



Clinical trial results:

A Prospective, Open-Label, Long-Term Safety and Efficacy Study of Teduglutide in Pediatric Patients With Short Bowel Syndrome Who Completed TED-C14-006 or SHP633-301

Summary

EudraCT number	2016-000849-30
Trial protocol	BE FI IT GB FR
Global end of trial date	05 November 2020

Results information

Result version number	v1 (current)
This version publication date	16 May 2021
First version publication date	16 May 2021

Trial information

Trial identification

Sponsor protocol code	SHP633-304
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02954458
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@takeda.com
Scientific contact	Study Director, Shire, +1 866 842 5335, ClinicalTransparency@takeda.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	05 November 2020
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	05 November 2020
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objective of this study was to evaluate the long-term safety and tolerability of teduglutide treatment in pediatric subjects with short bowel syndrome (SBS) who completed their core study.

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 (ICH) Good Clinical Practice Guideline E6 (1996), European Union (EU) 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 January 2017
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	Belgium: 1
Country: Number of subjects enrolled	Canada: 4
Country: Number of subjects enrolled	Finland: 4
Country: Number of subjects enrolled	United Kingdom: 12
Country: Number of subjects enrolled	Italy: 1
Country: Number of subjects enrolled	United States: 39
Worldwide total number of subjects	61
EEA total number of subjects	6

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)	6
Children (2-11 years)	51

Adolescents (12-17 years)	3
Adults (18-64 years)	1
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

The study was conducted at 23 sites across the United States, Belgium, Canada, United Kingdom, Finland, and Italy between 09 January 2017 (first subject first visit) and 05 Nov 2020 (last subject last visit).

Pre-assignment

Screening details:

Total of 61 subjects (children and infant) were enrolled in 4 groups: Non-teduglutide/Non-teduglutide(NTT/NTT), Non-teduglutide/Teduglutide(NTT/TED), Teduglutide /Non-teduglutide(TED/NTT) and Teduglutide/Teduglutide(TED/TED). Subjects who completed core study TED-C14-006 [2015-002252-27] or SHP633-301 [2017-003606-40] were eligible for this study.

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Non-teduglutide/Non-teduglutide Treatment (NTT/NTT)

Arm description:

Subjects who participated in standard of care arm in the core study TED-C14-006 [2015-002252-27] or SHP633-301 [2017-003606-40] were enrolled into this extension study but did not receive any teduglutide treatment in no-teduglutide period up to 39 months (Each visit =12 weeks of cycle up to 14 visits) in the study.

Arm type	Experimental
Investigational medicinal product name	Teduglutide
Investigational medicinal product code	SHP633
Other name	
Pharmaceutical forms	Powder and solvent for solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Subjects who participated in standard of care arm in the core study and did not receive any teduglutide treatment in the this extension study.

Arm title	Non-teduglutide/Teduglutide Treatment (NTT/TED)
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Arm description:

Subjects who participated in standard of care arm in the core study TED-C14-006 [2015-002252-27] or SHP633-301 [2017-003606-40] were enrolled into this extension study and received 0.05 milligram per kilogram (mg/kg) of teduglutide subcutaneous (SC) injections once daily up to 36 months (Up to 6 Cycles [each Cycle 1 to 4 = 28 weeks, Cycle 5 = 27 weeks, and Cycle 6 = 16 weeks]).

Arm type	Experimental
Investigational medicinal product name	Teduglutide
Investigational medicinal product code	SHP633
Other name	
Pharmaceutical forms	Powder and solvent for solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Subjects who participated in standard of care arm in the core study and received 0.05 mg/kg teduglutide once daily in this extension study.

Arm title	Teduglutide /Non-teduglutide Treatment (TED/NTT)
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Arm description:

Subjects who received teduglutide in the core study TED-C14-006 [2015-002252-27] or SHP633-301 [2017-003606-40] were enrolled into this extension study but did not receive any teduglutide treatment in no-teduglutide period up to 39 months (Each visit =12 weeks of cycle up to 14 visits) in the study.

Arm type	Experimental
Investigational medicinal product name	Teduglutide
Investigational medicinal product code	SHP633
Other name	
Pharmaceutical forms	Powder and solvent for solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Subjects received 0.05 mg/kg teduglutide in the core study but not in the this extension study;

Arm title	Teduglutide/Teduglutide Treatment (TED/TED)
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Arm description:

Subjects who received teduglutide in the core study TED-C14-006 [2015-002252-27] or SHP633-301 [2017-003606-40] were enrolled into this extension study received 0.05 mg/kg of teduglutide SC injections once daily up to 36 months (Up to 6 Cycles [each Cycle 1 to 4 = 28 weeks, Cycle 5 = 27 weeks, and Cycle 6 = 16 weeks]).

Arm type	Experimental
Investigational medicinal product name	Teduglutide
Investigational medicinal product code	SHP633
Other name	
Pharmaceutical forms	Powder and solvent for solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Subjects received 0.05 mg/kg teduglutide once daily in the core study and in this extension study.

Number of subjects in period 1	Non-teduglutide/Non-teduglutide Treatment (NTT/NTT)	Non-teduglutide/Teduglutide Treatment (NTT/TED)	Teduglutide /Non-teduglutide Treatment (TED/NTT)
Started	7	3	1
Completed	6	3	0
Not completed	1	0	1
Adverse event, serious fatal	-	-	-
Physician decision	-	-	1
Consent withdrawn by subject	-	-	-
Adverse event, non-fatal	-	-	-
Unspecified	-	-	-
Lost to follow-up	1	-	-

Number of subjects in period 1	Teduglutide/Teduglutide Treatment (TED/TED)
Started	50
Completed	38
Not completed	12
Adverse event, serious fatal	1

Physician decision	1
Consent withdrawn by subject	1
Adverse event, non-fatal	1
Unspecified	7
Lost to follow-up	1

Baseline characteristics

Reporting groups

Reporting group title	Non-teduglutide/Non-teduglutide Treatment (NTT/NTT)
Reporting group description: Subjects who participated in standard of care arm in the core study TED-C14-006 [2015-002252-27] or SHP633-301 [2017-003606-40] were enrolled into this extension study but did not receive any teduglutide treatment in no-teduglutide period up to 39 months (Each visit =12 weeks of cycle up to 14 visits) in the study.	
Reporting group title	Non-teduglutide/Teduglutide Treatment (NTT/TED)
Reporting group description: Subjects who participated in standard of care arm in the core study TED-C14-006 [2015-002252-27] or SHP633-301 [2017-003606-40] were enrolled into this extension study and received 0.05 milligram per kilogram (mg/kg) of teduglutide subcutaneous (SC) injections once daily up to 36 months (Up to 6 Cycles [each Cycle 1 to 4 = 28 weeks, Cycle 5 = 27 weeks, and Cycle 6 = 16 weeks]).	
Reporting group title	Teduglutide /Non-teduglutide Treatment (TED/NTT)
Reporting group description: Subjects who received teduglutide in the core study TED-C14-006 [2015-002252-27] or SHP633-301 [2017-003606-40] were enrolled into this extension study but did not receive any teduglutide treatment in no-teduglutide period up to 39 months (Each visit =12 weeks of cycle up to 14 visits) in the study.	
Reporting group title	Teduglutide/Teduglutide Treatment (TED/TED)
Reporting group description: Subjects who received teduglutide in the core study TED-C14-006 [2015-002252-27] or SHP633-301 [2017-003606-40] were enrolled into this extension study received 0.05 mg/kg of teduglutide SC injections once daily up to 36 months (Up to 6 Cycles [each Cycle 1 to 4 = 28 weeks, Cycle 5 = 27 weeks, and Cycle 6 = 16 weeks]).	

Reporting group values	Non-teduglutide/Non-teduglutide Treatment (NTT/NTT)	Non-teduglutide/Teduglutide Treatment (NTT/TED)	Teduglutide /Non-teduglutide Treatment (TED/NTT)
Number of subjects	7	3	1
Age categorical Units:			

Age Continuous			
Here, '99999' indicates that standard deviation was not estimated as only single subject was analysed for the specified arm.			
Units: years			
arithmetic mean	5.8	1.5	6.0
standard deviation	± 5.43	± 0.80	± 99999
Sex: Female, Male			
Units: Subjects			
Female	3	1	0
Male	4	2	1
Race, Customized			
Units: Subjects			
White	3	0	1
Black or African American	1	0	0
Asian	1	1	0
American Indian or Alaska Native	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0

Other	1	1	0
Not allowed based on local regulations	1	1	0
Ethnicity, Customized			
Units: Subjects			
Hispanic or Latino	3	1	0
Not Hispanic or Latino	3	1	1
Not allowed based on local regulations	1	1	0

Reporting group values	Teduglutide/Teduglutide Treatment (TED/TED)	Total	
Number of subjects	50	61	
Age categorical			
Units:			

Age Continuous			
Here, '99999' indicates that standard deviation was not estimated as only single subject was analysed for the specified arm.			
Units: years			
arithmetic mean	5.7		
standard deviation	± 3.69	-	
Sex: Female, Male			
Units: Subjects			
Female	16	20	
Male	34	41	
Race, Customized			
Units: Subjects			
White	38	42	
Black or African American	6	7	
Asian	1	3	
American Indian or Alaska Native	0	0	
Native Hawaiian or Other Pacific Islander	0	0	
Other	1	3	
Not allowed based on local regulations	4	6	
Ethnicity, Customized			
Units: Subjects			
Hispanic or Latino	10	14	
Not Hispanic or Latino	35	40	
Not allowed based on local regulations	5	7	

End points

End points reporting groups

Reporting group title	Non-teduglutide/Non-teduglutide Treatment (NTT/NTT)
Reporting group description: Subjects who participated in standard of care arm in the core study TED-C14-006 [2015-002252-27] or SHP633-301 [2017-003606-40] were enrolled into this extension study but did not receive any teduglutide treatment in no-teduglutide period up to 39 months (Each visit =12 weeks of cycle up to 14 visits) in the study.	
Reporting group title	Non-teduglutide/Teduglutide Treatment (NTT/TED)
Reporting group description: Subjects who participated in standard of care arm in the core study TED-C14-006 [2015-002252-27] or SHP633-301 [2017-003606-40] were enrolled into this extension study and received 0.05 milligram per kilogram (mg/kg) of teduglutide subcutaneous (SC) injections once daily up to 36 months (Up to 6 Cycles [each Cycle 1 to 4 = 28 weeks, Cycle 5 = 27 weeks, and Cycle 6 = 16 weeks]).	
Reporting group title	Teduglutide /Non-teduglutide Treatment (TED/NTT)
Reporting group description: Subjects who received teduglutide in the core study TED-C14-006 [2015-002252-27] or SHP633-301 [2017-003606-40] were enrolled into this extension study but did not receive any teduglutide treatment in no-teduglutide period up to 39 months (Each visit =12 weeks of cycle up to 14 visits) in the study.	
Reporting group title	Teduglutide/Teduglutide Treatment (TED/TED)
Reporting group description: Subjects who received teduglutide in the core study TED-C14-006 [2015-002252-27] or SHP633-301 [2017-003606-40] were enrolled into this extension study received 0.05 mg/kg of teduglutide SC injections once daily up to 36 months (Up to 6 Cycles [each Cycle 1 to 4 = 28 weeks, Cycle 5 = 27 weeks, and Cycle 6 = 16 weeks]).	

Primary: Number of Subjects With Treatment-emergent Adverse Events (TEAEs)

End point title	Number of Subjects With Treatment-emergent Adverse Events (TEAEs) ^[1]
End point description: An adverse event (AE) was any untoward medical occurrence in a clinical investigation subject administered a pharmaceutical product and that does not necessarily have a causal relationship with this treatment. TEAEs were defined as AEs that started or worsened on or after the date of first dose of teduglutide for subjects in the TED/TED, TED/NTT, and NTT/TED treatment groups, or after the core study baseline visit for subjects in the NTT/NTT group. The safety population consisted all enrolled subjects who provided informed consent and met all the inclusion criteria.	
End point type	Primary
End point timeframe: From start of study drug administration up to follow-up (up to Month 46)	
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	Non-teduglutide/Non-teduglutide Treatment (NTT/NTT)	Non-teduglutide/Teduglutide Treatment (NTT/TED)	Teduglutide /Non-teduglutide Treatment (TED/NTT)	Teduglutide/Teduglutide Treatment (TED/TED)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7	3	1	50
Units: Subjects	6	3	1	50

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in Average Total Urine Output at End of Treatment (EOT) of Last Cycle During Teduglutide Treatment Period

End point title	Change From Baseline in Average Total Urine Output at End of Treatment (EOT) of Last Cycle During Teduglutide Treatment Period ^{[2][3]}
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End point description:

Average total urine output was recorded over a 48-hour period of parental support (PS) stability before every scheduled site visit and within 1 week of implementing any PS adjustment. The Average daily urine output milliliter per kilogram per day (mL/kg/day) was calculated as: Total urine output over 48 hours / 2) / body weight (kilogram [kg]) where total urine output was calculated as the sum of the urine output in milliliter (mL) and the urine-only diaper weights in gram (g) (1g = 1mL) for the subject collected on the output diary form of electronic case report from (eCRF). The safety population consisted all enrolled subjects who provided informed consent and met all the inclusion criteria. Here, number of subjects analyzed refer to the subjects evaluable for this endpoint. Data was planned to be collected and analysed for NTT/TED, and TED/TED arm only.

End point type	Primary
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End point timeframe:

Baseline, EOT of last cycle (Up to Month 36) (Cycles 1, 2, 3, 4 = 28 weeks, Cycle 5 = 27 weeks, and Cycle 6 = 16 weeks)

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.

[3] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was only planned to be analysed for the reporting group of "Teduglutide" treatment period only.

End point values	Non-teduglutide/Te duglutide Treatment (NTT/TED)	Teduglutide/Te duglutide Treatment (TED/TED)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2	32		
Units: mL/kg/day				
arithmetic mean (standard deviation)	0.26 (± 1.692)	2.51 (± 22.607)		

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in Average Total Urine Output at Last Visit During Non-Teduglutide (NT) Period

End point title	Change From Baseline in Average Total Urine Output at Last Visit During Non-Teduglutide (NT) Period ^[4]
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End point description:

Average total urine output was recorded over a 48 hour period of PS stability before every scheduled site visit and within 1 week of implementing any PS adjustment. Average daily urine output mL/kg/day was calculated as: (Total urine output over 48 hours / 2) / body weight (kg) where total urine output was calculated as the sum of the urine output in mL and the urine-only diaper weights in gram (1g = 1mL) for the subject collected on the output diary form of electronic case report from (eCRF). The safety population consisted all enrolled subjects who provided informed consent and met all the inclusion criteria. Here, number of subjects analyzed refer to the subjects evaluable for this endpoint. Here, '99999' indicates that standard deviation was not estimated as only single subject was analysed for the specified arm.

End point type	Primary
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End point timeframe:

Baseline, Last visit in NT (up to Month 39) (Each visit= 12 weeks)

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	Non-teduglutide/Non-teduglutide Treatment (NTT/NTT)	Non-teduglutide/Teduglutide Treatment (NTT/TED)	Teduglutide /Non-teduglutide Treatment (TED/NTT)	Teduglutide/Teduglutide Treatment (TED/TED)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	0 ^[5]	1	11
Units: mL/kg/day				
arithmetic mean (standard deviation)	-0.89 (± 7.431)	()	15.01 (± 99999)	-6.87 (± 26.299)

Notes:

[5] - Data was not collected and analysed at this time point, for this respective arm.

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in Average Number of Stools per Day at EOT of Last Cycle During Teduglutide Treatment Period

End point title	Change From Baseline in Average Number of Stools per Day at EOT of Last Cycle During Teduglutide Treatment Period ^[6] ^[7]
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End point description:

Fecal output was recorded over a 48-hour period of PS stability before every scheduled site visit and within 1 week of implementing any PS adjustment. The average daily fecal output was summarized by the average number of stools per day. The average number of stools per day was calculated as (sum of the daily data in a 48-hour period/2). The safety population consisted all enrolled subjects who provided informed consent and met all the inclusion criteria. Here, number of subjects analyzed refer to the subjects evaluable for this endpoint. Data was planned to be collected and analysed for NTT/TED, and TED/TED arm only.

End point type	Primary
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End point timeframe:

Baseline, EOT of last cycle (Up to Month 36) (Cycles 1, 2, 3, 4 = 28 weeks, Cycle 5 = 27 weeks, and Cycle 6 = 16 weeks)

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.

[7] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was only planned to be analysed for the reporting group of "Teduglutide" treatment period only.

End point values	Non-teduglutide/Te duglutide Treatment (NTT/TED)	Teduglutide/Te duglutide Treatment (TED/TED)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0 ^[8]	32		
Units: Stools per day				
arithmetic mean (standard deviation)	()	-0.47 (± 2.272)		

Notes:

[8] - Data was not collected and analysed at this time point, for this respective arm.

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in Average Number of Stools per Day at Last Visit During Non-Teduglutide Period

End point title	Change From Baseline in Average Number of Stools per Day at Last Visit During Non-Teduglutide Period ^[9]
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End point description:

Fecal output was recorded over a 48-hour period of PS stability before every scheduled site visit and within 1 week of implementing any PS adjustment. The average daily fecal output was summarized by the average number of stools per day. The average number of stools per day was calculated as (sum of the daily data in a 48-hour period/2). The safety population consisted all enrolled subjects who provided informed consent and met all the inclusion criteria. Here, number of subjects analyzed refer to the subjects evaluable for this endpoint.

End point type	Primary
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End point timeframe:

Baseline, Last visit in NT (up to Month 39) (Each visit= 12 weeks)

Notes:

[9] - 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	Non-teduglutide/Non-teduglutide Treatment (NTT/NTT)	Non-teduglutide/Te duglutide Treatment (NTT/TED)	Teduglutide /Non-teduglutide Treatment (TED/NTT)	Teduglutide/Te duglutide Treatment (TED/TED)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	0 ^[10]	0 ^[11]	14
Units: Stools per day				
arithmetic mean (standard deviation)	-0.50 (± 0.913)	()	()	0.38 (± 1.780)

Notes:

[10] - Data was not collected and analysed at this time point, for this respective arm.

[11] - Data was not collected and analysed at this time point, for this respective arm.

Statistical analyses

Primary: Change From Baseline in Average Total Daily Stool/Mixed Stool Diaper Weight at EOT of Last Cycle During Teduglutide Treatment Period

End point title	Change From Baseline in Average Total Daily Stool/Mixed Stool Diaper Weight at EOT of Last Cycle During Teduglutide Treatment Period ^{[12][13]}
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End point description:

Fecal output was recorded over a 48-hour period of PS stability before every scheduled site visit and within 1 week of implementing any PS adjustment. The average daily fecal output was summarized by the average total daily stool/mixed stool diaper weight (gram per kilogram per day [g/kg/day]). The body weight was used to calculate the daily stool/mixed stool diaper weight (g/kg/day). The safety population consisted all enrolled subjects who provided informed consent and met all the inclusion criteria. Here, number of subjects analyzed refer to the subjects evaluable for this endpoint. Here, '99999' indicates that standard deviation was not estimated as only single subject was analysed for the specified arm. Data was planned to be collected and analysed for NTT/TED, and TED/TED arm only.

End point type	Primary
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End point timeframe:

Baseline, EOT of last cycle (Up to Month 36) (Cycles 1, 2, 3, 4 = 28 weeks, Cycle 5 = 27 weeks, and Cycle 6 = 16 weeks)

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.

[13] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was only planned to be analysed for the reporting group of "Teduglutide" treatment period only.

End point values	Non-teduglutide/Te duglutide Treatment (NTT/TED)	Teduglutide/Te duglutide Treatment (TED/TED)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1	7		
Units: g/day				
arithmetic mean (standard deviation)	0.00 (± 99999)	-11.35 (± 25.667)		

Statistical analyses

No statistical analyses for this end point

Primary: Change from Baseline in Average Total Daily Stool/Mixed Stool Diaper Weight at Last Visit During Non-Teduglutide Period

End point title	Change from Baseline in Average Total Daily Stool/Mixed Stool Diaper Weight at Last Visit During Non-Teduglutide Period ^[14]
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End point description:

Fecal output was recorded over a 48-hour period of PS stability before every scheduled site visit and within 1 week of implementing any PS adjustment. The average daily fecal output was summarized by the average total daily stool/mixed stool diaper weight (g/kg/day). The body weight was used to calculate the daily stool/mixed stool diaper weight (g/kg/day). The safety population consisted all enrolled subjects who provided informed consent and met all the inclusion criteria. Here, number of subjects analyzed refer to the subjects evaluable for this endpoint. Here, '99999' indicates that standard deviation was not estimated as only single subject was analysed for the specified arm.

End point type	Primary
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End point timeframe:

Baseline, Last visit in NT (up to Month 39) (Each visit= 12 weeks)

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	Non-teduglutide/Non-teduglutide Treatment (NTT/NTT)	Non-teduglutide/Teduglutide Treatment (NTT/TED)	Teduglutide/Non-teduglutide Treatment (TED/NTT)	Teduglutide/Teduglutide Treatment (TED/TED)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	0 ^[15]	0 ^[16]	4
Units: g/day				
arithmetic mean (standard deviation)	0.31 (± 99999)	()	()	-4.98 (± 20.892)

Notes:

[15] - Data was not collected and analysed at this time point, for this respective arm.

[16] - Data was not collected and analysed at this time point, for this respective arm.

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in Average Total Ostomy Output at EOT of Last Cycle During Teduglutide Treatment Period

End point title	Change From Baseline in Average Total Ostomy Output at EOT of Last Cycle During Teduglutide Treatment Period ^[17] ^[18]
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End point description:

Fecal output was recorded over a 48-hour period of PS stability before every scheduled site visit and within 1 week of implementing any PS adjustment. The average daily fecal output was summarized the average ostomy output per day (mL/kg/day). The safety population consisted all enrolled subjects who provided informed consent and met all the inclusion criteria. Here, number of subjects analyzed refer to the subjects evaluable for this endpoint. Data was planned to be collected and analysed for NTT/TED, and TED/TED arm only.

End point type	Primary
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End point timeframe:

Baseline, EOT of last cycle (Up to Month 36) (Cycles 1, 2, 3, 4 = 28 weeks, Cycle 5 = 27 weeks, and Cycle 6 = 16 weeks)

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.

[18] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was only planned to be analysed for the reporting group of "Teduglutide" treatment period only.

End point values	Non-teduglutide/Teduglutide Treatment (NTT/TED)	Teduglutide/Teduglutide Treatment (TED/TED)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2	5		
Units: mL/kg/day				

arithmetic mean (standard deviation)	-12.52 (± 11.675)	12.16 (± 35.079)		
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Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in Average Total Ostomy Output at Last Visit During Non-Teduglutide Period

End point title	Change From Baseline in Average Total Ostomy Output at Last Visit During Non-Teduglutide Period ^[19]
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End point description:

Fecal output was recorded over a 48-hour period of PS stability before every scheduled site visit and within 1 week of implementing any PS adjustment. The average daily fecal output was summarized the average ostomy output per day. The safety population consisted all enrolled subjects who provided informed consent and met all the inclusion criteria. Here, number of subjects analyzed refer to the subjects evaluable for this endpoint.

End point type	Primary
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End point timeframe:

Baseline, Last visit in NT (up to Month 39) (Each visit= 12 weeks)

Notes:

[19] - 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	Non-teduglutide/Non-teduglutide Treatment (NTT/NTT)	Non-teduglutide/Teduglutide Treatment (NTT/TED)	Teduglutide/Non-teduglutide Treatment (TED/NTT)	Teduglutide/Teduglutide Treatment (TED/TED)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[20]	0 ^[21]	0 ^[22]	2
Units: mL/kg/day				
arithmetic mean (standard deviation)	()	()	()	23.89 (± 37.835)

Notes:

[20] - Data was not collected and analysed at this time point, for this respective arm.

[21] - Data was not collected and analysed at this time point, for this respective arm.

[22] - Data was not collected and analysed at this time point, for this respective arm.

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in Average Bristol Stool Form Score at EOT of Last Cycle During Teduglutide Treatment Period

End point title	Change From Baseline in Average Bristol Stool Form Score at EOT of Last Cycle During Teduglutide Treatment Period ^{[23][24]}
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End point description:

Fecal output was recorded over a 48-hour period of PS stability before every scheduled site visit and within 1 week of implementing any PS adjustment. Average daily fecal output was summarized the average typical stool form score using Bristol Stool Form Scale. Average typical stool form score was calculated as (sum of the daily data in a 48-hour period / 2). Typical Stool Form based on Bristol Stool

Form Scale: 1 - Separate hard lumps, hard to pass, 2 - Sausage-shaped, but lumpy, 3 - Like a sausage but with cracks on the surface, 4- Like a sausage or snake, smooth and soft, 5- Soft blobs with clear-cut edges, 6- Fluffy pieces with ragged edges, a mushy stool, 7- Watery, no solid pieces. Entirely liquid. Analysis was planned based on safety population. Here, number of subjects analyzed refer to the subjects evaluable for this endpoint. Data was planned to be collected and analysed for NTT/TED, and TED/TED arm only.

End point type	Primary
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End point timeframe:

Baseline, EOT of last cycle (Up to Month 36) (Cycles 1, 2, 3, 4 = 28 weeks, Cycle 5 = 27 weeks, and Cycle 6 = 16 weeks)

Notes:

[23] - 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.

[24] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was only planned to be analysed for the reporting group of "Teduglutide" treatment period only.

End point values	Non-teduglutide/Teduglutide Treatment (NTT/TED)	Teduglutide/Teduglutide Treatment (TED/TED)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0 ^[25]	32		
Units: Score on a Scale				
arithmetic mean (standard deviation)	()	-0.54 (± 0.977)		

Notes:

[25] - Data was not collected and analysed at this time point, for this respective arm.

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in Average Bristol Stool Form Score at Last Visit During Non-Teduglutide Period

End point title	Change From Baseline in Average Bristol Stool Form Score at Last Visit During Non-Teduglutide Period ^[26]
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End point description:

Fecal output was recorded over a 48 hour period of PS stability before every scheduled site visit and within 1 week of implementing any PS adjustment. Average daily fecal output was summarized separately the average typical stool form score using Bristol Stool Form Scale. Average typical stool form score was calculated as (sum of the daily data in a 48-hour period / 2). Typical Stool Form based on Bristol Stool Form Scale: 1- Separate hard lumps, hard to pass, 2- Sausage-shaped, but lumpy, 3- Like a sausage but with cracks on the surface, 4 - Like a sausage or snake, smooth and soft, 5- Soft blobs with clear-cut edges, 6- Fluffy pieces with ragged edges, a mushy stool, 7- Watery, no solid pieces entirely liquid. Analysis were performed by safety population. Number of subjects analysed refer to the subjects evaluable for this endpoint. Here, '99999' indicates standard deviation was not estimated as only single subject was analysed.

End point type	Primary
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End point timeframe:

Baseline, Last visit in NT (up to Month 39) (Each visit= 12 weeks)

Notes:

[26] - 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	Non-teduglutide/Non-teduglutide Treatment (NTT/NTT)	Non-teduglutide/Teduglutide Treatment (NTT/TED)	Teduglutide/Non-teduglutide Treatment (TED/NTT)	Teduglutide/Teduglutide Treatment (TED/TED)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	0 ^[27]	1	14
Units: Score on a Scale				
arithmetic mean (standard deviation)	-0.25 (± 0.500)	()	0.00 (± 99999)	-0.08 (± 0.583)

Notes:

[27] - Data was not collected and analysed at this time point, for this respective arm.

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects With Positive Specific Antibodies

End point title	Number of Subjects With Positive Specific Antibodies ^{[28][29]}
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End point description:

Number of subjects with positive specific antibodies to teduglutide were used to summarize the presence of antibodies. The safety population consisted all enrolled subjects who provided informed consent and met all the inclusion criteria. Here, number of subjects analyzed refer to the subjects evaluable for this endpoint. Data was planned to be collected and analysed for NTT/TED, TED/NTT and TED/TED arms only.

End point type	Primary
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End point timeframe:

Baseline up to EOS (Up to Month 46)

Notes:

[28] - 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.

[29] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was only planned to be analysed for the reporting group of "Teduglutide" treatment period only.

End point values	Non-teduglutide/Teduglutide Treatment (NTT/TED)	Teduglutide/Non-teduglutide Treatment (TED/NTT)	Teduglutide/Teduglutide Treatment (TED/TED)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	3	1	40	
Units: Subjects	2	0	10	

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in Body Weight Z-score at EOT of Last Cycle During Teduglutide Treatment Period

End point title	Change From Baseline in Body Weight Z-score at EOT of Last
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End point description:

Body weight was measured using 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. The safety population consisted all enrolled subjects who provided informed consent and met all the inclusion criteria. Here, number of subjects analyzed refer to the subjects evaluable for this endpoint. Data was planned to be collected and analysed for NTT/TED, and TED/TED arm only.

End point type	Primary
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End point timeframe:

Baseline, EOT of last cycle (Up to Month 36) (Cycles 1, 2, 3, 4 = 28 weeks, Cycle 5 = 27 weeks, and Cycle 6 = 16 weeks)

Notes:

[30] - 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.

[31] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was only planned to be analysed for the reporting group of "Teduglutide" treatment period only.

End point values	Non-teduglutide/Teduglutide Treatment (NTT/TED)	Teduglutide/Teduglutide Treatment (TED/TED)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2	43		
Units: Z-score				
arithmetic mean (standard deviation)	0.087 (± 0.422)	-0.164 (± 0.951)		

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in Body Weight Z-score at Last Visit During Non-Teduglutide Period

End point title	Change From Baseline in Body Weight Z-score at Last Visit During Non-Teduglutide Period ^[32]
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End point description:

Body weight was measured using 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. The safety population consisted all enrolled subjects who provided informed consent and met all the inclusion criteria. Here, number of subjects analyzed refer to the subjects evaluable for this endpoint. Here, '99999' indicates that standard deviation was not estimated as only single subject was analysed for the specified arm. Data was planned to be collected and analysed for NTT/TED, and TED/TED arm only.

End point type	Primary
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End point timeframe:

Baseline, Last visit in NT (up to Month 39) (Each visit= 12 weeks)

Notes:

[32] - 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	Non-teduglutide/Non-teduglutide Treatment (NTT/NTT)	Non-teduglutide/Teduglutide Treatment (NTT/TED)	Teduglutide/Non-teduglutide Treatment (TED/NTT)	Teduglutide/Teduglutide Treatment (TED/TED)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	1	1	19
Units: Z-score				
arithmetic mean (standard deviation)	-0.489 (\pm 0.542)	-0.132 (\pm 99999)	0.013 (\pm 99999)	-0.363 (\pm 0.657)

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in Height Z-score at EOT of Last Cycle During Teduglutide Treatment Period

End point title	Change From Baseline in Height Z-score at EOT of Last Cycle During Teduglutide Treatment Period ^[33] ^[34]
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End point description:

Height was measured using 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 \geq 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. The safety population consisted all enrolled subjects who provided informed consent and met all the inclusion criteria. Here, number of subjects analyzed refer to the subjects evaluable for this endpoint. Data was planned to be collected and analysed for NTT/TED, and TED/TED arm only.

End point type	Primary
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End point timeframe:

Baseline, EOT of last cycle (Up to Month 36) (Cycles 1, 2, 3, 4 = 28 weeks, Cycle 5 = 27 weeks, and Cycle 6 = 16 weeks)

Notes:

[33] - 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.

[34] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was only planned to be analysed for the reporting group of "Teduglutide" treatment period only.

End point values	Non-teduglutide/Teduglutide Treatment (NTT/TED)	Teduglutide/Teduglutide Treatment (TED/TED)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2	27		
Units: Z-score				
arithmetic mean (standard deviation)	0.118 (\pm 0.968)	-0.277 (\pm 0.797)		

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in Height Z-score at Last Visit During Non-Teduglutide Period

End point title	Change From Baseline in Height Z-score at Last Visit During Non-Teduglutide Period ^[35]
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End point description:

Height was measured using 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. The safety population consisted all enrolled subjects who provided informed consent and met all the inclusion criteria. Here, number of subjects analyzed refer to the subjects evaluable for this endpoint. Here, '99999' indicates that standard deviation was not estimated as only single subject was analysed for the specified arm.

End point type	Primary
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End point timeframe:

Baseline, Last visit in NT (up to Month 39) (Each visit= 12 weeks)

Notes:

[35] - 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	Non-teduglutide/Non-teduglutide Treatment (NTT/NTT)	Non-teduglutide/Teduglutide Treatment (NTT/TED)	Teduglutide/Non-teduglutide Treatment (TED/NTT)	Teduglutide/Teduglutide Treatment (TED/TED)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	1	1	18
Units: Z-score				
arithmetic mean (standard deviation)	-0.518 (± 0.451)	-0.770 (± 99999)	0.220 (± 99999)	-0.132 (± 0.466)

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in Head Circumference Z-score at EOT of Last Cycle During Teduglutide Treatment Period

End point title	Change From Baseline in Head Circumference Z-score at EOT of Last Cycle During Teduglutide Treatment Period ^{[36][37]}
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End point description:

Head circumference was measured using 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. The safety population consisted all enrolled subjects who provided informed consent and met all the inclusion criteria. Here, number of subjects analyzed refer to the subjects evaluable for this endpoint. Data was planned to be collected and analysed for NTT/TED, and TED/TED arm only.

End point type	Primary
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End point timeframe:

Baseline, EOT of last cycle (Up to Month 36) (Cycles 1, 2, 3, 4 = 28 weeks, Cycle 5 = 27 weeks, and Cycle 6 = 16 weeks)

Notes:

[36] - 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.

[37] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was only planned to be analysed for the reporting group of "Teduglutide" treatment period only.

End point values	Non-teduglutide/Teduglutide Treatment (NTT/TED)	Teduglutide/Teduglutide Treatment (TED/TED)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0 ^[38]	2		
Units: Z-score				
arithmetic mean (standard deviation)	()	-0.727 (± 0.440)		

Notes:

[38] - Data was not collected and analysed at this time point, for this respective arm.

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in Head Circumference Z-score at Last Visit During Non-Teduglutide Period

End point title	Change From Baseline in Head Circumference Z-score at Last Visit During Non-Teduglutide Period ^[39]
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End point description:

Head circumference was measured using 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. The safety population consisted all enrolled subjects who provided informed consent and met all the inclusion criteria. Here, number of subjects analyzed refer to the subjects evaluable for this endpoint. Here, '99999' indicates that standard deviation was not estimated as only single subject was analysed for the specified arm.

End point type	Primary
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End point timeframe:

Baseline, Last visit in NT (up to Month 39) (Each visit= 12 weeks)

Notes:

[39] - 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	Non-teduglutide/Non-teduglutide Treatment (NTT/NTT)	Non-teduglutide/Teduglutide Treatment (NTT/TED)	Teduglutide/Non-teduglutide Treatment (TED/NTT)	Teduglutide/Teduglutide Treatment (TED/TED)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[40]	0 ^[41]	0 ^[42]	1
Units: Z-score				
arithmetic mean (standard deviation)	()	()	()	-0.309 (± 99999)

Notes:

[40] - Data was not collected and analysed at this time point, for this respective arm.

[41] - Data was not collected and analysed at this time point, for this respective arm.

[42] - Data was not collected and analysed at this time point, for this respective arm.

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in Body Mass Index (BMI) Z-score at EOT of Last Cycle During Teduglutide Treatment Period

End point title	Change From Baseline in Body Mass Index (BMI) Z-score at EOT of Last Cycle During Teduglutide Treatment Period ^[43] ^[44]
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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. The safety population consisted all enrolled subjects who provided informed consent and met all the inclusion criteria. Here, number of subjects analyzed refer to the subjects evaluable for this endpoint. Data was planned to be collected and analysed for NTT/TED, and TED/TED arm only.

End point type	Primary
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End point timeframe:

Baseline, EOT of last cycle (Up to Month 36) (Cycles 1, 2, 3, 4 = 28 weeks, Cycle 5 = 27 weeks, and Cycle 6 = 16 weeks)

Notes:

[43] - 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.

[44] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was only planned to be analysed for the reporting group of "Teduglutide" treatment period only.

End point values	Non-teduglutide/Teduglutide Treatment (NTT/TED)	Teduglutide/Teduglutide Treatment (TED/TED)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2	43		
Units: Z-score				
arithmetic mean (standard deviation)	0.215 (± 0.142)	0.035 (± 0.904)		

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in Body Mass Index (BMI) Z-score at Last Visit During Non-Teduglutide Period

End point title	Change From Baseline in Body Mass Index (BMI) Z-score at Last Visit During Non-Teduglutide Period ^[45]
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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. The safety population consisted all enrolled subjects who provided informed consent and met all the inclusion criteria. Here, number of subjects analyzed refer to the subjects evaluable for this endpoint. Here, '99999' indicates that standard deviation was not estimated as only single subject was analysed for the specified arm.

End point type	Primary
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End point timeframe:

Baseline, Last visit in NT (up to Month 39) (Each visit= 12 weeks)

Notes:

[45] - 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	Non-teduglutide/Non-teduglutide Treatment (NTT/NTT)	Non-teduglutide/Teduglutide Treatment (NTT/TED)	Teduglutide/Non-teduglutide Treatment (TED/NTT)	Teduglutide/Teduglutide Treatment (TED/TED)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	1	1	19
Units: Z-score				
arithmetic mean (standard deviation)	-0.545 (± 1.335)	0.791 (± 99999)	-0.564 (± 99999)	-0.148 (± 0.555)

Statistical analyses

No statistical analyses for this end point

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

End point title	Number of Subjects Who Achieved At least 20 Percent (%), 50%, and 75% Reduction From Baseline in Diary Parenteral Support (PS) Volume at End of Treatment (EOT) of Each Cycle During Teduglutide Treatment Period ^[46]
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End point description:

Number of subjects who achieved at least 20%, 50%, and 75% reduction from baseline in diary PS volume at EOT of last cycle during teduglutide treatment period was reported. The safety population consisted all enrolled subjects who provided informed consent and met all the inclusion criteria. Here, "n=number analysed" refer to subjects who were evaluable at given categories. Data was planned to be collected and analysed for NTT/TED, and TED/TED arm only

End point type	Secondary
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End point timeframe:

Baseline, EOT of each cycle 1, 2, 3, 4, 5, and 6 (Cycles 1, 2, 3, 4 = 28 weeks, Cycle 5 = 27 weeks, and Cycle 6 = 16 weeks)

Notes:

[46] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was only planned to be analysed for the reporting group of "Teduglutide" treatment period only.

End point values	Non-teduglutide/Teduglutide Treatment (NTT/TED)	Teduglutide/Teduglutide Treatment (TED/TED)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3	50		
Units: Subjects				
EOT of Cycle 1: \geq 20% Reduction (n=3, 50)	1	29		
EOT of Cycle 1: \geq 50% Reduction (n=3, 50)	0	13		
EOT of Cycle 1: \geq 75% Reduction (n=3, 50)	0	7		
EOT of Cycle 2: \geq 20% Reduction (n=2, 43)	1	29		
EOT of Cycle 2: \geq 50% Reduction (n=2, 43)	0	17		
EOT of Cycle 2: \geq 75% Reduction (n=2, 43)	0	9		
EOT of Cycle 3: \geq 20% Reduction (n=2, 33)	2	22		
EOT of Cycle 3: \geq 50% Reduction (n=2, 33)	0	14		
EOT of Cycle 3: \geq 75% Reduction (n=2, 33)	0	6		
EOT of Cycle 4: \geq 20% Reduction (n=1, 27)	1	20		
EOT of Cycle 4: \geq 50% Reduction (n=1, 27)	1	13		
EOT of Cycle 4: \geq 75% Reduction (n=1, 27)	0	7		
EOT of Cycle 5: \geq 20% Reduction (n=1, 20)	1	15		
EOT of Cycle 5: \geq 50% Reduction (n=1, 20)	1	13		
EOT of Cycle 5: \geq 75% Reduction (n=1, 20)	0	6		
EOT of Cycle 6: \geq 20% Reduction (n=0, 3)	0	2		
EOT of Cycle 6: \geq 50% Reduction (n=0, 3)	0	2		
EOT of Cycle 6: \geq 75% Reduction (n=0, 3)	0	1		

Statistical analyses

Secondary: Number of Subjects Who Achieved At least 20 Percent (%), 50%, and 75% Reduction From Baseline in Prescribed PS Volume at End of Treatment (EOT) of Each Cycle During Teduglutide Treatment Period

End point title	Number of Subjects Who Achieved At least 20 Percent (%), 50%, and 75% Reduction From Baseline in Prescribed PS Volume at End of Treatment (EOT) of Each Cycle During Teduglutide Treatment Period ^[47]
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End point description:

Number of subjects who achieved at least 20%, 50%, and 75% reduction from baseline in prescribed PS volume at EOT of each cycle during teduglutide treatment period was reported. The safety population consisted all enrolled subjects who provided informed consent and met all the inclusion criteria. Here, "n=number analysed" refer to subjects who were evaluable at given categories. Data was planned to be collected and analysed for NTT/TED, and TED/TED arm only.

End point type	Secondary
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End point timeframe:

Baseline, EOT of each cycle 1, 2, 3, 4, 5, and 6 (Cycles 1, 2, 3, 4 = 28 weeks, Cycle 5 = 27 weeks, and Cycle 6 = 16 weeks)

Notes:

[47] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was only planned to be analysed for the reporting group of "Teduglutide" treatment period only.

End point values	Non-teduglutide/Te duglutide Treatment (NTT/TED)	Teduglutide/Te duglutide Treatment (TED/TED)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3	50		
Units: Subjects				
EOT of Cycle 1: \geq 20% Reduction in PS (n=3, 50)	2	35		
EOT of Cycle 1: \geq 50% Reduction in PS (n=3, 50)	0	18		
EOT of Cycle 1: \geq 75% Reduction in PS (n=3, 50)	0	9		
EOT of Cycle 2: \geq 20% Reduction in PS (n=2, 43)	2	31		
EOT of Cycle 2: \geq 50% Reduction in PS (n=2, 43)	2	18		
EOT of Cycle 2: \geq 75% Reduction in PS (n=2, 43)	1	11		
EOT of Cycle 3: \geq 20% Reduction in PS (n=2, 33)	2	24		
EOT of Cycle 3: \geq 50% Reduction in PS (n=2, 33)	1	14		
EOT of Cycle 3: \geq 75% Reduction in PS (n=2, 33)	1	7		
EOT of Cycle 4: \geq 20% Reduction in PS (n=1, 27)	1	21		
EOT of Cycle 4: \geq 50% Reduction in PS (n=1, 27)	1	13		
EOT of Cycle 4: \geq 75% Reduction in PS (n=1, 27)	0	7		
EOT of Cycle 5: \geq 20% Reduction in PS (n=1, 20)	1	17		

EOT of Cycle 5: \geq 50% Reduction in PS (n=1, 20)	1	12		
EOT of Cycle 5: \geq 75% Reduction in PS (n=1, 20)	0	6		
EOT of Cycle 6: \geq 20% Reduction in PS (n=0, 3)	0	2		
EOT of Cycle 6: \geq 50% Reduction in PS (n=0, 3)	0	2		
EOT of Cycle 6: \geq 75% Reduction in PS (n=0, 3)	0	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Diary PS Volume at EOT of Each Cycle During Teduglutide Treatment Period

End point title	Change From Baseline in Diary PS Volume at EOT of Each Cycle During Teduglutide Treatment Period ^[48]
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End point description:

Change from baseline in diary PS volume at EOT of each cycle during teduglutide treatment period was reported. The safety population consisted all enrolled subjects who provided informed consent and met all the inclusion criteria. Here, number of subjects analysed refer to the subjects evaluable for this endpoint and "n=number analysed" refer to subjects evaluable at given categories. Here, '99999' indicates that standard deviation was not estimated as only single subject was analysed at specified time point and '9999' indicates that data was not estimated as no subject was analysed at specified time point. Data was planned to be collected and analysed for NTT/TED, and TED/TED arm only.

End point type	Secondary
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End point timeframe:

Baseline, EOT of each cycle 1, 2, 3, 4, 5, and 6 (Cycles 1, 2, 3, 4 = 28 weeks, Cycle 5 = 27 weeks, and Cycle 6 = 16 weeks)

Notes:

[48] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was only planned to be analysed for the reporting group of "Teduglutide" treatment period only.

End point values	Non-teduglutide/Teduglutide Treatment (NTT/TED)	Teduglutide/Teduglutide Treatment (TED/TED)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3	39		
Units: mL/kg/day				
arithmetic mean (standard deviation)				
Change at EOT of Cycle 1 (n=3, 39)	-14.87 (\pm 4.574)	-22.63 (\pm 18.125)		
Change at EOT of Cycle 2 (n=2, 38)	-8.98 (\pm 10.490)	-25.75 (\pm 22.480)		
Change at EOT of Cycle 3 (n=3, 29)	-34.81 (\pm 15.314)	-32.01 (\pm 28.837)		
Change at EOT of Cycle 4 (n=1, 25)	-57.45 (\pm 99999)	-32.61 (\pm 24.639)		
Change at EOT of Cycle 5 (n=1, 19)	-56.90 (\pm 99999)	-38.76 (\pm 21.148)		

Change at EOT of Cycle 6 (n=0, 3)	9999 (± 9999)	-40.51 (± 24.833)		
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Statistical analyses

No statistical analyses for this end point

Secondary: Percent Change From Baseline in Diary PS Volume at EOT of Each Cycle During Teduglutide Treatment Period

End point title	Percent Change From Baseline in Diary PS Volume at EOT of Each Cycle During Teduglutide Treatment Period ^[49]
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End point description:

Percent change from baseline in diary PS volume at EOT of each cycle during teduglutide treatment period was reported. The safety population consisted all enrolled subjects who provided informed consent and met all the inclusion criteria. Here, number of subjects analysed refer to the subjects evaluable for this endpoint and "n=number analysed" refer to subjects evaluable at given categories. Here, '99999' indicates that standard deviation was not estimated as only single subject was analysed at specified time point and '9999' indicates that data was not estimated as no subject was analysed at specified time point. Data was planned to be collected and analysed for NTT/TED, and TED/TED arm only.

End point type	Secondary
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End point timeframe:

Baseline, EOT of each cycle 1, 2, 3, 4, 5, and 6 (Cycles 1, 2, 3, 4 = 28 weeks, Cycle 5 = 27 weeks, and Cycle 6 = 16 weeks)

Notes:

[49] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was only planned to be analysed for the reporting group of "Teduglutide" treatment period only.

End point values	Non-teduglutide/Teduglutide Treatment (NTT/TED)	Teduglutide/Teduglutide Treatment (TED/TED)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3	39		
Units: Percent change arithmetic mean (standard deviation)				
Percent change at EOT of Cycle 1 (n=3, 39)	-23.23 (± 15.103)	-41.88 (± 34.100)		
Percent change at EOT of Cycle 2 (n=2, 38)	-13.29 (± 16.826)	-45.67 (± 38.377)		
Percent change at EOT of Cycle 3 (n=2, 29)	-38.66 (± 2.603)	-46.62 (± 37.756)		
Percent change at EOT of Cycle 4 (n=1, 25)	-50.99 (± 99999)	-51.28 (± 36.364)		
Percent change at EOT of Cycle 5 (n=1, 19)	-50.50 (± 99999)	-58.86 (± 33.522)		
Percent change at EOT of Cycle 6 (n=0, 3)	9999 (± 9999)	-52.87 (± 32.722)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Prescribed PS Volume at EOT of Each Cycle During Teduglutide Treatment Period

End point title	Change From Baseline in Prescribed PS Volume at EOT of Each Cycle During Teduglutide Treatment Period ^[50]
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End point description:

Change from baseline in prescribed PS volume at EOT of each cycle during teduglutide treatment period was reported. The safety population consisted all enrolled subjects who provided informed consent and met all the inclusion criteria. Here, "n=number analysed" refer to subjects who were evaluable at given categories. Here, '99999' indicates that standard deviation was not estimated as only single subject was analysed at specified time point and '9999' indicates that data was not estimated as no subject was analysed at specified time point. Data was planned to be collected and analysed for NTT/TED, and TED/TED arm only.

End point type	Secondary
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End point timeframe:

Baseline, EOT of each cycle 1, 2, 3, 4, 5, and 6 (Cycles 1, 2, 3, 4 = 28 weeks, Cycle 5 = 27 weeks, and Cycle 6 = 16 weeks)

Notes:

[50] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was only planned to be analysed for the reporting group of "Teduglutide" treatment period only.

End point values	Non-teduglutide/Teduglutide Treatment (NTT/TED)	Teduglutide/Teduglutide Treatment (TED/TED)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3	50		
Units: mL/kg/day				
arithmetic mean (standard deviation)				
Change at EOT of Cycle 1 (n=3, 50)	-22.57 (± 13.957)	-20.87 (± 20.957)		
Change at EOT of Cycle 2 (n=2, 43)	-65.88 (± 12.621)	-24.24 (± 24.914)		
Change at EOT of Cycle 3 (n=2, 33)	-58.82 (± 4.022)	-30.53 (± 26.449)		
Change at EOT of Cycle 4 (n=1, 27)	-68.72 (± 99999)	-34.53 (± 23.849)		
Change at EOT of Cycle 5 (n=1, 20)	-68.99 (± 99999)	-37.78 (± 22.850)		
Change at EOT of Cycle 6 (n=0, 3)	9999 (± 9999)	-39.10 (± 24.154)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percent Change From Baseline in Prescribed PS Volume at EOT of Each Cycle During Teduglutide Treatment Period

End point title	Percent Change From Baseline in Prescribed PS Volume at EOT of Each Cycle During Teduglutide Treatment Period ^[51]
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End point description:

Percent change from baseline in prescribed PS volume at EOT of each cycle during teduglutide treatment period was reported. The safety population consisted all enrolled subjects who provided informed consent and met all the inclusion criteria. Here, "n=number analysed" refer to subjects who were evaluable at given categories. Here, '99999' indicates that standard deviation was not estimated as only single subject was analysed at specified time point and '9999' indicates that data was not estimated as no subject was analysed at specified time point. Data was planned to be collected and analysed for NTT/TED, and TED/TED arm only.

End point type	Secondary
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End point timeframe:

Baseline, EOT of each cycle 1, 2, 3, 4, 5, and 6 (Cycles 1, 2, 3, 4 = 28 weeks, Cycle 5 = 27 weeks, and Cycle 6 = 16 weeks)

Notes:

[51] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was only planned to be analysed for the reporting group of "Teduglutide" treatment period only.

End point values	Non-teduglutide/Teduglutide Treatment (NTT/TED)	Teduglutide/Teduglutide Treatment (TED/TED)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3	50		
Units: Percent change				
arithmetic mean (standard deviation)				
Percent change at EOT of Cycle 1 (n=3, 50)	-28.82 (± 12.660)	-34.43 (± 52.810)		
Percent change at EOT of Cycle 2 (n=2, 43)	-73.03 (± 18.304)	-42.38 (± 42.375)		
Percent change at EOT of Cycle 3 (n=2, 33)	-67.01 (± 24.723)	-44.07 (± 36.002)		
Percent change at EOT of Cycle 4 (n=1, 27)	-55.20 (± 99999)	-52.78 (± 33.033)		
Percent change at EOT of Cycle 5 (n=1, 20)	-55.42 (± 99999)	-57.42 (± 34.250)		
Percent change at EOT of Cycle 6 (n=0, 3)	9999 (± 9999)	-52.62 (± 33.377)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Diary PS Caloric Intake at EOT of Each Cycle During Teduglutide Treatment Period

End point title	Change From Baseline in Diary PS Caloric Intake at EOT of
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End point description:

Change from baseline in diary PS caloric intake at EOT of each cycle during teduglutide treatment period was reported. Here, kilo-calories per kilogram per day was abbreviated as (kcal/kg/day). The safety population consisted all enrolled subjects who provided informed consent and met all the inclusion criteria. Here, number of subjects analysed refer to the subjects evaluable for this endpoint and "n=number analysed" refer to subjects evaluable at given categories. Here, '99999' indicates that standard deviation was not estimated as only single subject was analysed at specified time point and '9999' indicates that data was not estimated as no subject was analysed at specified time point. Data was planned to be collected and analysed for NTT/TED, and TED/TED arm only.

End point type	Secondary
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End point timeframe:

Baseline, EOT of each cycle 1, 2, 3, 4, 5, and 6 (Cycles 1, 2, 3, 4 = 28 weeks, Cycle 5 = 27 weeks, and Cycle 6 = 16 weeks)

Notes:

[52] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was only planned to be analysed for the reporting group of "Teduglutide" treatment period only.

End point values	Non-teduglutide/Teduglutide Treatment (NTT/TED)	Teduglutide/Teduglutide Treatment (TED/TED)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3	39		
Units: kcal/kg/day				
arithmetic mean (standard deviation)				
Change at EOT of Cycle 1 (n=3, 39)	-16.95 (± 15.141)	-17.40 (± 13.401)		
Change at EOT of Cycle 2 (n=2, 38)	-10.46 (± 0.023)	-18.71 (± 16.722)		
Change at EOT of Cycle 3 (n=2, 29)	-20.77 (± 0.206)	-22.09 (± 18.009)		
Change at EOT of Cycle 4 (n=1, 25)	-34.01 (± 99999)	-24.67 (± 18.859)		
Change at EOT of Cycle 5 (n=1, 19)	-33.68 (± 99999)	-30.20 (± 13.754)		
Change at EOT of Cycle 6 (n=0, 3)	9999 (± 9999)	-34.46 (± 20.080)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percent Change From Baseline in Diary PS Caloric Intake at EOT of Each Cycle During Teduglutide Treatment Period

End point title	Percent Change From Baseline in Diary PS Caloric Intake at EOT of Each Cycle During Teduglutide Treatment Period ^[53]
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End point description:

Percent change from baseline in diary PS Caloric intake at EOT of each cycle during teduglutide treatment period was reported. The safety population consisted all enrolled subjects who provided informed consent and met all the inclusion criteria. Here, number of subjects analysed refer to the subjects evaluable for this endpoint and "n=number analysed" refer to subjects evaluable at given categories. Here, '99999' indicates that standard deviation was not estimated as only single subject was

analysed at specified time point and '9999' indicates that data was not estimated as no subject was analysed at specified time point. Data was planned to be collected and analysed for NTT/TED, and TED/TED arm only.

End point type	Secondary
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End point timeframe:

Baseline, EOT of each cycle 1, 2, 3, 4, 5, and 6 (Cycles 1, 2, 3, 4 = 28 weeks, Cycle 5 = 27 weeks, and Cycle 6 = 16 weeks)

Notes:

[53] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was only planned to be analysed for the reporting group of "Teduglutide" treatment period only.

End point values	Non-teduglutide/Teduglutide Treatment (NTT/TED)	Teduglutide/Teduglutide Treatment (TED/TED)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3	39		
Units: Percent change arithmetic mean (standard deviation)				
Percent change at EOT of Cycle 1 (n=3, 39)	-35.21 (± 31.088)	-45.91 (± 35.484)		
Percent change at EOT of Cycle 2 (n=2, 38)	-14.63 (± 1.162)	-48.66 (± 38.282)		
Percent change at EOT of Cycle 3 (n=2, 29)	-29.03 (± 2.083)	-46.75 (± 38.042)		
Percent change at EOT of Cycle 4 (n=1, 25)	-50.31 (± 99999)	-53.23 (± 37.611)		
Percent change at EOT of Cycle 5 (n=1, 19)	-49.81 (± 99999)	-64.30 (± 30.289)		
Percent change at EOT of Cycle 6 (n=0, 3)	9999 (± 9999)	-50.89 (± 25.667)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Prescribed PS Caloric Intake at EOT of Each Cycle During Teduglutide Treatment Period

End point title	Change From Baseline in Prescribed PS Caloric Intake at EOT of Each Cycle During Teduglutide Treatment Period ^[54]
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End point description:

Change from baseline in prescribed PS caloric intake at EOT of each cycle during teduglutide treatment period was reported. The safety population consisted all enrolled subjects who provided informed consent and met all the inclusion criteria. Here, number of subjects analysed refer to the subjects evaluable for this endpoint and "n=number analysed" refer to subjects evaluable at given categories. Here, '99999' indicates that standard deviation was not estimated as only single subject was analysed at specified time point and '9999' indicates that data was not estimated as no subject was analysed at specified time point. Data was planned to be collected and analysed for NTT/TED, and TED/TED arm only.

End point type	Secondary
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End point timeframe:

Baseline, EOT of each cycle 1, 2, 3, 4, 5, and 6 (Cycles 1, 2, 3, 4 = 28 weeks, Cycle 5 = 27 weeks, and Cycle 6 = 16 weeks)

Notes:

[54] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was only planned to be analysed for the reporting group of "Teduglutide" treatment period only.

End point values	Non-teduglutide/Teduglutide Treatment (NTT/TED)	Teduglutide/Teduglutide Treatment (TED/TED)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3	49		
Units: kcal/kg/day				
arithmetic mean (standard deviation)				
Change at EOT of Cycle 1 (n=3, 49)	-16.94 (± 15.187)	-15.80 (± 17.337)		
Change at EOT of Cycle 2 (n=2, 42)	-37.91 (± 38.003)	-16.00 (± 18.918)		
Change at EOT of Cycle 3 (n=2, 32)	-44.01 (± 27.532)	-20.18 (± 15.633)		
Change at EOT of Cycle 4 (n=1, 27)	-34.59 (± 99999)	-24.48 (± 15.899)		
Change at EOT of Cycle 5 (n=1, 20)	-34.76 (± 99999)	-27.83 (± 15.311)		
Change at EOT of Cycle 6 (n=0, 3)	9999 (± 9999)	-33.30 (± 19.205)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percent Change From Baseline in Prescribed PS Caloric Intake at EOT of Each Cycle During Teduglutide Treatment Period

End point title	Percent Change From Baseline in Prescribed PS Caloric Intake at EOT of Each Cycle During Teduglutide Treatment Period ^[55]
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End point description:

Percent change from baseline in prescribed PS caloric intake at EOT of each cycle during teduglutide treatment period was reported. The safety population consisted all enrolled subjects who provided informed consent and met all the inclusion criteria. Here, number of subjects analysed refer to the subjects evaluable for this endpoint and "n=number analysed" refer to subjects evaluable at given categories. Here, '99999' indicates that standard deviation was not estimated as only single subject was analysed at specified time point and '9999' indicates that data was not estimated as no subject was analysed at specified time point. Data was planned to be collected and analysed for NTT/TED, and TED/TED arm only.

End point type	Secondary
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End point timeframe:

Baseline, EOT of each cycle 1, 2, 3, 4, 5, and 6 (Cycles 1, 2, 3, 4 = 28 weeks, Cycle 5 = 27 weeks, and Cycle 6 = 16 weeks)

Notes:

[55] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was only planned to be analysed for the reporting group of "Teduglutide" treatment period only.

End point values	Non-teduglutide/Te duglutide Treatment (NTT/TED)	Teduglutide/Te duglutide Treatment (TED/TED)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3	49		
Units: Percent change				
arithmetic mean (standard deviation)				
Percent change at EOT of Cycle 1 (n=3, 49)	-34.79 (± 31.100)	-40.67 (± 39.607)		
Percent change at EOT of Cycle 2 (n=2, 42)	-50.00 (± 47.944)	-42.75 (± 45.563)		
Percent change at EOT of Cycle 3 (n=2, 32)	-59.00 (± 32.825)	-44.74 (± 35.274)		
Percent change at EOT of Cycle 4 (n=1, 27)	-50.45 (± 99999)	-54.32 (± 32.153)		
Percent change at EOT of Cycle 5 (n=1, 20)	-50.69 (± 99999)	-59.49 (± 30.789)		
Percent change at EOT of Cycle 6 (n=0, 3)	9999 (± 9999)	-50.67 (± 26.310)		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects Who Achieved 100% Reduction in Complete Weaning of PS Volume at EOT of Each Cycle During Teduglutide Treatment Period

End point title	Number of Subjects Who Achieved 100% Reduction in Complete Weaning of PS Volume at EOT of Each Cycle During Teduglutide Treatment Period ^[56]
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End point description:

Number of subjects who achieved at least 100% reduction in complete weaning of PS volume at EOT of each cycle during teduglutide treatment period was reported. The safety population consisted all enrolled subjects who provided informed consent and met all the inclusion criteria. Here, "n=number analysed" refer to subjects who were evaluable at given categories. Data was planned to be collected and analysed for NTT/TED, and TED/TED arm only.

End point type	Secondary
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End point timeframe:

Baseline, EOT of each cycle 1, 2, 3, 4, 5, and 6 (Cycles 1, 2, 3, 4 = 28 weeks, Cycle 5 = 27 weeks, and Cycle 6 = 16 weeks)

Notes:

[56] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was only planned to be analysed for the reporting group of "Teduglutide" treatment period only.

End point values	Non-teduglutide/Te duglutide Treatment (NTT/TED)	Teduglutide/Te duglutide Treatment (TED/TED)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3	50		
Units: Subjects				
EOT of Cycle 1 (n=3, 50)	0	7		

EOT of Cycle 2 (n=2, 43)	0	8		
EOT of Cycle 3 (n=2, 33)	0	6		
EOT of Cycle 4 (n=1, 27)	0	6		
EOT of Cycle 5 (n=1, 20)	0	6		
EOT of Cycle 6 (n=0, 3)	0	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Hours per Day of Diary PS Usage at EOT of Each Cycle During Teduglutide Treatment Period

End point title	Change From Baseline in Hours per Day of Diary PS Usage at EOT of Each Cycle During Teduglutide Treatment Period ^[57]
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End point description:

Change from baseline in hours per day of diary PS usage at EOT of each cycle during teduglutide treatment period was reported. Hours per day of diary PS was calculated as: Hours per day of actual PS = (sum of hours per day for each day that PS intake data is recorded within the 7 days prior to the visit / number of days that PS hours per day data is recorded as non-zero within the 7 days prior to the visit). The safety population consisted all enrolled subjects who provided informed consent and met all the inclusion criteria. Here, number of subjects analysed refer to the subjects evaluable for this endpoint and "n=number analysed" refer to subjects evaluable at given categories. Here, '99999' indicates that standard deviation was not estimated as only single subject was analysed at specified time point and '9999' indicates that data was not estimated as no subject was analysed at specified time point. Data was planned to be collected and analysed for NTT/TED, and TED/TED arm only.

End point type	Secondary
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End point timeframe:

Baseline, EOT of each cycle 1, 2, 3, 4, 5, and 6 (Cycles 1, 2, 3, 4 = 28 weeks, Cycle 5 = 27 weeks, and Cycle 6 = 16 weeks)

Notes:

[57] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was only planned to be analysed for the reporting group of "Teduglutide" treatment period only.

End point values	Non-teduglutide/Teduglutide Treatment (NTT/TED)	Teduglutide/Teduglutide Treatment (TED/TED)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3	39		
Units: hours/day				
arithmetic mean (standard deviation)				
Change at EOT of Cycle 1 (n=3, 39)	-0.57 (± 0.990)	-3.58 (± 3.750)		
Change at EOT of Cycle 2 (n=2, 28)	-1.71 (± 2.424)	-3.55 (± 4.497)		
Change at EOT of Cycle 3 (n=2, 29)	-3.57 (± 2.222)	-4.19 (± 5.036)		
Change at EOT of Cycle 4 (n=1, 25)	-4.00 (± 99999)	-4.83 (± 5.069)		
Change at EOT of Cycle 5 (n=1, 19)	-4.00 (± 99999)	-5.64 (± 5.392)		
Change at EOT of Cycle 6 (n=0, 3)	9999 (± 9999)	-5.14 (± 4.536)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percent Change From Baseline in Hours per Day of Diary PS Usage at EOT of Each Cycle During Teduglutide Treatment Period

End point title	Percent Change From Baseline in Hours per Day of Diary PS Usage at EOT of Each Cycle During Teduglutide Treatment Period ^[58]
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End point description:

Percent change from baseline in hours per day of diary PS usage at EOT of each cycle during teduglutide treatment period was reported. Hours per day of diary PS was calculated as: Hours per day of actual PS = (sum of hours per day for each day that PS intake data is recorded within the 7 days prior to the visit / number of days that PS hours per day data is recorded as non-zero within the 7 days prior to the visit). Safety population consisted all enrolled subjects who provided informed consent and met all the inclusion criteria. Number of subjects analysed refer to the subjects evaluable for this endpoint and "n=number analysed" refer to subjects evaluable at given categories. Here, '99999' indicates that standard deviation was not estimated as only single subject was analysed at specified time point and '9999' indicates that data was not estimated as no subject was analysed at specified time point. Data was planned to be collected and analysed for NTT/TED, and TED/TED arm only.

End point type	Secondary
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End point timeframe:

Baseline, EOT of each cycle 1, 2, 3, 4, 5, and 6 (Cycles 1, 2, 3, 4 = 28 weeks, Cycle 5 = 27 weeks, and Cycle 6 = 16 weeks)

Notes:

[58] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was only planned to be analysed for the reporting group of "Teduglutide" treatment period only.

End point values	Non-teduglutide/Teduglutide Treatment (NTT/TED)	Teduglutide/Teduglutide Treatment (TED/TED)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3	39		
Units: Percent change				
arithmetic mean (standard deviation)				
Percent change at EOT of Cycle 1 (n=3, 39)	-4.76 (± 8.248)	-33.43 (± 35.645)		
Percent change at EOT of Cycle 2 (n=2, 38)	-14.29 (± 20.203)	-34.12 (± 41.982)		
Percent change at EOT of Cycle 3 (n=2, 29)	-26.98 (± 22.448)	-35.11 (± 41.822)		
Percent change at EOT of Cycle 4 (n=1, 25)	-22.22 (± 99999)	-40.68 (± 42.255)		
Percent change at EOT of Cycle 5 (n=1, 19)	-22.22 (± 99999)	-47.07 (± 44.248)		
Percent change at EOT of Cycle 6 (n=0, 3)	9999 (± 9999)	-42.86 (± 37.796)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Hours per Day of Prescribed PS Usage at EOT of Each Cycle During Teduglutide Treatment Period

End point title	Change From Baseline in Hours per Day of Prescribed PS Usage at EOT of Each Cycle During Teduglutide Treatment Period ^[59]
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End point description:

Change from baseline in hours per day of prescribed PS usage at EOT of each cycle during teduglutide treatment period was reported. Hours per day of prescribed PS was calculated as: Hours per day of actual PS = (sum of hours per day for each day that PS intake data is recorded within the 7 days prior to the visit / number of days that PS hours per day data is recorded as non-zero within the 7 days prior to the visit). The safety population consisted all enrolled subjects who provided informed consent and met all the inclusion criteria. Here, "n=number analysed" refer to subjects who were evaluable at given categories. Here, '99999' indicates that standard deviation was not estimated as only single subject was analysed at specified time point and '9999' indicates that data was not estimated as no subject was analysed at specified time point. Data was planned to be collected and analysed for NTT/TED, and TED/TED arm only.

End point type	Secondary
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End point timeframe:

Baseline, EOT of each cycle 1, 2, 3, 4, 5, and 6 (Cycles 1, 2, 3, 4 = 28 weeks, Cycle 5 = 27 weeks, and Cycle 6 = 16 weeks)

Notes:

[59] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was only planned to be analysed for the reporting group of "Teduglutide" treatment period only.

End point values	Non-teduglutide/Teduglutide Treatment (NTT/TED)	Teduglutide/Teduglutide Treatment (TED/TED)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3	50		
Units: hours/day				
arithmetic mean (standard deviation)				
Change at EOT of Cycle 1 (n=3, 50)	0.00 (± 0.000)	-2.60 (± 4.279)		
Change at EOT of Cycle 2 (n=2, 43)	-3.00 (± 4.243)	-2.78 (± 5.479)		
Change at EOT of Cycle 3 (n=2, 33)	-1.00 (± 1.414)	-2.79 (± 5.400)		
Change at EOT of Cycle 4 (n=1, 27)	-4.00 (± 99999)	-3.43 (± 5.849)		
Change at EOT of Cycle 5 (n=1, 20)	-4.00 (± 99999)	-3.93 (± 6.070)		
Change at EOT of Cycle 6 (n=0, 3)	9999 (± 9999)	0.00 (± 0.000)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percent Change From Baseline in Hours per Day of Prescribed PS Usage at EOT of Each Cycle During Teduglutide Treatment Period

End point title	Percent Change From Baseline in Hours per Day of Prescribed PS Usage at EOT of Each Cycle During Teduglutide Treatment Period ^[60]
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End point description:

Percent change from baseline in hours per day of prescribed PS usage at EOT of each cycle during teduglutide treatment period was reported. Hours per day of prescribed PS was calculated as: Hours per day of actual PS = (sum of hours per day for each day that PS intake data is recorded within the 7 days prior to the visit / number of days that PS hours per day data is recorded as non-zero within the 7 days prior to the visit). Safety population; all enrolled subjects who provided informed consent and met all the inclusion criteria. Here, number of subjects analysed refer to subjects evaluable for this endpoint and "n=number analysed" refer to subjects evaluable at given categories. Here, '99999' indicates that standard deviation was not estimated as only single subject was analysed at specified time point and '9999' indicates that data was not estimated as no subject was analysed at specified time point. Data was planned to be collected and analysed for NTT/TED, and TED/TED arm only.

End point type	Secondary
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End point timeframe:

Baseline, EOT of each cycle 1, 2, 3, 4, 5, and 6 (Cycles 1, 2, 3, 4 = 28 weeks, Cycle 5 = 27 weeks, and Cycle 6 = 16 weeks)

Notes:

[60] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was only planned to be analysed for the reporting group of "Teduglutide" treatment period only.

End point values	Non-teduglutide/Teduglutide Treatment (NTT/TED)	Teduglutide/Teduglutide Treatment (TED/TED)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3	49		
Units: Percent change				
arithmetic mean (standard deviation)				
Percent change at EOT of Cycle 1 (n=3, 49)	0.00 (± 0.000)	-21.27 (± 34.449)		
Percent change at EOT of Cycle 2 (n=2, 42)	-16.67 (± 23.570)	-22.75 (± 47.101)		
Percent change at EOT of Cycle 3 (n=2, 32)	-5.56 (± 7.857)	-20.64 (± 40.735)		
Percent change at EOT of Cycle 4 (n=1, 26)	-22.22 (± 99999)	-25.47 (± 43.906)		
Percent change at EOT of Cycle 5 (n=1, 19)	-22.22 (± 99999)	-32.28 (± 48.126)		
Percent change at EOT of Cycle 6 (n=0, 3)	9999 (± 9999)	0.00 (± 0.000)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Days per Week of Diary PS Usage at EOT of Each Cycle During Teduglutide Treatment Period

End point title	Change From Baseline in Days per Week of Diary PS Usage at EOT of Each Cycle During Teduglutide Treatment Period ^[61]
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End point description:

Change from baseline in days per week of diary PS usage at EOT of each cycle during teduglutide treatment period was reported. Days per week of diary PS was calculated as: Days per week of actual PS = (number of days with non-zero values for PS volume within the 7 days prior to the visit / number of days for which any PS intake data was recorded within the 7 days prior to the visit) * 7. The safety population consisted all enrolled subjects who provided informed consent and met all the inclusion criteria. Here, number of subjects analysed refer to the subjects evaluable for this endpoint and "n=number analysed" refer to subjects evaluable at given categories. Here, '99999' indicates that standard deviation was not estimated as only single subject was analysed at specified time point and '9999' indicates that data was not estimated as no subject was analysed at specified time point. Data was planned to be collected and analysed for NTT/TED, and TED/TED arm only.

End point type	Secondary
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End point timeframe:

Baseline, EOT of each cycle 1, 2, 3, 4, 5, and 6 (Cycles 1, 2, 3, 4 = 28 weeks, Cycle 5 = 27 weeks, and Cycle 6 = 16 weeks)

Notes:

[61] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was only planned to be analysed for the reporting group of "Teduglutide" treatment period only.

End point values	Non-teduglutide/Teduglutide Treatment (NTT/TED)	Teduglutide/Teduglutide Treatment (TED/TED)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3	39		
Units: Days/week				
arithmetic mean (standard deviation)				
Change at EOT of Cycle 1 (n=3, 39)	-0.33 (± 0.577)	-1.41 (± 2.432)		
Change at EOT of Cycle 2 (n=2, 38)	-1.00 (± 1.414)	-1.76 (± 2.508)		
Change at EOT of Cycle 3 (n=2, 29)	-1.50 (± 2.121)	-2.13 (± 2.756)		
Change at EOT of Cycle 4 (n=1, 25)	0.00 (± 99999)	-2.36 (± 2.956)		
Change at EOT of Cycle 5 (n=1, 19)	0.00 (± 99999)	-2.70 (± 3.107)		
Change at EOT of Cycle 6 (n=0, 3)	9999 (± 9999)	-3.00 (± 2.646)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percent Change From Baseline in Days per Week of Diary PS Usage at EOT of Each Cycle During Teduglutide Treatment Period

End point title	Percent Change From Baseline in Days per Week of Diary PS Usage at EOT of Each Cycle During Teduglutide Treatment Period ^[62]
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End point description:

Percent change from baseline in days per week of diary PS usage at EOT of each cycle during teduglutide treatment period was reported. Days per week of diary PS was calculated as: Days per week of actual PS = (number of days with non-zero values for PS volume within the 7 days prior to the visit / number of days for which any PS intake data was recorded within the 7 days prior to the visit) * 7. Safety population consisted all enrolled subjects who provided informed consent and met all the inclusion criteria. Here, number of subjects analysed refer to the subjects evaluable for this endpoint and "n=number analysed" refer to subjects evaluable at given categories. Here, '99999' indicates that standard deviation was not estimated as only single subject was analysed at specified time point and '9999' indicates that data was not estimated as no subject was analysed at specified time point. Data was planned to be collected and analysed for NTT/TED, and TED/TED arm only.

End point type	Secondary
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End point timeframe:

Baseline, EOT of each cycle 1, 2, 3, 4, 5, and 6 (Cycles 1, 2, 3, 4 = 28 weeks, Cycle 5 = 27 weeks, and Cycle 6 = 16 weeks)

Notes:

[62] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was only planned to be analysed for the reporting group of "Teduglutide" treatment period only.

End point values	Non-teduglutide/Teduglutide Treatment (NTT/TED)	Teduglutide/Teduglutide Treatment (TED/TED)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3	39		
Units: Percent change				
arithmetic mean (standard deviation)				
Percent change at EOT of Cycle 1 (n=3, 39)	-4.76 (± 8.248)	-23.40 (± 39.994)		
Percent change at EOT of Cycle 2 (n=2, 38)	-14.29 (± 20.203)	-29.07 (± 41.805)		
Percent change at EOT of Cycle 3 (n=2, 29)	-21.43 (± 30.305)	-31.37 (± 41.530)		
Percent change at EOT of Cycle 4 (n=1, 25)	0.00 (± 99999)	-34.66 (± 44.475)		
Percent change at EOT of Cycle 5 (n=1, 19)	0.00 (± 99999)	-39.50 (± 47.024)		
Percent change at EOT of Cycle 6 (n=0, 3)	9999 (± 9999)	-42.86 (± 37.796)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Days per Week of Prescribed PS Usage at EOT of Each Cycle During Teduglutide Treatment Period

End point title	Change From Baseline in Days per Week of Prescribed PS Usage at EOT of Each Cycle During Teduglutide Treatment Period ^[63]
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End point description:

Change from baseline in days per week of prescribed PS usage at EOT of each cycle during teduglutide treatment period was reported. Days per week of prescribed PS was calculated as: Days per week of actual PS = (number of days with non-zero values for PS volume within the 7 days prior to the visit / number of days for which any PS intake data was recorded within the 7 days prior to the visit) * 7. The safety population consisted all enrolled subjects who provided informed consent and met all the inclusion criteria. Here, "n=number analysed" refer to subjects who were evaluable at given categories. Here, '99999' indicates that standard deviation was not estimated as only single subject was analysed at specified time point and '9999' indicates that data was not estimated as no subject was analysed at specified time point. Data was planned to be collected and analysed for NTT/TED, and TED/TED arm only.

End point type	Secondary
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End point timeframe:

Baseline, EOT of each cycle 1, 2, 3, 4, 5, and 6 (Cycles 1, 2, 3, 4 = 28 weeks, Cycle 5 = 27 weeks, and Cycle 6 = 16 weeks)

Notes:

[63] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was only planned to be analysed for the reporting group of "Teduglutide" treatment period only.

End point values	Non-teduglutide/Teduglutide Treatment (NTT/TED)	Teduglutide/Teduglutide Treatment (TED/TED)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3	50		
Units: Days/week				
arithmetic mean (standard deviation)				
Change at EOT of Cycle 1 (n=3, 50)	-0.33 (± 0.577)	-1.42 (± 2.251)		
Change at EOT of Cycle 2 (n=2, 43)	-1.00 (± 1.414)	-1.65 (± 2.399)		
Change at EOT of Cycle 3 (n=2, 33)	-1.50 (± 2.121)	-1.85 (± 2.623)		
Change at EOT of Cycle 4 (n=1, 27)	0.00 (± 99999)	-2.15 (± 2.852)		
Change at EOT of Cycle 5 (n=1, 20)	0.00 (± 99999)	-2.75 (± 3.041)		
Change at EOT of Cycle 6 (n=0, 3)	9999 (± 9999)	-3.00 (± 2.646)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percent Change From Baseline in Days per Week of Prescribed PS Usage at EOT of Each Cycle During Teduglutide Treatment Period

End point title	Percent Change From Baseline in Days per Week of Prescribed PS Usage at EOT of Each Cycle During Teduglutide Treatment Period ^[64]
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End point description:

Percent change from baseline in days per week of prescribed PS usage at EOT of each cycle during teduglutide treatment period was reported. Days per week of prescribed PS was calculated as: Days per week of actual PS = (number of days with non-zero values for PS volume within the 7 days prior to the visit / number of days for which any PS intake data was recorded within the 7 days prior to the visit) * 7. Safety population consisted all enrolled subjects who provided informed consent and met all the inclusion criteria. Here, '99999' indicates that standard deviation was not estimated as only single subject was analysed at specified time point and '9999' indicates that data was not estimated as no subject was analysed at specified time point. Data was planned to be collected and analysed for NTT/TED, and TED/TED arm only.

End point type	Secondary
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End point timeframe:

Baseline, EOT of each cycle 1, 2, 3, 4, 5, and 6 (Cycles 1, 2, 3, 4 = 28 weeks, Cycle 5 = 27 weeks, and Cycle 6 = 16 weeks)

Notes:

[64] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was only planned to be analysed for the reporting group of "Teduglutide" treatment period only.

End point values	Non-teduglutide/Teduglutide Treatment (NTT/TED)	Teduglutide/Teduglutide Treatment (TED/TED)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3	50		
Units: Percent change				
arithmetic mean (standard deviation)				
Percent change at EOT of Cycle 1 (n=3, 50)	-4.76 (± 8.248)	-23.18 (± 36.926)		
Percent change at EOT of Cycle 2 (n=2, 43)	-14.29 (± 20.203)	-27.41 (± 40.209)		
Percent change at EOT of Cycle 3 (n=2, 33)	-21.43 (± 30.305)	-27.58 (± 40.258)		
Percent change at EOT of Cycle 4 (n=1, 27)	0.00 (± 99999)	-32.12 (± 43.730)		
Percent change at EOT of Cycle 5 (n=1, 20)	0.00 (± 99999)	-40.86 (± 46.839)		
Percent change at EOT of Cycle 6 (n=0, 3)	9999 (± 9999)	-42.86 (± 37.796)		

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 EOT of Each Cycle During Teduglutide Treatment Period

End point title	Change From Baseline In Pediatric Quality of Life Inventory (PedsQL) Generic Core Scale (GCS) Score at EOT of Each Cycle During Teduglutide Treatment Period ^[65]
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End point description:

PedsQL GCS was designed to measure health-related quality of life in pediatric subjects and adolescents (2 to 18 years of age). It encompasses 4 dimensions of functioning (physical [8 items], emotional [5 items], social [5 items], school [3 items]). Age groups were: Toddler (2-4 years), Young pediatric (5-7 years), Pediatric (8-12 years), and Teens (13-18 years). Depending on the subjects age, the questionnaire may be completed by parent/caregiver as appropriate. For Toddler group, PedsQL GCS consisted of 21 items, using a 5-point Likert scale (0 to 4); for all other groups, PedsQL GCS consisted of 23 items, with a 3-point Likert scale (0, 2, 4) for the young pediatric, and a 5-point Likert scale for the pediatric 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. Analysis: safety population. Data was planned to be collected and analysed for NTT/TED, and TED/TED arm only.

End point type	Other pre-specified
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End point timeframe:

Baseline, EOT of each cycle 1, 2, 3, 4, 5, and 6 (Cycles 1, 2, 3, 4 = 28 weeks, Cycle 5 = 27 weeks, and Cycle 6 = 16 weeks)

Notes:

[65] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was only planned to be analysed for the reporting group of "Teduglutide" treatment period only.

End point values	Non-teduglutide/Teduglutide Treatment (NTT/TED)	Teduglutide/Teduglutide Treatment (TED/TED)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2	42		
Units: Score on a scale				
arithmetic mean (standard deviation)				
Physical Functioning: EOT of Cycle 1 (n=2, 42)	-21.88 (± 8.839)	-2.44 (± 22.323)		
Physical Functioning: EOT of Cycle 2 (n=1, 34)	-18.75 (± 99999)	4.69 (± 22.327)		
Physical Functioning: EOT of Cycle 3 (n=1, 28)	-18.75 (± 99999)	-5.80 (± 27.093)		
Physical Functioning: EOT of Cycle 4 (n=1, 22)	-9.38 (± 99999)	4.12 (± 20.872)		
Physical Functioning: EOT of Cycle 5 (n=1, 11)	-15.63 (± 99999)	4.83 (± 20.840)		
Physical Functioning: EOT of Cycle 6 (n=0, 0)	9999 (± 9999)	9999 (± 9999)		

Emotional Functioning: EOT of Cycle 1 (n=2, 41)	-7.50 (± 10.607)	-2.07 (± 16.807)		
Emotional Functioning: EOT of Cycle 2 (n=1, 34)	5.00 (± 99999)	0.88 (± 15.249)		
Emotional Functioning: EOT of Cycle 3 (n=1, 28)	-15.00 (± 99999)	-0.36 (± 20.680)		
Emotional Functioning: EOT of Cycle 4 (n=1, 22)	5.00 (± 99999)	1.82 (± 22.811)		
Emotional Functioning: EOT of Cycle 5 (n=1, 11)	0.00 (± 99999)	1.36 (± 23.674)		
Emotional Functioning: EOT of Cycle 6 (n=0, 0)	9999 (± 9999)	9999 (± 9999)		
Social Functioning: EOT of Cycle 1 (n=2, 41)	-12.50 (± 17.678)	0.49 (± 18.262)		
Social Functioning: EOT of Cycle 2 (n=1, 34)	-25.00 (± 99999)	5.29 (± 20.484)		
Social Functioning: EOT of Cycle 3 (n=1, 28)	-30.00 (± 99999)	2.14 (± 24.662)		
Social Functioning: EOT of Cycle 4 (n=1, 22)	-15.00 (± 99999)	3.86 (± 23.193)		
Social Functioning: EOT of Cycle 5 (n=1, 11)	-15.00 (± 99999)	2.95 (± 20.458)		
Social Functioning: EOT of Cycle 6 (n=0, 0)	9999 (± 9999)	9999 (± 9999)		
School Functioning: EOT of Cycle 1 (n=0, 31)	9999 (± 9999)	3.33 (± 25.111)		
School Functioning: EOT of Cycle 2 (n=0, 25)	9999 (± 9999)	6.93 (± 27.096)		
School Functioning: EOT of Cycle 3 (n=0, 20)	9999 (± 9999)	1.17 (± 33.804)		
School Functioning: EOT of Cycle 4 (n=0, 15)	9999 (± 9999)	9.89 (± 25.233)		
School Functioning: EOT of Cycle 5 (n=0, 8)	9999 (± 9999)	8.33 (± 23.721)		
School Functioning: EOT of Cycle 6 (n=0, 0)	9999 (± 9999)	9999 (± 9999)		

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Change From Baseline In PedsQL GCS Score at Last Visit During Non-Teduglutide Period

End point title	Change From Baseline In PedsQL GCS Score at Last Visit During Non-Teduglutide Period
End point description:	
<p>PedsQL GCS was designed to measure health-related quality of life in pediatric subjects and adolescents (2 to 18 years of age). It encompasses 4 dimensions of functioning (physical [8 items], emotional [5 items], social [5 items], school [3 items]). Age groups were: Toddler (2-4 years), Young pediatric (5-7 years), Pediatric (8-12 years), and Teens (13-18 years). Depending on the subject's age, the questionnaire may be completed by parent/caregiver as appropriate. For the Toddler group, the PedsQL GCS consisted of 21 items, using a 5-point Likert scale (0 to 4); for all other groups, the PedsQL GCS consisted of 23 items, with a 3-point Likert scale (0, 2, 4) for the young pediatric, and a 5-point Likert scale for the pediatric 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. Analysis: safety population. Here, "n=number analysed" refer to subjects evaluable at given categories.</p>	
End point type	Other pre-specified

End point timeframe:

Baseline, Last visit in NT (up to Month 39) (Each visit= 12 weeks)

End point values	Non-teduglutide/Non-teduglutide Treatment (NTT/NTT)	Non-teduglutide/Teduglutide Treatment (NTT/TED)	Teduglutide/Non-teduglutide Treatment (TED/NTT)	Teduglutide/Teduglutide Treatment (TED/TED)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	1	1	14
Units: Score on a scale				
arithmetic mean (standard deviation)				
Physical Functioning: Last NT (n=4, 1, 1, 13)	3.91 (± 10.636)	-3.13 (± 99999)	31.25 (± 99999)	13.56 (± 22.573)
Emotional Functioning: Last NT (n=4, 1, 1, 14)	-2.50 (± 15.546)	-10.00 (± 99999)	0.00 (± 99999)	2.50 (± 23.101)
Social Functioning: Last NT (n=4, 1, 1, 13)	0.00 (± 4.082)	-10.00 (± 99999)	-10.00 (± 99999)	7.31 (± 16.535)
School Functioning: Last NT (n=3, 0, 1, 9)	11.67 (± 45.369)	9999 (± 9999)	0.00 (± 99999)	3.89 (± 25.954)

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Change From Baseline In PedsQL Total Family Impact Module Score at EOT of Each Cycle During Teduglutide Treatment Period

End point title	Change From Baseline In PedsQL Total Family Impact Module Score at EOT of Each Cycle During Teduglutide Treatment Period ^[66]
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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 family impact 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. Analysis was performed based on safety population. Here, "n=number analysed" refer to subjects evaluable at given categories. Here, '99999' indicates that standard deviation was not estimated as only single subject was analysed at specified time point and '9999' indicates that data was not estimated as no subject was analysed at specified time point. Data was planned to be collected and analysed for NTT/TED, and TED/TED arm only.

End point type	Other pre-specified
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End point timeframe:

Baseline, EOT of each cycle 1, 2, 3, 4, 5, and 6 (Cycles 1, 2, 3, 4 = 28 weeks, Cycle 5 = 27 weeks, and Cycle 6 = 16 weeks)

Notes:

[66] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was only planned to be analysed for the reporting group of "Teduglutide" treatment period only.

End point values	Non-teduglutide/Te duglutide Treatment (NTT/TED)	Teduglutide/Te duglutide Treatment (TED/TED)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3	43		
Units: Score on a Scale				
arithmetic mean (standard deviation)				
Change at EOT of Cycle 1 (n=3, 43)	-10.65 (± 9.326)	1.55 (± 15.071)		
Change at EOT of Cycle 2 (n=2, 34)	-2.78 (± 3.928)	4.62 (± 18.250)		
Change at EOT of Cycle 3 (n=2, 25)	-5.56 (± 5.893)	0.20 (± 20.861)		
Change at EOT of Cycle 4 (n=1, 22)	2.78 (± 99999)	5.27 (± 21.637)		
Change at EOT of Cycle 5 (n=1, 10)	-13.19 (± 99999)	5.08 (± 16.152)		
Change at EOT of Cycle 6 (n=0, 0)	9999 (± 9999)	9999 (± 9999)		

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Change From Baseline In PedsQL Total Family Impact Module Score at Last Visit During Non-Teduglutide Period

End point title	Change From Baseline In PedsQL Total Family Impact Module Score at Last Visit During Non-Teduglutide Period
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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 family impact 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 where 0=100, 1=75, 2=50, 3=25, and 4=0. Higher scores indicate improved quality of life. Analysis was performed based on safety population. Here, number of subjects analysed refer to the subjects evaluable for this endpoint. Here, '99999' indicates that standard deviation was not estimated as only single subject was analysed for the specified arm.

End point type	Other pre-specified
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End point timeframe:

Baseline, Last visit in NT (up to Month 39) (Each visit= 12 weeks)

End point values	Non-teduglutide/Non-teduglutide Treatment (NTT/NTT)	Non-teduglutide/Te duglutide Treatment (NTT/TED)	Teduglutide /Non-teduglutide Treatment (TED/NTT)	Teduglutide/Te duglutide Treatment (TED/TED)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	1	1	15
Units: Score on a scale				
arithmetic mean (standard deviation)	-3.47 (± 10.914)	-27.78 (± 99999)	-12.50 (± 99999)	6.44 (± 22.648)

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Change From Baseline In PedsQL Gastrointestinal Symptoms Module at EOT of Each Cycle During Teduglutide Treatment Period

End point title	Change From Baseline In PedsQL Gastrointestinal Symptoms Module at EOT of Each Cycle During Teduglutide Treatment Period ^[67]
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End point description:

PedsQL Gastrointestinal 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. Sub-scale 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. Analysis was performed based on safety population. Here, number of subjects analysed refer to the subjects evaluable for this endpoint and "n=number analysed" refer to subjects evaluable at given categories. Data was planned to be collected and analysed for NTT/TED, and TED/TED arm only.

End point type	Other pre-specified
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End point timeframe:

Baseline, EOT of each cycle 1, 2, 3, 4, 5, and 6 (Cycles 1, 2, 3, 4 = 28 weeks, Cycle 5 = 27 weeks, and Cycle 6 = 16 weeks)

Notes:

[67] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was only planned to be analysed for the reporting group of "Teduglutide" treatment period only.

End point values	Non-teduglutide/Teduglutide Treatment (NTT/TED)	Teduglutide/Teduglutide Treatment (TED/TED)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2	39		
Units: Score on a scale				
arithmetic mean (standard deviation)				
Food and Drink Limits: EOT of Cycle 1 (n=2, 39)	-12.50 (± 17.678)	1.71 (± 31.250)		
Food and Drink Limits: EOT of Cycle 2 (n=1, 31)	-4.17 (± 99999)	9.41 (± 35.583)		
Food and Drink Limits: EOT of Cycle 3 (n=1, 25)	-4.17 (± 99999)	11.83 (± 36.178)		
Food and Drink Limits: EOT of Cycle 4 (n=1, 22)	12.50 (± 99999)	18.56 (± 33.227)		
Food and Drink Limits: EOT of Cycle 5 (n=1, 10)	0.00 (± 99999)	13.33 (± 25.215)		
Food and Drink Limits: EOT of Cycle 6 (n=0, 0)	9999 (± 9999)	9999 (± 9999)		

Diarrhea: EOT of Cycle 1 (n=1, 36)	0.00 (± 99999)	8.56 (± 21.309)		
Diarrhea: EOT of Cycle 2 (n=1, 30)	0.00 (± 99999)	10.00 (± 19.162)		
Diarrhea: EOT of Cycle 3 (n=0, 23)	9999 (± 9999)	11.49 (± 23.665)		
Diarrhea: EOT of Cycle 4 (n=1, 20)	-3.57 (± 99999)	8.57 (± 23.702)		
Diarrhea: EOT of Cycle 5 (n=0, 9)	9999 (± 9999)	5.56 (± 27.147)		
Diarrhea: EOT of Cycle 6 (n=0, 0)	9999 (± 9999)	9999 (± 9999)		

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Change From Baseline In PedsQL Gastrointestinal Symptoms Module at Last Visit During Non-Teduglutide Period

End point title	Change From Baseline In PedsQL Gastrointestinal Symptoms Module at Last Visit During Non-Teduglutide Period
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End point description:

PedsQL gastrointestinal 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. Sub-scale 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. Analysis: safety population. Number of subjects analysed refer to the subjects evaluable for this endpoint and "n=number analysed" refer to subjects evaluable at given categories. '99999' indicates standard deviation was not estimated as only single subject was analysed for the specified arm.

End point type	Other pre-specified
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End point timeframe:

Baseline, Last visit in NT (up to Month 39) (Each visit= 12 weeks)

End point values	Non-teduglutide/Non-teduglutide Treatment (NTT/NTT)	Non-teduglutide/Teduglutide Treatment (NTT/TED)	Teduglutide/Non-teduglutide Treatment (TED/NTT)	Teduglutide/Teduglutide Treatment (TED/TED)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	1	1	12
Units: Score on a scale				
arithmetic mean (standard deviation)				
Food and Drink Limits: Last NT (n=4,1,1,12)	-7.29 (± 32.698)	-29.17 (± 99999)	-8.33 (± 99999)	5.35 (± 34.013)
Diarrhea: Last NT (n=4,0,1,10)	-4.46 (± 4.494)	9999 (± 9999)	3.57 (± 99999)	1.70 (± 19.555)

Statistical analyses

Adverse events

Adverse events information

Timeframe for reporting adverse events:

From start of study drug administration up to follow-up (up to Month 46)

Assessment type	Non-systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	19.1
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Reporting groups

Reporting group title	Non-teduglutide/Non-teduglutide Treatment (NTT/NTT)
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Reporting group description:

Subjects who participated in standard of care arm in the core study TED-C14-006 [NCT02682381] or SHP633-301 [NCT03571516] were enrolled into this extension study but did not receive any teduglutide treatment in no-teduglutide period up to 39 months (Each visit =12 weeks of cycle up to 14 visits) in the study.

Reporting group title	Non-teduglutide/Teduglutide Treatment (NTT/TED)
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Reporting group description:

Subjects who participated in standard of care arm in the core study TED-C14-006 [NCT02682381] or SHP633-301 [NCT03571516] were enrolled into this extension study and received 0.05 milligram per kilogram (mg/kg) of teduglutide subcutaneous (SC) injections once daily up to 36 months (Up to 6 Cycles [each Cycle 1 to 4 = 28 weeks, Cycle 5 = 27 weeks, and Cycle 6 = 16 weeks]).

Reporting group title	Teduglutide /Non-teduglutide Treatment (TED/NTT)
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Reporting group description:

Subjects who received teduglutide in the core study TED-C14-006 [NCT02682381] or SHP633-301 [NCT03571516] were enrolled into this extension study but did not receive any teduglutide treatment in no-teduglutide period up to 39 months (Each visit =12 weeks of cycle up to 14 visits) in the study.

Reporting group title	Teduglutide/Teduglutide Treatment (TED/TED)
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Reporting group description:

Subjects who received teduglutide in the core study TED-C14-006 [NCT02682381] or SHP633-301 [NCT03571516] were enrolled into this extension study received 0.05 mg/kg of teduglutide SC injections once daily up to 36 months (Up to 6 Cycles [each Cycle 1 to 4 = 28 weeks, Cycle 5 = 27 weeks, and Cycle 6 = 16 weeks]).

Serious adverse events	Non-teduglutide/Non-teduglutide Treatment (NTT/NTT)	Non-teduglutide/Teduglutide Treatment (NTT/TED)	Teduglutide /Non-teduglutide Treatment (TED/NTT)
Total subjects affected by serious adverse events			
subjects affected / exposed	4 / 7 (57.14%)	2 / 3 (66.67%)	1 / 1 (100.00%)
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 / 7 (0.00%)	0 / 3 (0.00%)	0 / 1 (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

Vena cava thrombosis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 1 (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
General disorders and administration site conditions			
Complication associated with device			
subjects affected / exposed	0 / 7 (0.00%)	1 / 3 (33.33%)	0 / 1 (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
Condition aggravated			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 1 (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
Granuloma			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 1 (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	0 / 7 (0.00%)	1 / 3 (33.33%)	0 / 1 (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
Immune system disorders			
Anaphylactic reaction			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 1 (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
Respiratory, thoracic and mediastinal disorders			
Acute respiratory failure			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 1 (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
Cough			

subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 1 (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
Hypocapnia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 1 (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
Respiratory failure			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 1 (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
Psychiatric disorders			
Mental status changes			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 1 (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
Product issues			
Device breakage			
subjects affected / exposed	1 / 7 (14.29%)	0 / 3 (0.00%)	0 / 1 (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 dislocation			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 1 (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
Device expulsion			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 1 (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
Device malfunction			
subjects affected / exposed	1 / 7 (14.29%)	0 / 3 (0.00%)	0 / 1 (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
Device occlusion			

subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 1 (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
Investigations			
Astrovirus test positive			
subjects affected / exposed	0 / 7 (0.00%)	1 / 3 (33.33%)	0 / 1 (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
Bacterial test positive			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 1 (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
Blood bilirubin increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 1 (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
Blood culture positive			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 1 (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
Enterovirus test positive			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 1 (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
Escherichia test positive			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 1 (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
Haemoglobin decreased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 1 (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
Injury, poisoning and procedural complications			

Abdominal wound dehiscence			
subjects affected / exposed	1 / 7 (14.29%)	0 / 3 (0.00%)	0 / 1 (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
Femur fracture			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 1 (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
Postoperative ileus			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 1 (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
Procedural haemorrhage			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 1 (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
Vascular access complication			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 1 (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			
Atrial thrombosis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 1 (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
Nervous system disorders			
Cerebral ischaemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 1 (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
Ischaemic stroke			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 1 (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

Lethargy			
subjects affected / exposed	1 / 7 (14.29%)	0 / 3 (0.00%)	0 / 1 (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
Seizure			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 1 (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 distension			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 1 (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
Abdominal pain			
subjects affected / exposed	0 / 7 (0.00%)	1 / 3 (33.33%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis			
subjects affected / exposed	0 / 7 (0.00%)	1 / 3 (33.33%)	0 / 1 (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
Colonic haematoma			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 1 (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
Diarrhoea			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 1 (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
Enterocutaneous fistula			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 1 (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
Faecaloma			

subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 1 (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 haemorrhage			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 1 (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
Haematochezia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 1 (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
Ileus			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 1 (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
Ileus paralytic			
subjects affected / exposed	0 / 7 (0.00%)	1 / 3 (33.33%)	0 / 1 (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
Intestinal dilatation			
subjects affected / exposed	0 / 7 (0.00%)	1 / 3 (33.33%)	0 / 1 (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
Mallory-Weiss syndrome			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 1 (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
Small intestinal stenosis			
subjects affected / exposed	0 / 7 (0.00%)	1 / 3 (33.33%)	0 / 1 (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
Vomiting			

subjects affected / exposed	0 / 7 (0.00%)	1 / 3 (33.33%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Cholangitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 1 (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
Cholelithiasis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 1 (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
Renal and urinary disorders			
Nephrolithiasis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 1 (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
Renal tubular acidosis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 1 (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
Tubulointerstitial nephritis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 1 (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
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	1 / 1 (100.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tenosynovitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	1 / 1 (100.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Infections and infestations Adenovirus infection subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 7 (0.00%) 0 / 0 0 / 0	0 / 3 (0.00%) 0 / 0 0 / 0	0 / 1 (0.00%) 0 / 0 0 / 0
Arthritis viral subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 7 (0.00%) 0 / 0 0 / 0	0 / 3 (0.00%) 0 / 0 0 / 0	0 / 1 (0.00%) 0 / 0 0 / 0
Bacteraemia subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 7 (0.00%) 0 / 0 0 / 0	0 / 3 (0.00%) 0 / 0 0 / 0	0 / 1 (0.00%) 0 / 0 0 / 0
Catheter site infection subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 7 (0.00%) 0 / 0 0 / 0	0 / 3 (0.00%) 0 / 0 0 / 0	0 / 1 (0.00%) 0 / 0 0 / 0
Cellulitis subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 7 (0.00%) 0 / 0 0 / 0	0 / 3 (0.00%) 0 / 0 0 / 0	0 / 1 (0.00%) 0 / 0 0 / 0
Clostridium difficile colitis subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 7 (0.00%) 0 / 0 0 / 0	0 / 3 (0.00%) 0 / 0 0 / 0	0 / 1 (0.00%) 0 / 0 0 / 0
Clostridium difficile infection subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 7 (0.00%) 0 / 0 0 / 0	0 / 3 (0.00%) 0 / 0 0 / 0	0 / 1 (0.00%) 0 / 0 0 / 0
Croup infectious subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 7 (0.00%) 0 / 0 0 / 0	0 / 3 (0.00%) 0 / 0 0 / 0	0 / 1 (0.00%) 0 / 0 0 / 0
Cystitis			

subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 1 (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
Device related infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 1 (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
Device related sepsis			
subjects affected / exposed	1 / 7 (14.29%)	0 / 3 (0.00%)	0 / 1 (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
Escherichia bacteraemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 1 (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	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 1 (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 astroviral			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 1 (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 clostridial			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 1 (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 viral			
subjects affected / exposed	2 / 7 (28.57%)	0 / 3 (0.00%)	0 / 1 (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
Gastrointestinal bacterial overgrowth			

subjects affected / exposed	1 / 7 (14.29%)	0 / 3 (0.00%)	0 / 1 (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
Hand-foot-and-mouth disease			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 1 (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
Infectious mononucleosis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 1 (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
Influenza			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 1 (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
Lower respiratory tract infection			
subjects affected / exposed	1 / 7 (14.29%)	0 / 3 (0.00%)	0 / 1 (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
Malassezia infection			
subjects affected / exposed	1 / 7 (14.29%)	0 / 3 (0.00%)	0 / 1 (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
Overgrowth bacterial			
subjects affected / exposed	0 / 7 (0.00%)	1 / 3 (33.33%)	0 / 1 (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
Pharyngitis streptococcal			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 1 (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
Pneumonia			

subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 1 (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
Pneumonia viral			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 1 (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
Pulmonary mycosis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 1 (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
Respiratory syncytial virus infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 1 (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
Rhinovirus infection			
subjects affected / exposed	0 / 7 (0.00%)	1 / 3 (33.33%)	0 / 1 (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
Rotavirus infection			
subjects affected / exposed	0 / 7 (0.00%)	1 / 3 (33.33%)	0 / 1 (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
Sepsis			
subjects affected / exposed	1 / 7 (14.29%)	0 / 3 (0.00%)	0 / 1 (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
Septic shock			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 1 (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
Staphylococcal bacteraemia			

subjects affected / exposed	2 / 7 (28.57%)	1 / 3 (33.33%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 1 (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
Staphylococcal sepsis			
subjects affected / exposed	1 / 7 (14.29%)	0 / 3 (0.00%)	0 / 1 (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
Upper respiratory tract infection			
subjects affected / exposed	1 / 7 (14.29%)	0 / 3 (0.00%)	0 / 1 (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
Urinary tract infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 1 (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
Viral infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 1 (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
Viral upper respiratory tract infection			
subjects affected / exposed	1 / 7 (14.29%)	0 / 3 (0.00%)	0 / 1 (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
Metabolism and nutrition disorders			
Acidosis			
subjects affected / exposed	1 / 7 (14.29%)	0 / 3 (0.00%)	0 / 1 (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
Dehydration			

subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 1 (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
Failure to thrive			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 1 (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
Feeding intolerance			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 1 (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
Hyperchloraemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 1 (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
Hypernatraemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 1 (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
Hypokalaemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 1 (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 / 7 (0.00%)	0 / 3 (0.00%)	0 / 1 (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 / 7 (0.00%)	0 / 3 (0.00%)	0 / 1 (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	0 / 7 (0.00%)	0 / 3 (0.00%)	1 / 1 (100.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Teduglutide/Teduglutide Treatment (TED/TED)		
Total subjects affected by serious adverse events			
subjects affected / exposed	41 / 50 (82.00%)		
number of deaths (all causes)	2		
number of deaths resulting from adverse events	0		
Vascular disorders			
Superior vena cava occlusion			
subjects affected / exposed	1 / 50 (2.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Vena cava thrombosis			
subjects affected / exposed	1 / 50 (2.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
General disorders and administration site conditions			
Complication associated with device			
subjects affected / exposed	1 / 50 (2.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Condition aggravated			
subjects affected / exposed	1 / 50 (2.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Granuloma			
subjects affected / exposed	1 / 50 (2.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pyrexia			

subjects affected / exposed	16 / 50 (32.00%)		
occurrences causally related to treatment / all	0 / 31		
deaths causally related to treatment / all	0 / 0		
Immune system disorders			
Anaphylactic reaction			
subjects affected / exposed	1 / 50 (2.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			
Acute respiratory failure			
subjects affected / exposed	1 / 50 (2.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cough			
subjects affected / exposed	1 / 50 (2.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hypocapnia			
subjects affected / exposed	1 / 50 (2.00%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Respiratory failure			
subjects affected / exposed	1 / 50 (2.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Psychiatric disorders			
Mental status changes			
subjects affected / exposed	1 / 50 (2.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Product issues			
Device breakage			

subjects affected / exposed	5 / 50 (10.00%)		
occurrences causally related to treatment / all	0 / 6		
deaths causally related to treatment / all	0 / 0		
Device dislocation			
subjects affected / exposed	2 / 50 (4.00%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Device expulsion			
subjects affected / exposed	1 / 50 (2.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Device malfunction			
subjects affected / exposed	0 / 50 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Device occlusion			
subjects affected / exposed	3 / 50 (6.00%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Investigations			
Astrovirus test positive			
subjects affected / exposed	0 / 50 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bacterial test positive			
subjects affected / exposed	1 / 50 (2.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Blood bilirubin increased			
subjects affected / exposed	1 / 50 (2.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Blood culture positive			

subjects affected / exposed	1 / 50 (2.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Enterovirus test positive			
subjects affected / exposed	1 / 50 (2.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Escherichia test positive			
subjects affected / exposed	1 / 50 (2.00%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Haemoglobin decreased			
subjects affected / exposed	1 / 50 (2.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Injury, poisoning and procedural complications			
Abdominal wound dehiscence			
subjects affected / exposed	0 / 50 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Femur fracture			
subjects affected / exposed	2 / 50 (4.00%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Postoperative ileus			
subjects affected / exposed	1 / 50 (2.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Procedural haemorrhage			
subjects affected / exposed	1 / 50 (2.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Vascular access complication			

subjects affected / exposed	1 / 50 (2.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cardiac disorders			
Atrial thrombosis			
subjects affected / exposed	1 / 50 (2.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Nervous system disorders			
Cerebral ischaemia			
subjects affected / exposed	1 / 50 (2.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Ischaemic stroke			
subjects affected / exposed	1 / 50 (2.00%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Lethargy			
subjects affected / exposed	0 / 50 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Seizure			
subjects affected / exposed	1 / 50 (2.00%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Abdominal distension			
subjects affected / exposed	1 / 50 (2.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Abdominal pain			
subjects affected / exposed	1 / 50 (2.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

Colitis				
subjects affected / exposed	0 / 50 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Colonic haematoma				
subjects affected / exposed	1 / 50 (2.00%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Diarrhoea				
subjects affected / exposed	2 / 50 (4.00%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Enterocutaneous fistula				
subjects affected / exposed	1 / 50 (2.00%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Faecaloma				
subjects affected / exposed	1 / 50 (2.00%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Gastrointestinal haemorrhage				
subjects affected / exposed	1 / 50 (2.00%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Haematochezia				
subjects affected / exposed	1 / 50 (2.00%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Ileus				
subjects affected / exposed	1 / 50 (2.00%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Ileus paralytic				

subjects affected / exposed	0 / 50 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Intestinal dilatation			
subjects affected / exposed	0 / 50 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Mallory-Weiss syndrome			
subjects affected / exposed	1 / 50 (2.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Small intestinal stenosis			
subjects affected / exposed	0 / 50 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vomiting			
subjects affected / exposed	2 / 50 (4.00%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Hepatobiliary disorders			
Cholangitis			
subjects affected / exposed	1 / 50 (2.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cholelithiasis			
subjects affected / exposed	2 / 50 (4.00%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Renal and urinary disorders			
Nephrolithiasis			
subjects affected / exposed	1 / 50 (2.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Renal tubular acidosis			

subjects affected / exposed	1 / 50 (2.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Tubulointerstitial nephritis			
subjects affected / exposed	1 / 50 (2.00%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 50 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Tenosynovitis			
subjects affected / exposed	0 / 50 (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	1 / 50 (2.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Arthritis viral			
subjects affected / exposed	1 / 50 (2.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Bacteraemia			
subjects affected / exposed	1 / 50 (2.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Catheter site infection			
subjects affected / exposed	1 / 50 (2.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

Cellulitis				
subjects affected / exposed	2 / 50 (4.00%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Clostridium difficile colitis				
subjects affected / exposed	1 / 50 (2.00%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Clostridium difficile infection				
subjects affected / exposed	1 / 50 (2.00%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Croup infectious				
subjects affected / exposed	1 / 50 (2.00%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Cystitis				
subjects affected / exposed	1 / 50 (2.00%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Device related infection				
subjects affected / exposed	15 / 50 (30.00%)			
occurrences causally related to treatment / all	0 / 25			
deaths causally related to treatment / all	0 / 0			
Device related sepsis				
subjects affected / exposed	4 / 50 (8.00%)			
occurrences causally related to treatment / all	0 / 4			
deaths causally related to treatment / all	0 / 0			
Escherichia bacteraemia				
subjects affected / exposed	1 / 50 (2.00%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Gastroenteritis				

subjects affected / exposed	1 / 50 (2.00%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Gastroenteritis astroviral				
subjects affected / exposed	1 / 50 (2.00%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Gastroenteritis clostridial				
subjects affected / exposed	1 / 50 (2.00%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Gastroenteritis viral				
subjects affected / exposed	0 / 50 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastrointestinal bacterial overgrowth				
subjects affected / exposed	1 / 50 (2.00%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Hand-foot-and-mouth disease				
subjects affected / exposed	1 / 50 (2.00%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Infectious mononucleosis				
subjects affected / exposed	1 / 50 (2.00%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Influenza				
subjects affected / exposed	6 / 50 (12.00%)			
occurrences causally related to treatment / all	0 / 6			
deaths causally related to treatment / all	0 / 0			
Lower respiratory tract infection				

subjects affected / exposed	0 / 50 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Malassezia infection				
subjects affected / exposed	0 / 50 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Overgrowth bacterial				
subjects affected / exposed	0 / 50 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pharyngitis streptococcal				
subjects affected / exposed	1 / 50 (2.00%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pneumonia				
subjects affected / exposed	1 / 50 (2.00%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pneumonia viral				
subjects affected / exposed	1 / 50 (2.00%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pulmonary mycosis				
subjects affected / exposed	1 / 50 (2.00%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Respiratory syncytial virus infection				
subjects affected / exposed	1 / 50 (2.00%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Rhinovirus infection				

subjects affected / exposed	1 / 50 (2.00%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Rotavirus infection				
subjects affected / exposed	0 / 50 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Sepsis				
subjects affected / exposed	2 / 50 (4.00%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Septic shock				
subjects affected / exposed	1 / 50 (2.00%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Staphylococcal bacteraemia				
subjects affected / exposed	0 / 50 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Staphylococcal infection				
subjects affected / exposed	1 / 50 (2.00%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Staphylococcal sepsis				
subjects affected / exposed	0 / 50 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Upper respiratory tract infection				
subjects affected / exposed	2 / 50 (4.00%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Urinary tract infection				

subjects affected / exposed	3 / 50 (6.00%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Viral infection			
subjects affected / exposed	2 / 50 (4.00%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 50 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Metabolism and nutrition disorders			
Acidosis			
subjects affected / exposed	1 / 50 (2.00%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Dehydration			
subjects affected / exposed	2 / 50 (4.00%)		
occurrences causally related to treatment / all	0 / 7		
deaths causally related to treatment / all	0 / 0		
Failure to thrive			
subjects affected / exposed	1 / 50 (2.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Feeding intolerance			
subjects affected / exposed	2 / 50 (4.00%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Hyperchloraemia			
subjects affected / exposed	1 / 50 (2.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hypernatraemia			

subjects affected / exposed	1 / 50 (2.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hypokalaemia			
subjects affected / exposed	1 / 50 (2.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hyponatraemia			
subjects affected / exposed	1 / 50 (2.00%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Lactic acidosis			
subjects affected / exposed	1 / 50 (2.00%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Metabolic acidosis			
subjects affected / exposed	4 / 50 (8.00%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	Non-teduglutide/Non-teduglutide Treatment (NTT/NTT)	Non-teduglutide/Teduglutide Treatment (NTT/TED)	Teduglutide /Non-teduglutide Treatment (TED/NTT)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	6 / 7 (85.71%)	3 / 3 (100.00%)	1 / 1 (100.00%)
Surgical and medical procedures			
Catheter removal			
subjects affected / exposed	1 / 7 (14.29%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
General disorders and administration site conditions			
Catheter site discharge			

subjects affected / exposed	1 / 7 (14.29%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Catheter site extravasation			
subjects affected / exposed	2 / 7 (28.57%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	2	0	0
Catheter site haemorrhage			
subjects affected / exposed	2 / 7 (28.57%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	2	0	0
Complication associated with device			
subjects affected / exposed	0 / 7 (0.00%)	1 / 3 (33.33%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Fatigue			
subjects affected / exposed	1 / 7 (14.29%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Influenza like illness			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	1 / 1 (100.00%)
occurrences (all)	0	0	1
Medical device site pain			
subjects affected / exposed	0 / 7 (0.00%)	1 / 3 (33.33%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Pyrexia			
subjects affected / exposed	2 / 7 (28.57%)	1 / 3 (33.33%)	1 / 1 (100.00%)
occurrences (all)	2	1	1
Thirst			
subjects affected / exposed	1 / 7 (14.29%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Respiratory, thoracic and mediastinal disorders			
Bronchospasm			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	1 / 1 (100.00%)
occurrences (all)	0	0	1
Cough			
subjects affected / exposed	1 / 7 (14.29%)	2 / 3 (66.67%)	0 / 1 (0.00%)
occurrences (all)	1	3	0
Epistaxis			

subjects affected / exposed	1 / 7 (14.29%)	1 / 3 (33.33%)	0 / 1 (0.00%)
occurrences (all)	2	2	0
Nasal congestion			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	1 / 7 (14.29%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Rhinitis allergic			
subjects affected / exposed	1 / 7 (14.29%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	2	0	0
Rhinorrhoea			
subjects affected / exposed	1 / 7 (14.29%)	1 / 3 (33.33%)	0 / 1 (0.00%)
occurrences (all)	1	2	0
Psychiatric disorders			
Learning disability			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	1 / 1 (100.00%)
occurrences (all)	0	0	1
Product issues			
Device breakage			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Device malfunction			
subjects affected / exposed	1 / 7 (14.29%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Device occlusion			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Blood 25-hydroxycholecalciferol increased			

subjects affected / exposed	1 / 7 (14.29%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Blood bicarbonate decreased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Blood bicarbonate increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	1 / 1 (100.00%)
occurrences (all)	0	0	1
Blood creatinine increased			
subjects affected / exposed	1 / 7 (14.29%)	1 / 3 (33.33%)	0 / 1 (0.00%)
occurrences (all)	1	1	0
Blood triglycerides increased			
subjects affected / exposed	0 / 7 (0.00%)	1 / 3 (33.33%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Blood urea increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Blood urine present			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Body temperature increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
C-reactive protein increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Carcinoembryonic antigen increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	1 / 1 (100.00%)
occurrences (all)	0	0	1
Crystal urine present			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0

Gastrointestinal stoma output increased			
subjects affected / exposed	0 / 7 (0.00%)	1 / 3 (33.33%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Haemoglobin decreased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
International normalised ratio increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	1 / 1 (100.00%)
occurrences (all)	0	0	2
Lipase increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Prothrombin time prolonged			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	1 / 1 (100.00%)
occurrences (all)	0	0	2
Transaminases increased			
subjects affected / exposed	0 / 7 (0.00%)	1 / 3 (33.33%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
White blood cells urine positive			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Abdominal wound dehiscence			
subjects affected / exposed	1 / 7 (14.29%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Anastomotic ulcer			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Contusion			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	1 / 7 (14.29%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Gastrointestinal stoma complication			

subjects affected / exposed	0 / 7 (0.00%)	1 / 3 (33.33%)	0 / 1 (0.00%)
occurrences (all)	0	2	0
Gastrostomy tube site complication			
subjects affected / exposed	0 / 7 (0.00%)	1 / 3 (33.33%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Laceration			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Ligament sprain			
subjects affected / exposed	1 / 7 (14.29%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	2	0	0
Post procedural discomfort			
subjects affected / exposed	1 / 7 (14.29%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Procedural pain			
subjects affected / exposed	2 / 7 (28.57%)	1 / 3 (33.33%)	0 / 1 (0.00%)
occurrences (all)	3	1	0
Skin abrasion			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Soft tissue injury			
subjects affected / exposed	1 / 7 (14.29%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Stoma site reaction			
subjects affected / exposed	1 / 7 (14.29%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Cardiac disorders			
Tachycardia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Dizziness			
subjects affected / exposed	1 / 7 (14.29%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Headache			

subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 3 (0.00%) 0	0 / 1 (0.00%) 0
Lethargy subjects affected / exposed occurrences (all)	1 / 7 (14.29%) 3	0 / 3 (0.00%) 0	0 / 1 (0.00%) 0
Blood and lymphatic system disorders			
Anaemia subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	1 / 3 (33.33%) 1	0 / 1 (0.00%) 0
Coagulopathy subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 3 (0.00%) 0	1 / 1 (100.00%) 1
Lymphadenopathy subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 3 (0.00%) 0	0 / 1 (0.00%) 0
Ear and labyrinth disorders			
Ear pain subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 3 (0.00%) 0	0 / 1 (0.00%) 0
Eye disorders			
Dry eye subjects affected / exposed occurrences (all)	1 / 7 (14.29%) 1	0 / 3 (0.00%) 0	0 / 1 (0.00%) 0
Gastrointestinal disorders			
Abdominal distension subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 3 (0.00%) 0	0 / 1 (0.00%) 0
Abdominal pain subjects affected / exposed occurrences (all)	1 / 7 (14.29%) 4	1 / 3 (33.33%) 1	0 / 1 (0.00%) 0
Abdominal pain upper subjects affected / exposed occurrences (all)	1 / 7 (14.29%) 1	0 / 3 (0.00%) 0	0 / 1 (0.00%) 0
Abnormal faeces subjects affected / exposed occurrences (all)	1 / 7 (14.29%) 1	0 / 3 (0.00%) 0	0 / 1 (0.00%) 0
Anal incontinence			

subjects affected / exposed	1 / 7 (14.29%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Colitis			
subjects affected / exposed	0 / 7 (0.00%)	1 / 3 (33.33%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Constipation			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	1 / 7 (14.29%)	1 / 3 (33.33%)	0 / 1 (0.00%)
occurrences (all)	1	2	0
Enteritis			
subjects affected / exposed	1 / 7 (14.29%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Flatulence			
subjects affected / exposed	1 / 7 (14.29%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	2	0	0
Frequent bowel movements			
subjects affected / exposed	0 / 7 (0.00%)	1 / 3 (33.33%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 7 (0.00%)	1 / 3 (33.33%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Haematochezia			
subjects affected / exposed	1 / 7 (14.29%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Nausea			
subjects affected / exposed	1 / 7 (14.29%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Toothache			
subjects affected / exposed	0 / 7 (0.00%)	1 / 3 (33.33%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Vomiting			
subjects affected / exposed	4 / 7 (57.14%)	3 / 3 (100.00%)	1 / 1 (100.00%)
occurrences (all)	12	11	1
Hepatobiliary disorders			

Drug-induced liver injury subjects affected / exposed occurrences (all)	1 / 7 (14.29%) 1	0 / 3 (0.00%) 0	0 / 1 (0.00%) 0
Skin and subcutaneous tissue disorders			
Erythema subjects affected / exposed occurrences (all)	1 / 7 (14.29%) 1	0 / 3 (0.00%) 0	0 / 1 (0.00%) 0
Pain of skin subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	1 / 3 (33.33%) 1	0 / 1 (0.00%) 0
Rash subjects affected / exposed occurrences (all)	1 / 7 (14.29%) 1	1 / 3 (33.33%) 2	1 / 1 (100.00%) 1
Rash erythematous subjects affected / exposed occurrences (all)	1 / 7 (14.29%) 1	0 / 3 (0.00%) 0	0 / 1 (0.00%) 0
Rash papular subjects affected / exposed occurrences (all)	1 / 7 (14.29%) 1	0 / 3 (0.00%) 0	0 / 1 (0.00%) 0
Renal and urinary disorders			
Haematuria subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 3 (0.00%) 0	0 / 1 (0.00%) 0
Nephrolithiasis subjects affected / exposed occurrences (all)	1 / 7 (14.29%) 1	0 / 3 (0.00%) 0	0 / 1 (0.00%) 0
Musculoskeletal and connective tissue disorders			
Pain in extremity subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 3 (0.00%) 0	1 / 1 (100.00%) 1
Tenosynovitis subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 3 (0.00%) 0	1 / 1 (100.00%) 1
Infections and infestations			
Device related infection			

subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Ear infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis viral			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal bacterial overgrowth			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Malassezia infection			
subjects affected / exposed	1 / 7 (14.29%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	2	0	0
Nasopharyngitis			
subjects affected / exposed	1 / 7 (14.29%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Otitis media			
subjects affected / exposed	1 / 7 (14.29%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Otitis media acute			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	0 / 7 (0.00%)	1 / 3 (33.33%)	1 / 1 (100.00%)
occurrences (all)	0	1	1
Staphylococcal sepsis			
subjects affected / exposed	1 / 7 (14.29%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Upper respiratory tract infection			

subjects affected / exposed	3 / 7 (42.86%)	1 / 3 (33.33%)	0 / 1 (0.00%)
occurrences (all)	5	1	0
Urinary tract infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Varicella			
subjects affected / exposed	1 / 7 (14.29%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Viral infection			
subjects affected / exposed	1 / 7 (14.29%)	1 / 3 (33.33%)	0 / 1 (0.00%)
occurrences (all)	2	2	0
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Acidosis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Decreased appetite			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Dehydration			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Hyperchloraemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Hypoglycaemia			
subjects affected / exposed	1 / 7 (14.29%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Hypokalaemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Hyponatraemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0

Metabolic acidosis subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 3 (0.00%) 0	1 / 1 (100.00%) 1
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Non-serious adverse events	Teduglutide/Teduglutide Treatment (TED/TED)		
Total subjects affected by non-serious adverse events subjects affected / exposed	50 / 50 (100.00%)		
Surgical and medical procedures Catheter removal subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0		
General disorders and administration site conditions Catheter site discharge subjects affected / exposed occurrences (all)	1 / 50 (2.00%) 1		
Catheter site extravasation subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0		
Catheter site haemorrhage subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0		
Complication associated with device subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0		
Fatigue subjects affected / exposed occurrences (all)	8 / 50 (16.00%) 9		
Influenza like illness subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0		
Medical device site pain subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0		
Pyrexia subjects affected / exposed occurrences (all)	16 / 50 (32.00%) 21		

Thirst subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0		
Respiratory, thoracic and mediastinal disorders Bronchospasm subjects affected / exposed occurrences (all) Cough subjects affected / exposed occurrences (all) Epistaxis subjects affected / exposed occurrences (all) Nasal congestion subjects affected / exposed occurrences (all) Oropharyngeal pain subjects affected / exposed occurrences (all) Rhinitis allergic subjects affected / exposed occurrences (all) Rhinorrhoea subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0 16 / 50 (32.00%) 41 2 / 50 (4.00%) 10 7 / 50 (14.00%) 11 5 / 50 (10.00%) 6 0 / 50 (0.00%) 0 10 / 50 (20.00%) 26		
Psychiatric disorders Learning disability subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0		
Product issues Device breakage subjects affected / exposed occurrences (all) Device malfunction subjects affected / exposed occurrences (all)	7 / 50 (14.00%) 12 2 / 50 (4.00%) 4		

Device occlusion subjects affected / exposed occurrences (all)	5 / 50 (10.00%) 8		
Investigations			
Alanine aminotransferase increased subjects affected / exposed occurrences (all)	10 / 50 (20.00%) 16		
Aspartate aminotransferase increased subjects affected / exposed occurrences (all)	4 / 50 (8.00%) 4		
Blood 25-hydroxycholecalciferol increased subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0		
Blood bicarbonate decreased subjects affected / exposed occurrences (all)	4 / 50 (8.00%) 4		
Blood bicarbonate increased subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0		
Blood creatinine increased subjects affected / exposed occurrences (all)	1 / 50 (2.00%) 1		
Blood triglycerides increased subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0		
Blood urea increased subjects affected / exposed occurrences (all)	4 / 50 (8.00%) 4		
Blood urine present subjects affected / exposed occurrences (all)	3 / 50 (6.00%) 3		
Body temperature increased subjects affected / exposed occurrences (all)	3 / 50 (6.00%) 3		
C-reactive protein increased			

subjects affected / exposed	8 / 50 (16.00%)		
occurrences (all)	9		
Carcinoembryonic antigen increased			
subjects affected / exposed	0 / 50 (0.00%)		
occurrences (all)	0		
Crystal urine present			
subjects affected / exposed	3 / 50 (6.00%)		
occurrences (all)	3		
Gamma-glutamyltransferase increased			
subjects affected / exposed	4 / 50 (8.00%)		
occurrences (all)	6		
Gastrointestinal stoma output increased			
subjects affected / exposed	2 / 50 (4.00%)		
occurrences (all)	3		
Haemoglobin decreased			
subjects affected / exposed	4 / 50 (8.00%)		
occurrences (all)	4		
International normalised ratio increased			
subjects affected / exposed	3 / 50 (6.00%)		
occurrences (all)	4		
Lipase increased			
subjects affected / exposed	4 / 50 (8.00%)		
occurrences (all)	4		
Prothrombin time prolonged			
subjects affected / exposed	3 / 50 (6.00%)		
occurrences (all)	4		
Transaminases increased			
subjects affected / exposed	1 / 50 (2.00%)		
occurrences (all)	1		
White blood cells urine positive			
subjects affected / exposed	3 / 50 (6.00%)		
occurrences (all)	3		
Injury, poisoning and procedural complications			

Abdominal wound dehiscence subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0		
Anastomotic ulcer subjects affected / exposed occurrences (all)	3 / 50 (6.00%) 4		
Contusion subjects affected / exposed occurrences (all)	5 / 50 (10.00%) 11		
Fall subjects affected / exposed occurrences (all)	1 / 50 (2.00%) 1		
Gastrointestinal stoma complication subjects affected / exposed occurrences (all)	2 / 50 (4.00%) 2		
Gastrostomy tube site complication subjects affected / exposed occurrences (all)	4 / 50 (8.00%) 6		
Laceration subjects affected / exposed occurrences (all)	4 / 50 (8.00%) 4		
Ligament sprain subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0		
Post procedural discomfort subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0		
Procedural pain subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0		
Skin abrasion subjects affected / exposed occurrences (all)	4 / 50 (8.00%) 6		
Soft tissue injury subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0		

Stoma site reaction subjects affected / exposed occurrences (all)	2 / 50 (4.00%) 3		
Cardiac disorders Tachycardia subjects affected / exposed occurrences (all)	3 / 50 (6.00%) 3		
Nervous system disorders Dizziness subjects affected / exposed occurrences (all) Headache subjects affected / exposed occurrences (all) Lethargy subjects affected / exposed occurrences (all)	4 / 50 (8.00%) 4 11 / 50 (22.00%) 24 3 / 50 (6.00%) 5		
Blood and lymphatic system disorders Anaemia subjects affected / exposed occurrences (all) Coagulopathy subjects affected / exposed occurrences (all) Lymphadenopathy subjects affected / exposed occurrences (all)	2 / 50 (4.00%) 4 2 / 50 (4.00%) 2 4 / 50 (8.00%) 5		
Ear and labyrinth disorders Ear pain subjects affected / exposed occurrences (all)	3 / 50 (6.00%) 4		
Eye disorders Dry eye subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0		
Gastrointestinal disorders			

Abdominal distension			
subjects affected / exposed	6 / 50 (12.00%)		
occurrences (all)	6		
Abdominal pain			
subjects affected / exposed	15 / 50 (30.00%)		
occurrences (all)	33		
Abdominal pain upper			
subjects affected / exposed	7 / 50 (14.00%)		
occurrences (all)	10		
Abnormal faeces			
subjects affected / exposed	0 / 50 (0.00%)		
occurrences (all)	0		
Anal incontinence			
subjects affected / exposed	0 / 50 (0.00%)		
occurrences (all)	0		
Colitis			
subjects affected / exposed	0 / 50 (0.00%)		
occurrences (all)	0		
Constipation			
subjects affected / exposed	3 / 50 (6.00%)		
occurrences (all)	3		
Diarrhoea			
subjects affected / exposed	14 / 50 (28.00%)		
occurrences (all)	29		
Enteritis			
subjects affected / exposed	1 / 50 (2.00%)		
occurrences (all)	1		
Flatulence			
subjects affected / exposed	3 / 50 (6.00%)		
occurrences (all)	3		
Frequent bowel movements			
subjects affected / exposed	2 / 50 (4.00%)		
occurrences (all)	2		
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 50 (0.00%)		
occurrences (all)	0		

Haematochezia subjects affected / exposed occurrences (all)	4 / 50 (8.00%) 6		
Nausea subjects affected / exposed occurrences (all)	7 / 50 (14.00%) 7		
Toothache subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0		
Vomiting subjects affected / exposed occurrences (all)	25 / 50 (50.00%) 77		
Hepatobiliary disorders Drug-induced liver injury subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0		
Skin and subcutaneous tissue disorders Erythema subjects affected / exposed occurrences (all)	1 / 50 (2.00%) 1		
Pain of skin subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0		
Rash subjects affected / exposed occurrences (all)	11 / 50 (22.00%) 20		
Rash erythematous subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0		
Rash papular subjects affected / exposed occurrences (all)	1 / 50 (2.00%) 1		
Renal and urinary disorders Haematuria subjects affected / exposed occurrences (all)	3 / 50 (6.00%) 4		
Nephrolithiasis			

subjects affected / exposed	1 / 50 (2.00%)		
occurrences (all)	1		
Musculoskeletal and connective tissue disorders			
Pain in extremity			
subjects affected / exposed	5 / 50 (10.00%)		
occurrences (all)	7		
Tenosynovitis			
subjects affected / exposed	0 / 50 (0.00%)		
occurrences (all)	0		
Infections and infestations			
Device related infection			
subjects affected / exposed	3 / 50 (6.00%)		
occurrences (all)	4		
Ear infection			
subjects affected / exposed	5 / 50 (10.00%)		
occurrences (all)	5		
Gastroenteritis viral			
subjects affected / exposed	3 / 50 (6.00%)		
occurrences (all)	4		
Gastrointestinal bacterial overgrowth			
subjects affected / exposed	4 / 50 (8.00%)		
occurrences (all)	7		
Influenza			
subjects affected / exposed	5 / 50 (10.00%)		
occurrences (all)	8		
Malassezia infection			
subjects affected / exposed	0 / 50 (0.00%)		
occurrences (all)	0		
Nasopharyngitis			
subjects affected / exposed	9 / 50 (18.00%)		
occurrences (all)	15		
Otitis media			
subjects affected / exposed	3 / 50 (6.00%)		
occurrences (all)	4		
Otitis media acute			

subjects affected / exposed	3 / 50 (6.00%)		
occurrences (all)	5		
Respiratory tract infection			
subjects affected / exposed	4 / 50 (8.00%)		
occurrences (all)	4		
Rhinitis			
subjects affected / exposed	5 / 50 (10.00%)		
occurrences (all)	9		
Staphylococcal sepsis			
subjects affected / exposed	0 / 50 (0.00%)		
occurrences (all)	0		
Upper respiratory tract infection			
subjects affected / exposed	15 / 50 (30.00%)		
occurrences (all)	41		
Urinary tract infection			
subjects affected / exposed	3 / 50 (6.00%)		
occurrences (all)	15		
Varicella			
subjects affected / exposed	2 / 50 (4.00%)		
occurrences (all)	2		
Viral infection			
subjects affected / exposed	9 / 50 (18.00%)		
occurrences (all)	13		
Viral upper respiratory tract infection			
subjects affected / exposed	4 / 50 (8.00%)		
occurrences (all)	5		
Metabolism and nutrition disorders			
Acidosis			
subjects affected / exposed	3 / 50 (6.00%)		
occurrences (all)	3		
Decreased appetite			
subjects affected / exposed	5 / 50 (10.00%)		
occurrences (all)	5		
Dehydration			
subjects affected / exposed	3 / 50 (6.00%)		
occurrences (all)	4		

Hyperchloraemia			
subjects affected / exposed	3 / 50 (6.00%)		
occurrences (all)	3		
Hypoglycaemia			
subjects affected / exposed	2 / 50 (4.00%)		
occurrences (all)	2		
Hypokalaemia			
subjects affected / exposed	4 / 50 (8.00%)		
occurrences (all)	7		
Hyponatraemia			
subjects affected / exposed	3 / 50 (6.00%)		
occurrences (all)	3		
Metabolic acidosis			
subjects affected / exposed	5 / 50 (10.00%)		
occurrences (all)	6		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
22 November 2016	Protocol Amendment 1: <ul style="list-style-type: none">- The collection of all actual and prescribed EN data was removed to reduce the burden on the subjects and investigators. Enteral nutrition data are not required as the efficacy endpoints are limited to PS parameters.- Parental height and gestational age at birth were removed from medical history.- Changes were made to the Health economics and outcomes research endpoints to include the beginning of each treatment cycle (CxD1) as additional baseline. These changes were for clarity and consistency with other teduglutide studies.
23 March 2017	Protocol Amendment 2: <ul style="list-style-type: none">- Revised the criteria for ET of the study: stopping criteria were extended to all NCI CTCAE Grade 3 and 4 severity events reported as related to the investigational product, and no longer limited to the events described in Table 8-1, titled "CTCAE Criteria for Adverse Events that May Lead to Dose Interruption (Prospective Period of Observation Only)."
16 May 2018	Protocol Amendment 3: <ul style="list-style-type: none">- To minimize risk to subjects, a new escape criterion was added, allowing those who had escaped during the follow-up period of a previous teduglutide treatment to omit the follow-up period during subsequent teduglutide treatment cycles. For subjects who previously escaped the follow-up period, CxW24 assessments could be combined with the next pretreatment visit assessments.- Updated the information on the clinical studies with teduglutide in pediatric subjects to include the results of TED-C14-006 and a description of the additional core study, SHP633-301.- Added new PK simulation data to further support dosing.- Specified that an interim analysis was planned when 6 months of safety data had been collected for subjects entering from TED-C14-006. Additional interim analyses could be conducted as needed.

01 October 2019	<p>Protocol Amendment 4:</p> <ul style="list-style-type: none"> - Extended the planned study period to December 2020. - Clarification of the follow-up period escape criteria and their use in combining the CxW24 and pretreatment visits was added. - Clarified that AEs will be collected for 4 weeks after the last dose of teduglutide in the study even if the EOS/ET occurs within that timeframe. - The definition of an overdose was clarified as the administration of the investigational product at a dose or frequency greater than 0.05 mg/kg subcutaneous once daily. An overdose occurred if any of the following criteria were met: <ul style="list-style-type: none"> - More than 0.05 mg/kg was given at any one time - Consecutive doses were spaced less than 12 hours apart - Any more than 0.05 mg/kg given in one day - The teduglutide dose interruption criteria were updated to specify events leading to an interruption of teduglutide treatment and events leading to a permanent discontinuation of teduglutide treatment. Investigational product was interrupted if any of the following events occurred: <ul style="list-style-type: none"> - An AE of special interest - An AE that is of NCI CTCAE severity Grade 3 or 4 and related to teduglutide - Intestinal obstruction - Biliary obstruction related to teduglutide - Pancreatic duct obstruction related to teduglutide - Heart failure with severe fluid overload related to teduglutide. - Investigational product was permanently discontinued if any of the following events occurred: <ul style="list-style-type: none"> - Pregnancy - Severe hypersensitivity, such as anaphylaxis determined by the investigator to be related to study drug. This does not include the presence of anti-teduglutide antibodies, mild injection site reactions or mild symptoms that according to the investigator do not pose a significant risk to the subject. - Confirmed drug-induced liver injury (DILI) related to teduglutide. - Any malignancy.
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Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported