was analysed. Since baseline scores were unavailable for TED/NTT group, data was not analysed for this arm.

End point type	Other pre-specified

End point timeframe:

Baseline: From end of retrospective study period, Week 12 and 24 of each treatment cycle

End point values	Prospective TED/TED Group			
Subject group type	Reporting group			
Number of subjects analysed	19			
Units: Score on a scale				
arithmetic mean (standard deviation)				
Food and Drink Limits: Cycle1Week12 (n=18) Food and Drink Limits: Cycle1Week24 (n=19)	-2.08 (± 30.460) -7.06 (± 27.524)			

Food and Drink Limits: Cycle2Week12 (n=15)	-0.83 (± 29.723)			
Food and Drink Limits: Cycle2Week24 (n=17)	9.31 (± 26.292)			
Food and Drink Limits: Cycle3Week12 (n=14)	1.19 (± 35.784)			
Food and Drink Limits: Cycle3Week24 (n=11)	-0.08 (± 29.511)			
Food and Drink Limits: Cycle4Week12 (n=9)	-4.63 (± 33.750)			
Food and Drink Limits: Cycle4Week24 (n=8)	1.04 (± 35.895)			
Food and Drink Limits: Cycle5Week12 (n=7)	1.19 (± 21.343)			
Food and Drink Limits: Cycle5Week24 (n=6)	-17.36 (± 44.986)			
Food and Drink Limits: Cycle6Week12 (n=3)	-1.39 (± 30.142)			
Food and Drink Limits: Cycle6Week24 (n=1)	-45.83 (± 99999)			
Diarrhea: Cycle1Week12 (n=18)	7.79 (± 23.137)			
Diarrhea: Cycle1Week24 (n=18)	9.33 (± 23.279)			
Diarrhea: Cycle2Week12 (n=15)	5.48 (± 15.144)			
Diarrhea: Cycle2Week24 (n=17)	6.72 (± 19.880)			
Diarrhea: Cycle3Week12 (n=14)	13.27 (± 22.124)			
Diarrhea: Cycle3Week24 (n=11)	5.19 (± 21.569)			
Diarrhea: Cycle4Week12 (n=9)	9.13 (± 18.653)			
Diarrhea: Cycle4Week24 (n=8)	12.95 (± 26.448)			
Diarrhea: Cycle5Week12 (n=7)	10.71 (± 23.237)			
Diarrhea: Cycle5Week24 (n=6)	8.33 (± 30.612)			
Diarrhea: Cycle6Week12 (n=3)	5.95 (± 22.961)			
Diarrhea: Cycle6Week24 (n=1)	-7.14 (± 99999)			

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Change From Baseline In Pediatric Quality of Life Inventory (PedsQL) Gastrointestinal Symptoms Module at End of Study (EOS) During the End of Non-Teduglutide Treatment (NTT) Periods of Prospective Study Period

End point title	Change From Baseline In Pediatric Quality of Life Inventory (PedsQL) Gastrointestinal Symptoms Module at End of Study (EOS) During the End of Non-Teduglutide Treatment (NTT) Periods of Prospective Study Period

End point description:

PedsQL GI symptoms module was composed of 58 items, comprised of 10 different symptom scales that

assess gastrointestinal symptom-related quality of life: food and drink limits, trouble swallowing, heartburn and reflux, nausea and vomiting, gas and bloating, constipation, blood in poop, and diarrhea. Only the scales of food and drink limits (6 items) and diarrhea (7 items) was used in this study. Subscale score was calculated as the sum of the items over the number of items answered in the scale. Scores are transformed on a scale from 0 to 100 were 0=100, 1=75, 2=50, 3=25, and 4=0. Higher scores indicate improved quality of life. Safety population analysis. Here, n=number of subjects analysed refer to subjects evaluable for this category. Here, '99999' indicates that standard deviation was not estimated as only single subject was analysed. Since baseline scores were unavailable for TED/NTT group, data was not analysed for this arm.

End point type	Other pre-specified

End point timeframe:

Baseline: From end of retrospective study period, EOS (up to Week 28)

End point values	Prospective TED/NTT Group	Prospective TED/TED Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[29]	0[30]		
Units: Score on a scale				
arithmetic mean (standard deviation)				
Food and Drink Limits :EOS	()	()		
Diarrhea: EOS	()	()		

Notes:

[29] - No subjects were analysed at EOS.

[30] - No subjects were analysed at EOS.

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events: From start of screening up to follow up (Week 28)	
Assessment type	Non-systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	19.1

Reporting groups	
Reporting group title	Retrospective TED/NTT Group
Reporting group description: Subjects who received teduglutide 0.05 milligrams per kilogram (mg/kg) subcutaneous injection once daily in TED-C13-003 (2013-004588-30) and didn't received teduglutide in retrospective period in the current study SHP633-303.	
Reporting group title	Retrospective TED/TED Group
Reporting group description: Subjects who received teduglutide 0.05 mg/kg subcutaneous injection once daily in TED-C13-003 (2013-004588-30) and also received teduglutide in retrospective period in the current study SHP633-303.	
Reporting group title	Prospective TED/NTT Group
Reporting group description: Subjects who received teduglutide 0.05 mg/kg subcutaneous injection once daily in TED-C13-003 (2013-004588-30) and didn't received teduglutide in prospective period in the current study SHP633-303 up to 24 weeks.	
Reporting group title	Prospective TED/TED Group
Reporting group description: Subjects who received teduglutide 0.05 mg/kg subcutaneous injection once daily in TED-C13-003 (2013-004588-30) and also received teduglutide in prospective period in the current study SHP633-303 up to 24 weeks.	

Serious adverse events	Retrospective TED/NTT Group	Retrospective TED/TED Group	Prospective TED/NTT Group
Total subjects affected by serious adverse events			
subjects affected / exposed	23 / 24 (95.83%)	4 / 5 (80.00%)	3 / 5 (60.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Vascular disorders			
Superior vena cava occlusion			
subjects affected / exposed	0 / 24 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Superior vena cava syndrome			

subjects affected / exposed	1 / 24 (4.17%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures			
Catheter management			
subjects affected / exposed	1 / 24 (4.17%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Central venous catheterisation			
subjects affected / exposed	2 / 24 (8.33%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Complication associated with device			
subjects affected / exposed	1 / 24 (4.17%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Face oedema			
subjects affected / exposed	0 / 24 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperpyrexia			
subjects affected / exposed	1 / 24 (4.17%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oedema peripheral			
subjects affected / exposed	0 / 24 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	14 / 24 (58.33%)	3 / 5 (60.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 31	0 / 6	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Systemic inflammatory response syndrome			
subjects affected / exposed	1 / 24 (4.17%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	1 / 24 (4.17%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory failure			
subjects affected / exposed	1 / 24 (4.17%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tachypnoea			
subjects affected / exposed	1 / 24 (4.17%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Product issues			
Device breakage			
subjects affected / exposed	6 / 24 (25.00%)	1 / 5 (20.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 8	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device dislocation			
subjects affected / exposed	0 / 24 (0.00%)	1 / 5 (20.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device failure			
subjects affected / exposed	1 / 24 (4.17%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device malfunction			

subjects affected / exposed	5 / 24 (20.83%)	1 / 5 (20.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 5	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device occlusion			
subjects affected / exposed	1 / 24 (4.17%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Influenza a virus test positive			
subjects affected / exposed	0 / 24 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcus test positive			
subjects affected / exposed	1 / 24 (4.17%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Weight decreased			
subjects affected / exposed	0 / 24 (0.00%)	1 / 5 (20.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Anastomotic ulcer			
subjects affected / exposed	1 / 24 (4.17%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foot fracture			
subjects affected / exposed	1 / 24 (4.17%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital, familial and genetic disorders			
Congenital megacolon			

subjects affected / exposed	0 / 24 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Tachycardia			
subjects affected / exposed	1 / 24 (4.17%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 24 (4.17%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile neutropenia			
subjects affected / exposed	0 / 24 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhagic anaemia			
subjects affected / exposed	0 / 24 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Microcytic anaemia			
subjects affected / exposed	0 / 24 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal adhesions			
subjects affected / exposed	0 / 24 (0.00%)	0 / 5 (0.00%)	1 / 5 (20.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	1 / 24 (4.17%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Duodenal ulcer			
subjects affected / exposed	0 / 24 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enteritis			
subjects affected / exposed	1 / 24 (4.17%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Functional gastrointestinal disorder			
subjects affected / exposed	1 / 24 (4.17%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 24 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal hypomotility			
subjects affected / exposed	1 / 24 (4.17%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileus			
subjects affected / exposed	1 / 24 (4.17%)	1 / 5 (20.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileus paralytic			
subjects affected / exposed	1 / 24 (4.17%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal obstruction			
subjects affected / exposed	0 / 24 (0.00%)	0 / 5 (0.00%)	1 / 5 (20.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			

subjects affected / exposed	2 / 24 (8.33%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal haemorrhage			
subjects affected / exposed	1 / 24 (4.17%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Short-bowel syndrome			
subjects affected / exposed	1 / 24 (4.17%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal obstruction			
subjects affected / exposed	1 / 24 (4.17%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal stenosis			
subjects affected / exposed	1 / 24 (4.17%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	2 / 24 (8.33%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Hepatic failure			
subjects affected / exposed	1 / 24 (4.17%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Jaundice			
subjects affected / exposed	1 / 24 (4.17%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			

