Trial record **1 of 1** for: NCT00798967

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Study of Teduglutide Effectiveness in Parenteral Nutrition (PN)-Dependent Short Bowel Syndrome (SBS) Subjects (STEPS)

ClinicalTrials.gov Identifier: NCT00798967

Recruitment Status : Completed
First Posted : November 27, 2008
Results First Posted : February 1, 2012
Last Update Posted : June 3, 2021

Sponsor:
Shire

Collaborator:
Nycomed

Information provided by (Responsible Party):
Takeda (Shire)

Study Details | Tabular View | Study Results | Disclaimer | How to Read a Study Record

Study Type	Interventional
Study Design	Allocation: Randomized; Intervention Model: Parallel Assignment; Masking: Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor); Primary Purpose: Treatment
Condition	Short Bowel Syndrome
Interventions	Drug: teduglutide Drug: placebo
Enrollment	86

Participant Flow

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Recruitment Details	First Patient Screened - November 25, 2008; Last Patient Screened - July 13, 2010; First Patient Randomized - March 3, 2009; Last Patient Randomized - July 22, 2010; Locations - hospitals and transplant centers; Subjects must be on parenteral nutrition (PN) and/or intravenous (I.V.) fluids.
Pre-assignment Details	Stage 1 was screening, optimization, and stabilization periods. At screening, if the PN/I.V. volume is not stable per protocol, s/he entered an optimization period (up to 8 weeks) to find the minimally tolerated stable volume of PN/I.V.. Prior to randomization, all entered 4-8 weeks of stabilization period on that volume of PN/I.V.

Arm/Group Title	Teduglutide	Placebo
Arm/Group Description	0.05 mg/kg/day subcutaneous (sc) dose of teduglutide	Matching sc dose of placebo to teduglutide
Period Title: **Overall Study**		
Started	43	43

Discontinued During Dosing Period	4	4
Completed	39	39
Not Completed	4	4
Reason Not Completed		
Adverse Event	2	3
Withdrawal by Subject	0	1
Physician Decision	1	0
Randomized in error by site	1	0

Baseline Characteristics Go to

Arm/Group Title	Teduglutide	Placebo	Total
Arm/Group Description	0.05 mg/kg/day subcutaneous (sc) dose of teduglutide	Matching sc dose of placebo to teduglutide	Total of all reporting groups
Overall Number of Baseline Participants	43	43	86
Baseline Analysis Population Description	[Not Specified]		
Age, Continuous Mean (Standard Deviation) Unit of measure: Years			
Number Analyzed	43 participants	43 participants	86 participants
	50.9 (12.6)	49.7 (15.6)	50.3 (14.1)
Sex: Female, Male Measure Type: Count of Participants Unit of measure: Participants			
Number Analyzed	43 participants	43 participants	86 participants
Female	22 51.2%	24 55.8%	46 53.5%
Male	21 48.8%	19 44.2%	40 46.5%

Outcome Measures Go to

1. Primary Outcome

Title	Responder
Description	Comparison of subjects treated with teduglutide to placebo who achieve a 20 to 100% reduction from baseline in weekly parenteral nutrition/intravenous fluid (PN/I.V.) volume at weeks 20 and 24.
Time Frame	Weeks 20 and 24

Outcome Measure Data

Analysis Population Description

Percentages were based on the number of subjects in the Intent to Treat (ITT) population.

Arm/Group Title	Teduglutide	Placebo
Arm/Group Description:	0.05 mg/kg/day subcutaneous (sc) dose of teduglutide	Matching sc dose of placebo to teduglutide
Overall Number of Participants Analyzed	43	43
Measure Type: Number Unit of Measure: subjects		
	27	13

Statistical Analysis 1

Statistical Analysis Overview	Comparison Group Selection	Teduglutide, Placebo
	Comments	[Not Specified]
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not Specified]
Statistical Test of Hypothesis	P-Value	0.002
	Comments	Cochran-Mantel-Haenszel (CMH) test adjusted for the randomization stratification variable (<= 6 or > 6 L/week of PN at baseline)

Method	Cochran-Mantel-Haenszel
Comments	[Not Specified]

2. Secondary Outcome

Title	Absolute Change in PN/I.V. Volume From Baseline to Last Time Point
Description	Absolute change in the volume of PN/I.V. from baseline (Week 0) to the visit when the last data point was collected (week 4 through week 24, or earlier if the subject discontinued early).
Time Frame	Week 0 to last visit when data was collected.

Outcome Measure Data

Analysis Population Description

Intent-to-Treat (ITT) was defined for efficacy analyses which included all randomized patients.

Arm/Group Title	Teduglutide	Placebo
Arm/Group Description:	0.05 mg/kg/day sc dose of teduglutide	Matching sc dose of placebo to teduglutide
Overall Number of Participants Analyzed	40	43
Mean (Standard Deviation) Unit of Measure: Liters/Week		
	-4.28 (3.81)	-2.38 (2.79)

Statistical Analysis 1

Statistical Analysis Overview	Comparison Group Selection	Teduglutide, Placebo
	Comments	Last Dosing Visit
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not Specified]
Statistical Test of Hypothesis	P-Value	< 0.001
	Comments	[Not Specified]
	Method	ANCOVA
	Comments	[Not Specified]

Adverse Events

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Time Frame	Adverse event data were collected for each subject from the time informed consent was signed to end of study. For this reporting of adverse event, the most commonly reported treatment emergent adverse events (>=3 subjects at SOC level) are listed.
Adverse Event Reporting Description	All adverse experience reporting used the Safety population which consisted of 85 subjects who received at least one dose of study drug. There were 42 subjects treated with teduglutide, whereas 43 subjects received placebo. Adverse experience monitoring was performed through investigator assessment and safety laboratory testing at every visit.

Arm/Group Title	Teduglutide	Placebo
Arm/Group Description	0.05 mg/kg/day subcutaneous (sc) dose of teduglutide	Matching sc dose of placebo to teduglutide

All-Cause Mortality

	Teduglutide		**Placebo**	
	Affected / at Risk (%)		Affected / at Risk (%)	
Total	--/--		--/--	

Serious Adverse Events

	Teduglutide		**Placebo**	
	Affected / at Risk (%)	# Events	Affected / at Risk (%)	# Events
Total	15/42 (35.71%)		12/43 (27.91%)	
Gastrointestinal disorders				
Small intestinal stenosis †1	1/42 (2.38%)	1	0/43 (0.00%)	0
General disorders				

Catheter-related complication †1	1/42 (2.38%)	1	0/43 (0.00%)	0
Implant site extravasation †1	1/42 (2.38%)	1	1/43 (2.33%)	1
Hepatobiliary disorders				
Cholecystitis acute †1	1/42 (2.38%)	1	0/43 (0.00%)	0
Hepatitis cholestatic †1	0/42 (0.00%)	0	1/43 (2.33%)	1
Infections and infestations				
Adenovirus infection †1	1/42 (2.38%)	1	0/43 (0.00%)	0
Bacteremia †1	0/42 (0.00%)	0	3/43 (6.98%)	3
Catheter sepsis †1	1/42 (2.38%)	1	0/43 (0.00%)	0
Catheter-related infection †1	5/42 (11.90%)	5	1/43 (2.33%)	1
Central line infection †1	2/42 (4.76%)	2	3/43 (6.98%)	3
Infective thrombosis †1	1/42 (2.38%)	1	0/43 (0.00%)	0
Influenza †1	1/42 (2.38%)	1	0/43 (0.00%)	0
Pneumonia †1	1/42 (2.38%)	1	0/43 (0.00%)	0
Pneumonia influenzal †1	0/42 (0.00%)	0	1/43 (2.33%)	1
Rectal abscess †1	1/42 (2.38%)	1	0/43 (0.00%)	0
Soft tissue infection †1	0/42 (0.00%)	0	1/43 (2.33%)	1
Urinary tract infection †1	2/42 (4.76%)	2	1/43 (2.33%)	1
Viral infection †1	1/42 (2.38%)	1	0/43 (0.00%)	0
Injury, poisoning and procedural complications				
Device breakage †1	0/42 (0.00%)	0	1/43 (2.33%)	1
Device dislocation †1	0/42 (0.00%)	0	2/43 (4.65%)	2
Device failure †1	0/42 (0.00%)	0	1/43 (2.33%)	1
Device malfunction †1	0/42 (0.00%)	0	1/43 (2.33%)	1
Fall †1	0/42 (0.00%)	0	1/43 (2.33%)	1
Metabolism and nutrition disorders				
Dehydration †1	1/42 (2.38%)	1	0/43 (0.00%)	0
Psychiatric disorders				
Suicide attempt †1	0/42 (0.00%)	0	1/43 (2.33%)	1
Respiratory, thoracic and mediastinal disorders				
Pleural effusion †1	0/42 (0.00%)	0	1/43 (2.33%)	1
Vascular disorders				
Subclavian vein thrombosis †1	1/42 (2.38%)	1	0/43 (0.00%)	0

† Indicates events were collected by systematic assessment
1 Term from vocabulary, MedDRA (12.0)

Other (Not Including Serious) Adverse Events

Frequency Threshold for Reporting Other Adverse Events	5%			
	Teduglutide		**Placebo**	
	Affected / at Risk (%)	# Events	Affected / at Risk (%)	# Events
Total	35/42 (83.33%)		34/43 (79.07%)	
Gastrointestinal disorders				
Abdominal distension †1	9/42 (21.43%)	14	1/43 (2.33%)	2
Abdominal pain †1	13/42 (30.95%)	14	10/43 (23.26%)	14
Diarrhea †1	3/42 (7.14%)	4	5/43 (11.63%)	7
Flatulence †1	5/42 (11.90%)	5	3/43 (6.98%)	3
Nausea †1	12/42 (28.57%)	19	8/43 (18.60%)	12
Vomiting †1	5/42 (11.90%)	5	4/43 (9.30%)	10
General disorders				
Edema peripheral †1	7/42 (16.67%)	8	2/43 (4.65%)	3
Fatigue †1	4/42 (9.52%)	5	3/43 (6.98%)	3
Pyrexia †1	4/42 (9.52%)	5	4/43 (9.30%)	5
Infections and infestations				

Central line systemic infections †1	7/42 (16.67%)	12	7/43 (16.28%)	8
Nasopharyngitis †1	3/42 (7.14%)	3	0/43 (0.00%)	0
Urinary tract infection †1	6/42 (14.29%)	6	4/43 (9.30%)	5
Injury, poisoning and procedural complications				
Gastrointestinal stoma complication †1	10/42 (23.81%)	11	3/43 (6.98%)	3
Investigations				
Weight increased †1	3/42 (7.14%)	3	3/43 (6.98%)	3
Respiratory, thoracic and mediastinal disorders				
Dyspnea †1	3/42 (7.14%)	3	0/43 (0.00%)	0

† Indicates events were collected by systematic assessment
1 Term from vocabulary, MedDRA (12.0)

Limitations and Caveats

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[Not Specified]

More Information

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Certain Agreements

Principal Investigators are NOT employed by the organization sponsoring the study.

There IS an agreement between Principal Investigators and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.

The terms and conditions of NPS Pharmaceuticals agreements with its investigators may vary. However, NPS does not prohibit any investigator from publishing. Any publications from a single-site are postponed until the publication of the pooled data (i.e., data from all sites) in the clinical trial.

Results Point of Contact

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Publications of Results:

Jeppesen PB, Sanguinetti EL, Buchman A, Howard L, Scolapio JS, Ziegler TR, Gregory J, Tappenden KA, Holst J, Mortensen PB. Teduglutide (ALX-0600), a dipeptidyl peptidase IV resistant glucagon-like peptide 2 analogue, improves intestinal function in short bowel syndrome patients. Gut. 2005 Sep;54(9):1224-31.

Publications automatically indexed to this study by ClinicalTrials.gov Identifier (NCT Number):

Jeppesen PB, Gabe SM, Seidner DL, Lee HM, Olivier C. Citrulline correlations in short bowel syndrome-intestinal failure by patient stratification: Analysis of 24 weeks of teduglutide treatment from a randomized controlled study. Clin Nutr. 2020 Aug;39(8):2479-2486. doi: 10.1016/j.clnu.2019.11.001. Epub 2019 Nov 9.

Jeppesen PB, Gabe SM, Seidner DL, Lee HM, Olivier C. Factors Associated With Response to Teduglutide in Patients With Short-Bowel Syndrome and Intestinal Failure. Gastroenterology. 2018 Mar;154(4):874-885. doi: 10.1053/j.gastro.2017.11.023. Epub 2017 Nov 22.

Fujioka K, Jeejeebhoy K, Pape UF, Li B, Youssef NN, Schneider SM. Patients With Short Bowel on Narcotics During 2 Randomized Trials Have Abdominal Complaints Independent of Teduglutide. JPEN J Parenter Enteral Nutr. 2017 Nov;41(8):1419-1422. doi: 10.1177/0148607116663481. Epub 2016 Aug 9.

Vipperla K, O'Keefe SJ. Study of teduglutide effectiveness in parenteral nutrition-dependent short-bowel syndrome subjects. Expert Rev Gastroenterol Hepatol. 2013 Nov;7(8):683-7. doi: 10.1586/17474124.2013.842894. Epub 2013 Oct 17. Review.

Jeppesen PB, Pertkiewicz M, Forbes A, Pironi L, Gabe SM, Joly F, Messing B, Loth S, Youssef NN, Heinze H, Berghöfer P. Quality of life in patients with short bowel syndrome treated with the new glucagon-like peptide-2 analogue teduglutide--analyses from a randomised, placebo-controlled study. Clin Nutr. 2013 Oct;32(5):713-21. doi: 10.1016/j.clnu.2013.03.016. Epub 2013 Mar 28.

Berghöfer P, Fragkos KC, Baxter JP, Forbes A, Joly F, Heinze H, Loth S, Pertkiewicz M, Messing B, Jeppesen PB. Development and validation of the disease-specific Short Bowel Syndrome-Quality of Life (SBS-QoL™) scale. Clin Nutr. 2013 Oct;32(5):789-96. doi: 10.1016/j.clnu.2012.12.001. Epub 2012 Dec 12.

Jeppesen PB, Pertkiewicz M, Messing B, Iyer K, Seidner DL, O'keefe SJ, Forbes A, Heinze H, Joelsson B. Teduglutide reduces need for parenteral support among patients with short bowel syndrome with intestinal failure. Gastroenterology. 2012 Dec;143(6):1473-1481.e3. doi: 10.1053/j.gastro.2012.09.007. Epub 2012 Sep 11.

Responsible Party:	Takeda (Shire)
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