Skin irritation			
subjects affected / exposed	1 / 24 (4.17%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Adenovirus infection			
subjects affected / exposed	1 / 24 (4.17%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacteraemia			
subjects affected / exposed	2 / 24 (8.33%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacterial infection			
subjects affected / exposed	1 / 24 (4.17%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchiolitis			
subjects affected / exposed	1 / 24 (4.17%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 5 (0.00%)	1 / 5 (20.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cystitis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 5 (0.00%)	1 / 5 (20.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device related infection			
subjects affected / exposed	17 / 24 (70.83%)	2 / 5 (40.00%)	1 / 5 (20.00%)
occurrences causally related to treatment / all	0 / 33	0 / 6	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device related sepsis			

subjects affected / exposed	0 / 24 (0.00%)	1 / 5 (20.00%)	1 / 5 (20.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterococcal infection			
subjects affected / exposed	1 / 24 (4.17%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fungal infection			
subjects affected / exposed	0 / 24 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	1 / 24 (4.17%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis viral			
subjects affected / exposed	0 / 24 (0.00%)	0 / 5 (0.00%)	1 / 5 (20.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza			
subjects affected / exposed	5 / 24 (20.83%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 5	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metapneumovirus infection			
subjects affected / exposed	1 / 24 (4.17%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Micrococcus infection			
subjects affected / exposed	1 / 24 (4.17%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteomyelitis			

subjects affected / exposed	1 / 24 (4.17%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Parainfluenzae virus infection			
subjects affected / exposed	1 / 24 (4.17%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory syncytial virus bronchiolitis			
subjects affected / exposed	1 / 24 (4.17%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory syncytial virus infection			
subjects affected / exposed	1 / 24 (4.17%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rhinovirus infection			
subjects affected / exposed	1 / 24 (4.17%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rotavirus infection			
subjects affected / exposed	1 / 24 (4.17%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	1 / 24 (4.17%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal bacteraemia			
subjects affected / exposed	1 / 24 (4.17%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal sepsis			

subjects affected / exposed	0 / 24 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection			
subjects affected / exposed	1 / 24 (4.17%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	2 / 24 (8.33%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urosepsis			
subjects affected / exposed	2 / 24 (8.33%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral infection			
subjects affected / exposed	1 / 24 (4.17%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral pharyngitis			
subjects affected / exposed	0 / 24 (0.00%)	1 / 5 (20.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 24 (0.00%)	1 / 5 (20.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	2 / 24 (8.33%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Electrolyte imbalance			

subjects affected / exposed	2 / 24 (8.33%)	1 / 5 (20.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Feeding intolerance			
subjects affected / exposed	0 / 24 (0.00%)	1 / 5 (20.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoalbuminaemia			
subjects affected / exposed	0 / 24 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia			
subjects affected / exposed	0 / 24 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lactic acidosis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolic acidosis			
subjects affected / exposed	1 / 24 (4.17%)	0 / 5 (0.00%)	1 / 5 (20.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Weight gain poor			
subjects affected / exposed	1 / 24 (4.17%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Prospective TED/TED Group		
Total subjects affected by serious adverse events			
subjects affected / exposed	17 / 19 (89.47%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		

Vascular disorders			
Superior vena cava occlusion			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Superior vena cava syndrome			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Surgical and medical procedures			
Catheter management			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Central venous catheterisation			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
General disorders and administration site conditions			
Complication associated with device			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Face oedema			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hyperpyrexia			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Oedema peripheral			

subjects affected / exposed	1 / 19 (5.26%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pyrexia				
subjects affected / exposed	7 / 19 (36.84%)			
occurrences causally related to treatment / all	0 / 12			
deaths causally related to treatment / all	0 / 0			
Systemic inflammatory response syndrome				
subjects affected / exposed	0 / 19 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Respiratory, thoracic and mediastinal disorders				
Asthma				
subjects affected / exposed	0 / 19 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Respiratory failure				
subjects affected / exposed	0 / 19 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Tachypnoea				
subjects affected / exposed	0 / 19 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Product issues				
Device breakage				
subjects affected / exposed	0 / 19 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Device dislocation				
subjects affected / exposed	0 / 19 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

Device failure				
subjects affected / exposed	0 / 19 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Device malfunction				
subjects affected / exposed	0 / 19 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Device occlusion				
subjects affected / exposed	0 / 19 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Investigations				
Influenza a virus test positive				
subjects affected / exposed	1 / 19 (5.26%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Staphylococcus test positive				
subjects affected / exposed	0 / 19 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Weight decreased				
subjects affected / exposed	0 / 19 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Injury, poisoning and procedural complications				
Anastomotic ulcer				
subjects affected / exposed	1 / 19 (5.26%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Foot fracture				
subjects affected / exposed	0 / 19 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

Congenital, familial and genetic disorders			
Congenital megacolon			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cardiac disorders			
Tachycardia			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Febrile neutropenia			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Haemorrhagic anaemia			
subjects affected / exposed	2 / 19 (10.53%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Microcytic anaemia			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Abdominal adhesions			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Diarrhoea			

subjects affected / exposed	1 / 19 (5.26%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Duodenal ulcer				
subjects affected / exposed	1 / 19 (5.26%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Enteritis				
subjects affected / exposed	0 / 19 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Functional gastrointestinal disorder				
subjects affected / exposed	0 / 19 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastrointestinal haemorrhage				
subjects affected / exposed	2 / 19 (10.53%)			
occurrences causally related to treatment / all	0 / 6			
deaths causally related to treatment / all	0 / 0			
Gastrointestinal hypomotility				
subjects affected / exposed	0 / 19 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Ileus				
subjects affected / exposed	2 / 19 (10.53%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Ileus paralytic				
subjects affected / exposed	0 / 19 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Intestinal obstruction				

subjects affected / exposed	0 / 19 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pancreatitis				
subjects affected / exposed	0 / 19 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Rectal haemorrhage				
subjects affected / exposed	0 / 19 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Short-bowel syndrome				
subjects affected / exposed	2 / 19 (10.53%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Small intestinal obstruction				
subjects affected / exposed	0 / 19 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Small intestinal stenosis				
subjects affected / exposed	0 / 19 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Vomiting				
subjects affected / exposed	1 / 19 (5.26%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Hepatobiliary disorders				
Hepatic failure				
subjects affected / exposed	0 / 19 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Jaundice				

subjects affected / exposed	0 / 19 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Skin and subcutaneous tissue disorders			
Skin irritation			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Adenovirus infection			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bacteraemia			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Bacterial infection			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Bronchiolitis			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cellulitis			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cystitis			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Device related infection			

subjects affected / exposed	9 / 19 (47.37%)			
occurrences causally related to treatment / all	0 / 13			
deaths causally related to treatment / all	0 / 0			
Device related sepsis				
subjects affected / exposed	1 / 19 (5.26%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Enterococcal infection				
subjects affected / exposed	0 / 19 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Fungal infection				
subjects affected / exposed	1 / 19 (5.26%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Gastroenteritis				
subjects affected / exposed	2 / 19 (10.53%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Gastroenteritis viral				
subjects affected / exposed	2 / 19 (10.53%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Influenza				
subjects affected / exposed	4 / 19 (21.05%)			
occurrences causally related to treatment / all	0 / 4			
deaths causally related to treatment / all	0 / 0			
Metapneumovirus infection				
subjects affected / exposed	0 / 19 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Micrococcus infection				

subjects affected / exposed	0 / 19 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Osteomyelitis				
subjects affected / exposed	0 / 19 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Parainfluenzae virus infection				
subjects affected / exposed	0 / 19 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Respiratory syncytial virus bronchiolitis				
subjects affected / exposed	0 / 19 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Respiratory syncytial virus infection				
subjects affected / exposed	0 / 19 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Rhinovirus infection				
subjects affected / exposed	0 / 19 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Rotavirus infection				
subjects affected / exposed	0 / 19 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Sepsis				
subjects affected / exposed	1 / 19 (5.26%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Staphylococcal bacteraemia				

subjects affected / exposed	0 / 19 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Staphylococcal sepsis				
subjects affected / exposed	1 / 19 (5.26%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Upper respiratory tract infection				
subjects affected / exposed	2 / 19 (10.53%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Urinary tract infection				
subjects affected / exposed	0 / 19 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Urosepsis				
subjects affected / exposed	0 / 19 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Viral infection				
subjects affected / exposed	2 / 19 (10.53%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Viral pharyngitis				
subjects affected / exposed	0 / 19 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Viral upper respiratory tract infection				
subjects affected / exposed	1 / 19 (5.26%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Metabolism and nutrition disorders				
Dehydration				

subjects affected / exposed	0 / 19 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Electrolyte imbalance			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Feeding intolerance			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypoalbuminaemia			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hyponatraemia			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Lactic acidosis			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Metabolic acidosis			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Weight gain poor			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	Retrospective TED/NTT Group	Retrospective TED/TED Group	Prospective TED/NTT Group
Total subjects affected by non-serious adverse events			
subjects affected / exposed	1 / 24 (4.17%)	1 / 5 (20.00%)	4 / 5 (80.00%)
Vascular disorders			
Flushing			
subjects affected / exposed	0 / 24 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Administration site extravasation			
subjects affected / exposed	0 / 24 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Catheter site inflammation			
subjects affected / exposed	0 / 24 (0.00%)	0 / 5 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Fatigue			
subjects affected / exposed	0 / 24 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Generalised oedema			
subjects affected / exposed	0 / 24 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Ill-defined disorder			
subjects affected / exposed	0 / 24 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Injection site induration			
subjects affected / exposed	0 / 24 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Injection site pain			
subjects affected / exposed	0 / 24 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Injection site reaction			
subjects affected / exposed	0 / 24 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Injection site swelling			

subjects affected / exposed	0 / 24 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Medical device site irritation			
subjects affected / exposed	0 / 24 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	0 / 24 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Secretion discharge			
subjects affected / exposed	0 / 24 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Food allergy			
subjects affected / exposed	0 / 24 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hypersensitivity			
subjects affected / exposed	0 / 24 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Seasonal allergy			
subjects affected / exposed	0 / 24 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 24 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Dyspnoea			
subjects affected / exposed	0 / 24 (0.00%)	0 / 5 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Epistaxis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			
subjects affected / exposed	0 / 24 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			

subjects affected / exposed	0 / 24 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Pleuritic pain			
subjects affected / exposed	0 / 24 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	0 / 24 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Aggression			
subjects affected / exposed	0 / 24 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Attention deficit/hyperactivity disorder			
subjects affected / exposed	0 / 24 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Depression			
subjects affected / exposed	0 / 24 (0.00%)	0 / 5 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Sleep disorder			
subjects affected / exposed	0 / 24 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Product issues			
Device dislocation			
subjects affected / exposed	0 / 24 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Device leakage			
subjects affected / exposed	0 / 24 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Device occlusion			
subjects affected / exposed	0 / 24 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 24 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Bacterial test positive			

subjects affected / exposed	0 / 24 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Blood albumin decreased			
subjects affected / exposed	0 / 24 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Blood creatine increased			
subjects affected / exposed	0 / 24 (0.00%)	0 / 5 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Blood creatinine increased			
subjects affected / exposed	0 / 24 (0.00%)	0 / 5 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	2
Blood iron decreased			
subjects affected / exposed	0 / 24 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Blood sodium decreased			
subjects affected / exposed	0 / 24 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Blood urine present			
subjects affected / exposed	0 / 24 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Body temperature increased			
subjects affected / exposed	0 / 24 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
C-reactive protein increased			
subjects affected / exposed	0 / 24 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 24 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal stoma output increased			
subjects affected / exposed	0 / 24 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Haematocrit decreased			

subjects affected / exposed	0 / 24 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Haemoglobin decreased			
subjects affected / exposed	0 / 24 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Heart rate increased			
subjects affected / exposed	0 / 24 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hepatic enzyme increased			
subjects affected / exposed	0 / 24 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Lipase increased			
subjects affected / exposed	0 / 24 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Lymph node palpable			
subjects affected / exposed	0 / 24 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Occult blood positive			
subjects affected / exposed	0 / 24 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Platelet count increased			
subjects affected / exposed	0 / 24 (0.00%)	0 / 5 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Serum ferritin decreased			
subjects affected / exposed	0 / 24 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Streptococcus test positive			
subjects affected / exposed	0 / 24 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Vitamin a decreased			
subjects affected / exposed	0 / 24 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed	0 / 24 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
White blood cells urine positive			

subjects affected / exposed	0 / 24 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
pH urine increased			
subjects affected / exposed	0 / 24 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Gastrointestinal stoma complication			
subjects affected / exposed	0 / 24 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Infusion related reaction			
subjects affected / exposed	0 / 24 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Medication error			
subjects affected / exposed	0 / 24 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Procedural pain			
subjects affected / exposed	0 / 24 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Skin abrasion			
subjects affected / exposed	0 / 24 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Dizziness			
subjects affected / exposed	0 / 24 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Dysarthria			
subjects affected / exposed	0 / 24 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	0 / 24 (0.00%)	0 / 5 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Lethargy			
subjects affected / exposed	1 / 24 (4.17%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Migraine			

subjects affected / exposed	0 / 24 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Seizure			
subjects affected / exposed	0 / 24 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Syncope			
subjects affected / exposed	0 / 24 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 24 (0.00%)	0 / 5 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	2
Lymphadenopathy			
subjects affected / exposed	0 / 24 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	0 / 24 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Middle ear effusion			
subjects affected / exposed	0 / 24 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Visual impairment			
subjects affected / exposed	0 / 24 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	0 / 24 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Abdominal distension			
subjects affected / exposed	0 / 24 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Abdominal pain			
subjects affected / exposed	0 / 24 (0.00%)	1 / 5 (20.00%)	2 / 5 (40.00%)
occurrences (all)	0	1	4
Abdominal pain upper			

subjects affected / exposed	0 / 24 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	0 / 24 (0.00%)	1 / 5 (20.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Diarrhoea			
subjects affected / exposed	0 / 24 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			
subjects affected / exposed	0 / 24 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Faecal volume increased			
subjects affected / exposed	0 / 24 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Faeces discoloured			
subjects affected / exposed	0 / 24 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	0 / 24 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Frequent bowel movements			
subjects affected / exposed	0 / 24 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Gastritis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis eosinophilic			
subjects affected / exposed	0 / 24 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 24 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Haematochezia			
subjects affected / exposed	0 / 24 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Lip swelling			

subjects affected / exposed	0 / 24 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	0 / 24 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Oral mucosal erythema			
subjects affected / exposed	0 / 24 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Perianal erythema			
subjects affected / exposed	0 / 24 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Post-tussive vomiting			
subjects affected / exposed	0 / 24 (0.00%)	0 / 5 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Proctalgia			
subjects affected / exposed	0 / 24 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Proctitis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Rectal discharge			
subjects affected / exposed	0 / 24 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Toothache			
subjects affected / exposed	0 / 24 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	0 / 24 (0.00%)	0 / 5 (0.00%)	2 / 5 (40.00%)
occurrences (all)	0	0	3
Skin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed	0 / 24 (0.00%)	0 / 5 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Cold sweat			
subjects affected / exposed	0 / 24 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0

Dry skin			
subjects affected / exposed	0 / 24 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Eczema			
subjects affected / exposed	0 / 24 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	0 / 24 (0.00%)	0 / 5 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Nodular rash			
subjects affected / exposed	0 / 24 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	0 / 24 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 24 (0.00%)	0 / 5 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Rash erythematous			
subjects affected / exposed	0 / 24 (0.00%)	0 / 5 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Rash pruritic			
subjects affected / exposed	0 / 24 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Swelling face			
subjects affected / exposed	0 / 24 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Haematuria			
subjects affected / exposed	0 / 24 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	0 / 24 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			

Arthralgia			
subjects affected / exposed	0 / 24 (0.00%)	0 / 5 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Back pain			
subjects affected / exposed	0 / 24 (0.00%)	0 / 5 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Musculoskeletal pain			
subjects affected / exposed	0 / 24 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	0 / 24 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Bronchiolitis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 5 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Cellulitis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 5 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Croup infectious			
subjects affected / exposed	0 / 24 (0.00%)	0 / 5 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Device related infection			
subjects affected / exposed	0 / 24 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Ear infection			
subjects affected / exposed	0 / 24 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Escherichia urinary tract infection			
subjects affected / exposed	0 / 24 (0.00%)	0 / 5 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Furuncle			
subjects affected / exposed	0 / 24 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			

subjects affected / exposed	0 / 24 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis viral			
subjects affected / exposed	0 / 24 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Impetigo			
subjects affected / exposed	0 / 24 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	0 / 24 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Lyme disease			
subjects affected / exposed	0 / 24 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Otitis media			
subjects affected / exposed	0 / 24 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Pharyngitis streptococcal			
subjects affected / exposed	0 / 24 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection			
subjects affected / exposed	0 / 24 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Rhinovirus infection			
subjects affected / exposed	0 / 24 (0.00%)	0 / 5 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Upper respiratory tract infection			
subjects affected / exposed	0 / 24 (0.00%)	0 / 5 (0.00%)	3 / 5 (60.00%)
occurrences (all)	0	0	5
Urinary tract infection			
subjects affected / exposed	0 / 24 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Viral infection			

subjects affected / exposed	0 / 24 (0.00%)	0 / 5 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 24 (0.00%)	0 / 5 (0.00%)	2 / 5 (40.00%)
occurrences (all)	0	0	2
Metabolism and nutrition disorders			
Acidosis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Decreased appetite			
subjects affected / exposed	0 / 24 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Dehydration			
subjects affected / exposed	0 / 24 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hyperkalaemia			
subjects affected / exposed	0 / 24 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hypocalcaemia			
subjects affected / exposed	0 / 24 (0.00%)	0 / 5 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Hypochloraemia			
subjects affected / exposed	0 / 24 (0.00%)	0 / 5 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hypoglycaemia			
subjects affected / exposed	0 / 24 (0.00%)	0 / 5 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Hypokalaemia			
subjects affected / exposed	0 / 24 (0.00%)	0 / 5 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Metabolic acidosis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 5 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1

Non-serious adverse events	Prospective TED/TED Group		
Total subjects affected by non-serious adverse events			

subjects affected / exposed	18 / 19 (94.74%)		
Vascular disorders			
Flushing			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences (all)	1		
General disorders and administration site conditions			
Administration site extravasation			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences (all)	1		
Catheter site inflammation			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences (all)	1		
Fatigue			
subjects affected / exposed	2 / 19 (10.53%)		
occurrences (all)	3		
Generalised oedema			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences (all)	1		
Ill-defined disorder			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences (all)	1		
Injection site induration			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences (all)	1		
Injection site pain			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences (all)	2		
Injection site reaction			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences (all)	1		
Injection site swelling			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences (all)	1		
Medical device site irritation			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences (all)	1		

Pyrexia			
subjects affected / exposed	2 / 19 (10.53%)		
occurrences (all)	2		
Secretion discharge			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences (all)	1		
Immune system disorders			
Food allergy			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences (all)	4		
Hypersensitivity			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences (all)	1		
Seasonal allergy			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences (all)	2		
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	6 / 19 (31.58%)		
occurrences (all)	8		
Dyspnoea			
subjects affected / exposed	2 / 19 (10.53%)		
occurrences (all)	2		
Epistaxis			
subjects affected / exposed	2 / 19 (10.53%)		
occurrences (all)	10		
Nasal congestion			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences (all)	1		
Oropharyngeal pain			
subjects affected / exposed	3 / 19 (15.79%)		
occurrences (all)	3		
Pleuritic pain			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences (all)	1		
Rhinorrhoea			

subjects affected / exposed	1 / 19 (5.26%)		
occurrences (all)	1		
Psychiatric disorders			
Aggression			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences (all)	1		
Attention deficit/hyperactivity disorder			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences (all)	1		
Depression			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Sleep disorder			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences (all)	1		
Product issues			
Device dislocation			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences (all)	1		
Device leakage			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences (all)	1		
Device occlusion			
subjects affected / exposed	3 / 19 (15.79%)		
occurrences (all)	4		
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences (all)	1		
Bacterial test positive			
subjects affected / exposed	3 / 19 (15.79%)		
occurrences (all)	3		
Blood albumin decreased			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences (all)	1		
Blood creatine increased			

subjects affected / exposed	0 / 19 (0.00%)			
occurrences (all)	0			
Blood creatinine increased				
subjects affected / exposed	0 / 19 (0.00%)			
occurrences (all)	0			
Blood iron decreased				
subjects affected / exposed	1 / 19 (5.26%)			
occurrences (all)	1			
Blood sodium decreased				
subjects affected / exposed	1 / 19 (5.26%)			
occurrences (all)	1			
Blood urine present				
subjects affected / exposed	1 / 19 (5.26%)			
occurrences (all)	1			
Body temperature increased				
subjects affected / exposed	1 / 19 (5.26%)			
occurrences (all)	1			
C-reactive protein increased				
subjects affected / exposed	5 / 19 (26.32%)			
occurrences (all)	6			
Gamma-glutamyltransferase increased				
subjects affected / exposed	1 / 19 (5.26%)			
occurrences (all)	1			
Gastrointestinal stoma output increased				
subjects affected / exposed	1 / 19 (5.26%)			
occurrences (all)	1			
Haematocrit decreased				
subjects affected / exposed	1 / 19 (5.26%)			
occurrences (all)	1			
Haemoglobin decreased				
subjects affected / exposed	1 / 19 (5.26%)			
occurrences (all)	1			
Heart rate increased				

subjects affected / exposed	1 / 19 (5.26%)		
occurrences (all)	2		
Hepatic enzyme increased			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences (all)	1		
Lipase increased			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences (all)	1		
Lymph node palpable			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences (all)	1		
Occult blood positive			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences (all)	1		
Platelet count increased			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Serum ferritin decreased			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences (all)	1		
Streptococcus test positive			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences (all)	1		
Vitamin a decreased			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences (all)	1		
Weight decreased			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences (all)	1		
White blood cells urine positive			
subjects affected / exposed	2 / 19 (10.53%)		
occurrences (all)	2		
pH urine increased			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences (all)	1		
Injury, poisoning and procedural			

complications			
Gastrointestinal stoma complication			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences (all)	2		
Infusion related reaction			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences (all)	3		
Medication error			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences (all)	1		
Procedural pain			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences (all)	1		
Skin abrasion			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences (all)	1		
Nervous system disorders			
Dizziness			
subjects affected / exposed	3 / 19 (15.79%)		
occurrences (all)	4		
Dysarthria			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences (all)	1		
Headache			
subjects affected / exposed	5 / 19 (26.32%)		
occurrences (all)	16		
Lethargy			
subjects affected / exposed	3 / 19 (15.79%)		
occurrences (all)	6		
Migraine			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences (all)	1		
Seizure			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences (all)	1		
Syncope			

subjects affected / exposed	1 / 19 (5.26%)		
occurrences (all)	1		
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	3 / 19 (15.79%)		
occurrences (all)	7		
Lymphadenopathy			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences (all)	1		
Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences (all)	1		
Middle ear effusion			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences (all)	1		
Eye disorders			
Visual impairment			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences (all)	1		
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences (all)	1		
Abdominal distension			
subjects affected / exposed	3 / 19 (15.79%)		
occurrences (all)	3		
Abdominal pain			
subjects affected / exposed	7 / 19 (36.84%)		
occurrences (all)	22		
Abdominal pain upper			
subjects affected / exposed	2 / 19 (10.53%)		
occurrences (all)	7		
Constipation			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Diarrhoea			

subjects affected / exposed	5 / 19 (26.32%)			
occurrences (all)	10			
Dyspepsia				
subjects affected / exposed	2 / 19 (10.53%)			
occurrences (all)	3			
Faecal volume increased				
subjects affected / exposed	2 / 19 (10.53%)			
occurrences (all)	3			
Faeces discoloured				
subjects affected / exposed	1 / 19 (5.26%)			
occurrences (all)	1			
Flatulence				
subjects affected / exposed	1 / 19 (5.26%)			
occurrences (all)	1			
Frequent bowel movements				
subjects affected / exposed	2 / 19 (10.53%)			
occurrences (all)	3			
Gastritis				
subjects affected / exposed	2 / 19 (10.53%)			
occurrences (all)	2			
Gastroenteritis eosinophilic				
subjects affected / exposed	1 / 19 (5.26%)			
occurrences (all)	1			
Gastrooesophageal reflux disease				
subjects affected / exposed	1 / 19 (5.26%)			
occurrences (all)	1			
Haematochezia				
subjects affected / exposed	2 / 19 (10.53%)			
occurrences (all)	3			
Lip swelling				
subjects affected / exposed	2 / 19 (10.53%)			
occurrences (all)	2			
Nausea				
subjects affected / exposed	3 / 19 (15.79%)			
occurrences (all)	7			
Oral mucosal erythema				

subjects affected / exposed	1 / 19 (5.26%)		
occurrences (all)	1		
Perianal erythema			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences (all)	1		
Post-tussive vomiting			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Proctalgia			
subjects affected / exposed	2 / 19 (10.53%)		
occurrences (all)	3		
Proctitis			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences (all)	1		
Rectal discharge			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences (all)	8		
Toothache			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences (all)	1		
Vomiting			
subjects affected / exposed	10 / 19 (52.63%)		
occurrences (all)	55		
Skin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Cold sweat			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences (all)	1		
Dry skin			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences (all)	1		
Eczema			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences (all)	2		

Erythema			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Nodular rash			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences (all)	1		
Pruritus			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences (all)	1		
Rash			
subjects affected / exposed	4 / 19 (21.05%)		
occurrences (all)	4		
Rash erythematous			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Rash pruritic			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences (all)	1		
Swelling face			
subjects affected / exposed	2 / 19 (10.53%)		
occurrences (all)	2		
Renal and urinary disorders			
Haematuria			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences (all)	1		
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences (all)	1		
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences (all)	1		
Back pain			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		

Musculoskeletal pain			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences (all)	1		
Pain in extremity			
subjects affected / exposed	2 / 19 (10.53%)		
occurrences (all)	2		
Infections and infestations			
Bronchiolitis			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Cellulitis			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Croup infectious			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences (all)	1		
Device related infection			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences (all)	1		
Ear infection			
subjects affected / exposed	2 / 19 (10.53%)		
occurrences (all)	2		
Escherichia urinary tract infection			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Furuncle			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences (all)	1		
Gastroenteritis			
subjects affected / exposed	3 / 19 (15.79%)		
occurrences (all)	5		
Gastroenteritis viral			
subjects affected / exposed	3 / 19 (15.79%)		
occurrences (all)	3		
Impetigo			

subjects affected / exposed	1 / 19 (5.26%)		
occurrences (all)	1		
Influenza			
subjects affected / exposed	2 / 19 (10.53%)		
occurrences (all)	3		
Lyme disease			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences (all)	1		
Nasopharyngitis			
subjects affected / exposed	3 / 19 (15.79%)		
occurrences (all)	7		
Otitis media			
subjects affected / exposed	2 / 19 (10.53%)		
occurrences (all)	4		
Pharyngitis streptococcal			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences (all)	3		
Respiratory tract infection			
subjects affected / exposed	2 / 19 (10.53%)		
occurrences (all)	4		
Rhinovirus infection			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Upper respiratory tract infection			
subjects affected / exposed	7 / 19 (36.84%)		
occurrences (all)	18		
Urinary tract infection			
subjects affected / exposed	3 / 19 (15.79%)		
occurrences (all)	3		
Viral infection			
subjects affected / exposed	3 / 19 (15.79%)		
occurrences (all)	5		
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Metabolism and nutrition disorders			

Acidosis			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences (all)	1		
Decreased appetite			
subjects affected / exposed	2 / 19 (10.53%)		
occurrences (all)	2		
Dehydration			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences (all)	1		
Hyperkalaemia			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences (all)	1		
Hypocalcaemia			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Hypochloraemia			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences (all)	1		
Hypoglycaemia			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Hypokalaemia			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Metabolic acidosis			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
22 November 2016	Protocol Amendment 1: - Reporting of AEs during the retrospective period was clarified and corrected for consistency across safety sections of the protocol. Only non-serious AEs related (instead of possibly related) to teduglutide needed to be reported. No changes to the protocol were made for the reporting of all AESIs or any SAEs, regardless of relationship to teduglutide, that occurred during the retrospective period. - Clarification that the interim analysis was to be conducted on all retrospective data, and other interim analyses might also be conducted if needed.
17 March 2017	Protocol Amendment 2: - Inclusion criterion 1 to ensure that subjects whose prior exposure to teduglutide in Study the core study may not have been enough to assess efficacy were eligible to receive treatment in Study SHP633-303. - To specify that a severe TEAE that might lead to dose interruption was also to be graded according to the NCI CTCAE severity grading criteria, in addition to the standard severity categorization (US Department of Health and Human Services et al., 2010). These events were no longer limited to only the events described in the former table entitled "CTCAE Criteria for Adverse Events that May Lead to Dose Interruption (Prospective Period of Observation Only)." Therefore, this table (Table 8-1 of the protocol) was deleted from the protocol.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported