Clinical trial results:
Efficacy, Safety and Tolerability of a Bowel Cleansing Preparation (BLI800) in Pediatric Subjects Undergoing Colonoscopy

Summary

EudraCT number	2019-003749-14
Trial protocol	Outside EU/EEA
Global end of trial date	14 January 2015

Results information

Result version number	v1 (current)
This version publication date	04 April 2020
First version publication date	04 April 2020

Trial information

Trial identification

Sponsor protocol code	BLI800-501

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02189850
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Braintree Laboratories
Sponsor organisation address	60 Columbian St. West, Braintree, Massachusetts, United States, 02185
Public contact	Medical Director, Ipsen Pharma, clinical.trials@ipsen.com
Scientific contact	Medical Director, Ipsen Pharma, clinical.trials@ipsen.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	Yes
EMA paediatric investigation plan number(s)	EMEA-000816-PIP02-10
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	Yes

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	14 January 2015
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	14 January 2015
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The objective of this study was to compare the safety, tolerability and efficacy of the Food and Drug Administration approved split-dose adult regimen of BLI800 (i.e., two 6 ounce [oz] bottles of oral solution, each bottle containing: sodium sulfate 17.5 grams (g), potassium sulfate 3.13 g, magnesium sulfate 1.6 g) to a reduced 3/4 volume of BLI800 (4.5 oz per dose), as bowel preparations prior to colonoscopy in pediatric participants aged 12 to 17 years.

Protection of trial subjects:

This study was conducted in full compliance to Federal Regulations (including the International Conference on Harmonization/Good Clinical Practice Guidelines and Health Insurance Portability and Accountability Act Privacy Regulations). The Investigators and all study staff conducted the study in compliance with this protocol. The Investigators were responsible for explaining the purpose, nature, and potential risks of the study to each subject. All caregivers were required to sign an informed consent form and participants of age to provide signed assent form.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	28 May 2014
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	United States: 32
Worldwide total number of subjects	32
EEA total number of subjects	0

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	32

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

Subject disposition

Recruitment

Recruitment details:

This Phase 2 randomized, parallel, multi-center, open-label study was conducted at 6 study centers between 28 May 2014 and 14 January 2015 in pediatric participants requiring colonoscopy for routinely accepted indications. One study center did not enroll any participants due to the enrollment target being met.

Pre-assignment

Screening details:

A screening visit (Visit 1) was performed between 30 days to 6 days prior to colonoscopy. A total of 32 participants were screened and randomized into the study, of which 29 participants received treatment.

Period 1

Period 1 title	Overall Trial (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	BLI800 6 oz

Arm description:

Participants received BLI800 6 oz (full adult dose) oral sulfate solution on Day 0 (in evening before the day of colonoscopy) and a second 6 oz dose on the morning of Day 1 (at least 3 hours prior to the colonoscopy procedure).

Arm type	Experimental
Investigational medicinal product name	BLI800
Investigational medicinal product code	
Other name	Suprep
Pharmaceutical forms	Oral solution
Routes of administration	Oral use

Dosage and administration details:

A 6 oz bottle of BLI800 oral sulfate solution containing sodium sulfate, potassium sulfate and magnesium sulfate was taken with water on Day 0 (in evening before the day of colonoscopy) and a second 6 oz bottle was taken with water on the morning of Day 1 (at least 3 hours prior to the colonoscopy procedure).

Arm title	BLI800 4.5 oz

Arm description:

Participants received BLI800 4.5 oz (3/4 adult dose) oral sulfate solution on Day 0 (in evening before the day of colonoscopy) and a second 4.5 oz dose on the morning of Day 1 (at least 3 hours prior to the colonoscopy procedure).

Arm type	Experimental
Investigational medicinal product name	BLI800
Investigational medicinal product code	
Other name	Suprep
Pharmaceutical forms	Oral solution
Routes of administration	Oral use

Dosage and administration details:

A 4.5 oz bottle of BLI800 oral sulfate solution containing sodium sulfate, potassium sulfate and magnesium sulfate was taken with water on Day 0 (in evening before the day of colonoscopy) and a second 4.5 oz bottle was taken with water on the morning of Day 1 (at least 3 hours prior to the colonoscopy procedure).

Number of subjects in period 1	BLI800 6 oz	BLI800 4.5 oz
Started	17	15
Received treatment	16	13
Underwent colonoscopy procedure	16	12
Completed	14	11
Not completed	3	4
Consent withdrawn by subject	-	1
Lost to follow-up	2	1
Did not receive treatment	1	2

Baseline characteristics

Reporting groups	
Reporting group title	BLI800 6 oz
Reporting group description:	
Participants received BLI800 6 oz (full adult dose) oral sulfate solution on Day 0 (in evening before the day of colonoscopy) and a second 6 oz dose on the morning of Day 1 (at least 3 hours prior to the colonoscopy procedure).	
Reporting group title	BLI800 4.5 oz
Reporting group description:	
Participants received BLI800 4.5 oz (3/4 adult dose) oral sulfate solution on Day 0 (in evening before the day of colonoscopy) and a second 4.5 oz dose on the morning of Day 1 (at least 3 hours prior to the colonoscopy procedure).	

Reporting group values	BLI800 6 oz	BLI800 4.5 oz	Total
Number of subjects	17	15	32
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	17	15	32
Adults (18-64 years)	0	0	0
From 65-84 years	0	0	0
85 years and over	0	0	0
Gender categorical Units: Subjects			
Female	8	10	18
Male	9	5	14
Race Units: Subjects			
Black or African American	4	2	6
White	13	12	25
Other	0	1	1

End points

End points reporting groups

Reporting group title	BLI800 6 oz

Reporting group description:

Participants received BLI800 6 oz (full adult dose) oral sulfate solution on Day 0 (in evening before the day of colonoscopy) and a second 6 oz dose on the morning of Day 1 (at least 3 hours prior to the colonoscopy procedure).

Reporting group title	BLI800 4.5 oz

Reporting group description:

Participants received BLI800 4.5 oz (3/4 adult dose) oral sulfate solution on Day 0 (in evening before the day of colonoscopy) and a second 4.5 oz dose on the morning of Day 1 (at least 3 hours prior to the colonoscopy procedure).

Primary: Percentage of Participants With Treatment Emergent Adverse Events (TEAEs) and Serious Adverse Events (SAEs)

End point title	Percentage of Participants With Treatment Emergent Adverse Events (TEAEs) and Serious Adverse Events (SAEs)

End point description:

An adverse event (AE) is any untoward medical occurrence associated with the use of a drug in humans, whether or not considered drug related. An AE can therefore be any unfavorable and unintended sign, symptom, or disease temporally associated with the use of a medicinal product. An AE is 'serious' if it: results in death; is life-threatening; requires hospitalization or prolongation of existing hospitalization; results in persistent or significant disability or incapacity; consists of a congenital anomaly or birth defect; requires medical or surgical intervention to prevent permanent impairment or damage. A TEAE is defined as any AE that began or worsened following start of BLI800 dosing. A treatment-related AE is defined as any TEAE that was assessed by Investigator as possibly, probably or definitely related to BLI800 solution. Intent-To-Treat (ITT) analysis set included all participants randomized that took any portion of BLI800 solution.

End point type	Primary

End point timeframe:

From first administration of BLI800 solution (Day 0) up to Day 32.

End point values	BLI800 6 oz	BLI800 4.5 oz		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	16	13		
Units: percentage of participants				
number (not applicable)				
Any TEAE	81.3	92.3		
Any Treatment-related TEAE	68.8	84.7		
Any SAE	0	0		

Statistical analyses

Statistical analysis title	Treatment difference for TEAEs and SAEs
Comparison groups	BLI800 6 oz v BLI800 4.5 oz

Number of subjects included in analysis	29
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.791
Method	Fisher exact
Confidence interval	
level	95 %
sides	2-sided
lower limit	-31.2
upper limit	20.1

Primary: Percentage of Participants With Successful Preparation for Colonoscopy Procedure

End point title	Percentage of Participants With Successful Preparation for Colonoscopy Procedure

End point description:

The colonoscopist assessed colon cleansing using a four point scale ranging from 1 to 4. Where, 1 = poor; 2 = fair; 3 = good and 4 = excellent. Preparation success is defined as bowel cleansing graded either excellent or good. Grades 3 and 4 were considered "successful" and grades 1 and 2 were considered "failures". The ITT analysis set included all participants randomized that took any portion of BLI800 solution. One participant in the BLI800 4.5 oz group was excluded as non-evaluable for efficacy analysis.

End point type	Primary

End point timeframe:

At Day 1

End point values	BLI800 6 oz	BLI800 4.5 oz		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	16	13[1]		
Units: percentage of participants				
number (not applicable)				
Success	81.3	83.3		
Failure	18.8	16.7		

Notes:

[1] - One ITT participant was excluded as non-evaluable for efficacy analysis.

Statistical analyses

Statistical analysis title	Treatment difference for preparation success
Comparison groups	BLI800 6 oz v BLI800 4.5 oz
Number of subjects included in analysis	29
Analysis specification	Pre-specified
Analysis type	other[2]
P-value	= 0.923
Method	Cochran-Mantel-Haenszel

Confidence interval	
level	95 %
sides	2-sided
lower limit	-30.6
upper limit	26.4

Notes:

[2] - Confidence Interval (CI) for percentage success difference between treatments was from a chi-square test.

Secondary: Investigator Grading of Residual Stool Assessment by Colon Segment

End point title	Investigator Grading of Residual Stool Assessment by Colon Segment

End point description:

The colonoscopist evaluated the five colonic segments for amounts of residual stool with a score ranging from 1 to 4. Where, 1 = absent; 2 = small; 3 = moderate and 4 = excess. The ITT analysis set included all participants randomized that took any portion of BLI800 solution. One participant in the BLI800 4.5 oz group was excluded as non-evaluable for efficacy analysis. Number of participants at each of the indicated grades for the five colon segments are reported.

End point type	Secondary

End point timeframe:

At Day 1

End point values	BLI800 6 oz	BLI800 4.5 oz		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	16	13[3]		
Units: participants				
Stool cecum: Absent	7	8		
Stool cecum: Small	5	2		
Stool cecum: Moderate	2	0		
Stool cecum: Excess	1	1		
Stool ascending colon: Absent	9	9		
Stool ascending colon: Small	4	1		
Stool ascending colon: Moderate	1	1		
Stool ascending colon: Excess	1	0		
Stool transverse colon: Absent	11	10		
Stool transverse colon: Small	2	0		
Stool transverse colon: Moderate	3	1		
Stool transverse colon: Excess	0	0		
Stool descending colon: Absent	11	10		
Stool descending colon: Small	2	0		
Stool descending colon: Moderate	3	1		
Stool descending colon: Excess	0	1		
Stool sigmoid and rectum: Absent	9	8		
Stool sigmoid and rectum: Small	5	3		
Stool sigmoid and rectum: Moderate	2	0		
Stool sigmoid and rectum: Excess	0	1		

Notes:

[3] - One ITT participant was excluded as non-evaluable for efficacy analysis.

Statistical analyses

Statistical analysis title	Treatment difference for stool cecum
Comparison groups	BLI800 4.5 oz v BLI800 6 oz
Number of subjects included in analysis	29
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.578
Method	Chi-squared

Statistical analysis title	Treatment difference for stool ascending colon
Comparison groups	BLI800 6 oz v BLI800 4.5 oz
Number of subjects included in analysis	29
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.722
Method	Chi-squared

Statistical analysis title	Treatment difference for stool transverse colon
Comparison groups	BLI800 6 oz v BLI800 4.5 oz
Number of subjects included in analysis	29
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.497
Method	Chi-squared

Statistical analysis title	Treatment difference for stool descending colon
Comparison groups	BLI800 6 oz v BLI800 4.5 oz
Number of subjects included in analysis	29
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.453
Method	Chi-squared

Statistical analysis title	Treatment difference for stool sigmoid and rectum
Comparison groups	BLI800 6 oz v BLI800 4.5 oz

Number of subjects included in analysis	29
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.457
Method	Chi-squared

Secondary: Investigator Grading of Residual Fluid Assessment by Colon Segment

End point title	Investigator Grading of Residual Fluid Assessment by Colon Segment

End point description:

The colonoscopist evaluated the five colonic segments for amounts of residual fluid with a score ranging from 1 to 4. Where, 1 = absent; 2 = small; 3 = moderate and 4 = excess. The ITT analysis set included all participants randomized that took any portion of BLI800 solution. One participant in the BLI800 4.5 oz group was excluded as non-evaluable for efficacy analysis. Number of participants at each of the indicated grades for the five colon segments are reported.

End point type	Secondary

End point timeframe:

At Day 1

End point values	BLI800 6 oz	BLI800 4.5 oz		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	16	13[4]		
Units: participants				
Fluid cecum: Absent	5	4		
Fluid cecum: Small	5	4		
Fluid cecum: Moderate	5	2		
Fluid cecum: Excess	0	1		
Fluid ascending colon: Absent	8	7		
Fluid ascending colon: Small	5	3		
Fluid ascending colon: Moderate	2	1		
Fluid ascending colon: Excess	0	0		
Fluid transverse colon: Absent	9	9		
Fluid transverse colon: Small	4	1		
Fluid transverse colon: Moderate	3	1		
Fluid transverse colon: Excess	0	0		
Fluid descending colon: Absent	3	8		
Fluid descending colon: Small	8	2		
Fluid descending colon: Moderate	4	1		
Fluid descending colon: Excess	1	1		
Fluid sigmoid and rectum: Absent	4	9		
Fluid sigmoid and rectum: Small	7	2		
Fluid sigmoid and rectum: Moderate	4	0		
Fluid sigmoid and rectum: Excess	1	1		

Notes:

[4] - One ITT participant was excluded as non-evaluable for efficacy analysis.

Statistical analyses

Statistical analysis title	Treatment difference for fluid cecum
Comparison groups	BLI800 6 oz v BLI800 4.5 oz
Number of subjects included in analysis	29
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.64
Method	Chi-squared

Statistical analysis title	Treatment difference for fluid ascending colon
Comparison groups	BLI800 6 oz v BLI800 4.5 oz
Number of subjects included in analysis	29
Analysis specification	Pre-specified
Analysis type	other
P-value	= 1
Method	Chi-squared

Statistical analysis title	Treatment difference for fluid transverse colon
Comparison groups	BLI800 6 oz v BLI800 4.5 oz
Number of subjects included in analysis	29
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.436
Method	Chi-squared

Statistical analysis title	Treatment difference for fluid descending colon
Comparison groups	BLI800 6 oz v BLI800 4.5 oz
Number of subjects included in analysis	29
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.06
Method	Chi-squared

Statistical analysis title	Treatment difference for fluid sigmoid and rectum
Comparison groups	BLI800 6 oz v BLI800 4.5 oz

Number of subjects included in analysis	29
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.032
Method	Chi-squared

Secondary: Percentage of Participants who had Adequate Cleansing for Evaluation

End point title	Percentage of Participants who had Adequate Cleansing for Evaluation

End point description:

The colonoscopist evaluated whether or not cleansing was adequate for examination. The ITT analysis set included all participants randomized that took any portion of BLI800 solution. One participant in the BLI800 4.5 oz group was excluded as non-evaluable for efficacy analysis.

End point type	Secondary

End point timeframe:

At Day 1

End point values	BLI800 6 oz	BLI800 4.5 oz		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	16	13		
Units: percentage of participants				
number (not applicable)				
Yes	87.5	83.3		
No	12.5	16.7		

Statistical analyses

Statistical analysis title	Treatment difference for adequate cleansing
Comparison groups	BLI800 6 oz v BLI800 4.5 oz
Number of subjects included in analysis	29
Analysis specification	Pre-specified
Analysis type	other[5]
P-value	= 1
Method	Chi-squared
Confidence interval	
level	95 %
sides	2-sided
lower limit	-22.4
upper limit	30.8

Notes:

[5] - The CI for percentage difference between treatments was from a chi-square test.

Secondary: Percentage of Participants With Need for Re-Preparation

End point title	Percentage of Participants With Need for Re-Preparation

End point description:

The colonoscopist evaluated whether or not cleansing was adequate for examination. If the preparation was not adequate, the need for re-preparation was recorded. The ITT analysis set included all participants randomized that took any portion of BLI800 solution. One participant in the BLI800 4.5 oz group was excluded as non-evaluable for efficacy analysis. Only participants who did not have an adequate cleansing were evaluated for this endpoint.

End point type	Secondary

End point timeframe:

At Day 1

End point values	BLI800 6 oz	BLI800 4.5 oz		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2	2		
Units: percentage of participants				
number (not applicable)				
Yes	0	0		
No	100.0	100.0		

Statistical analyses

No statistical analyses for this end point

Secondary: Duration of Colonoscopy

End point title	Duration of Colonoscopy

End point description:

Start time and completion time of colonoscopy were recorded. The ITT analysis set included all participants randomized that took any portion of BLI800 solution. One participant in the BLI800 4.5 oz group was excluded as non-evaluable for efficacy analysis.

End point type	Secondary

End point timeframe:

At Day 1

End point values	BLI800 6 oz	BLI800 4.5 oz		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	16	13[6]		
Units: minute				
arithmetic mean (standard deviation)	19.7 (± 12.57)	26.4 (± 26.97)		

Notes:

[6] - One ITT participant was excluded as non-evaluable for efficacy analysis.

Statistical analyses

No statistical analyses for this end point

Secondary: Volume of Intraprocedural Water Needed to Irrigate the Colon

End point title	Volume of Intraprocedural Water Needed to Irrigate the Colon

End point description:

Volume of water used to improve visualization was measured. The ITT analysis set included all participants randomized that took any portion of BLI800 solution. One participant in the BLI800 4.5 oz group was excluded as non-evaluable for efficacy analysis.

End point type	Secondary

End point timeframe:

At Day 1

End point values	BLI800 6 oz	BLI800 4.5 oz		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	16	13[7]		
Units: milliliter				
arithmetic mean (standard deviation)	29.4 (± 59.75)	17.9 (± 58.99)		

Notes:

[7] - One ITT participant was excluded as non-evaluable for efficacy analysis.

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With Procedures That Reached the Cecum

End point title	Percentage of Participants With Procedures That Reached the Cecum

End point description:

The colonoscopist evaluated whether or not the cecum was reached. The ITT analysis set included all participants randomized that took any portion of BLI800 solution. One participant in the BLI800 4.5 oz group was excluded as non-evaluable for efficacy analysis.

End point type	Secondary

End point timeframe:

At Day 1

End point values	BLI800 6 oz	BLI800 4.5 oz		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	16	13[8]		
Units: percentage of participants				
number (not applicable)				
Yes	93.8	91.7		
No	6.3	8.3		

Notes:

[8] - One ITT participant was excluded as non-evaluable for efficacy analysis.

Statistical analyses

Statistical analysis title	Treatment difference for cecum reached
Comparison groups	BLI800 6 oz v BLI800 4.5 oz
Number of subjects included in analysis	29
Analysis specification	Pre-specified
Analysis type	other[9]
P-value	= 1
Method	Fisher exact
Confidence interval	
level	95 %
sides	2-sided
lower limit	-17.5
upper limit	21.7

Notes:

[9] - The CI for percentage attempted difference between treatments was from a chi-square test.

Secondary: Time to Reach Cecum

End point title	Time to Reach Cecum

End point description:

Time to reach cecum was recorded. The ITT analysis set included all participants randomized that took any portion of BLI800 solution. One participant in the BLI800 4.5 oz group was excluded as non-evaluable for efficacy analysis. Only participants recorded as 'Yes' for cecum reached were evaluated for this endpoint.

End point type	Secondary

End point timeframe:

At Day 1

End point values	BLI800 6 oz	BLI800 4.5 oz		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	15	11		
Units: minute				
arithmetic mean (standard deviation)	9.3 (± 9.10)	15.5 (± 25.33)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants for Each Preparation Cleansing Grade

End point title	Percentage of Participants for Each Preparation Cleansing Grade

End point description:

The colonoscopist assessed colon cleansing using a four point scale ranging from 1 to 4. Where, 1 = poor; 2 = fair; 3 = good and 4 = excellent. The ITT analysis set included all participants randomized that took any portion of BLI800 solution. One participant was excluded as non-evaluable for efficacy analysis.

End point type	Secondary

End point timeframe:

At Day 1

End point values	BLI800 6 oz	BLI800 4.5 oz		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	16	13[10]		
Units: percentage of participant				
number (not applicable)				
Excellent	37.5	75.0		
Good	43.8	8.3		
Fair	6.3	8.3		
Poor	12.5	8.3		

Notes:

[10] - One ITT participant was excluded as non-evaluable for efficacy analysis.

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events:	
From first administration of BLI800 solution (Day 0) up to Day 32.	
Adverse event reporting additional description:	
The ITT analysis set included all participants randomized that took any portion of BLI800 solution.	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	21.0

Reporting groups	
Reporting group title	BLI800 6 oz
Reporting group description:	
Participants received BLI800 6 oz (full adult dose) oral sulfate solution on Day 0 (in evening before the day of colonoscopy) and a second 6 oz dose on the morning of Day 1 (at least 3 hours prior to the colonoscopy procedure).	
Reporting group title	BLI800 4.5 oz
Reporting group description:	
Participants received BLI800 4.5 oz (3/4 adult dose) oral sulfate solution on Day 0 (in evening before the day of colonoscopy) and a second 4.5 oz dose on the morning of Day 1 (at least 3 hours prior to the colonoscopy procedure).	

Serious adverse events	BLI800 6 oz	BLI800 4.5 oz	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 16 (0.00%)	0 / 13 (0.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	

Frequency threshold for reporting non-serious adverse events: 0 %

Non-serious adverse events	BLI800 6 oz	BLI800 4.5 oz	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	13 / 16 (81.25%)	12 / 13 (92.31%)	
Investigations			
Bacterial test			
subjects affected / exposed	1 / 16 (6.25%)	0 / 13 (0.00%)	
occurrences (all)	1	0	
Blood bilirubin increased			
subjects affected / exposed	1 / 16 (6.25%)	0 / 13 (0.00%)	
occurrences (all)	1	0	

Blood creatine phosphokinase increased			
subjects affected / exposed	2 / 16 (12.50%)	1 / 13 (7.69%)	
occurrences (all)	2	1	
Liver function test abnormal			
subjects affected / exposed	1 / 16 (6.25%)	0 / 13 (0.00%)	
occurrences (all)	1	0	
Protein urine present			
subjects affected / exposed	1 / 16 (6.25%)	0 / 13 (0.00%)	
occurrences (all)	1	0	
Urinary casts			
subjects affected / exposed	1 / 16 (6.25%)	0 / 13 (0.00%)	
occurrences (all)	2	0	
Nervous system disorders			
Headache			
subjects affected / exposed	0 / 16 (0.00%)	3 / 13 (23.08%)	
occurrences (all)	0	3	
Syncope			
subjects affected / exposed	0 / 16 (0.00%)	1 / 13 (7.69%)	
occurrences (all)	0	2	
General disorders and administration site conditions			
Chills			
subjects affected / exposed	0 / 16 (0.00%)	1 / 13 (7.69%)	
occurrences (all)	0	1	
Injection site pain			
subjects affected / exposed	0 / 16 (0.00%)	1 / 13 (7.69%)	
occurrences (all)	0	1	
Pyrexia			
subjects affected / exposed	1 / 16 (6.25%)	0 / 13 (0.00%)	
occurrences (all)	1	0	
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	0 / 16 (0.00%)	1 / 13 (7.69%)	
occurrences (all)	0	1	
Abdominal distention			
subjects affected / exposed	5 / 16 (31.25%)	8 / 13 (61.54%)	
occurrences (all)	5	8	

Abdominal pain			
subjects affected / exposed	0 / 16 (0.00%)	3 / 13 (23.08%)	
occurrences (all)	0	4	
Abdominal pain upper			
subjects affected / exposed	5 / 16 (31.25%)	4 / 13 (30.77%)	
occurrences (all)	5	6	
Abdominal tenderness			
subjects affected / exposed	0 / 16 (0.00%)	1 / 13 (7.69%)	
occurrences (all)	0	1	
Anal fissure			
subjects affected / exposed	1 / 16 (6.25%)	1 / 13 (7.69%)	
occurrences (all)	1	1	
Anorectal discomfort			
subjects affected / exposed	0 / 16 (0.00%)	1 / 13 (7.69%)	
occurrences (all)	0	1	
Diarrhoea			
subjects affected / exposed	0 / 16 (0.00%)	1 / 13 (7.69%)	
occurrences (all)	0	2	
Eructation			
subjects affected / exposed	0 / 16 (0.00%)	1 / 13 (7.69%)	
occurrences (all)	0	1	
Gastric ulcer			
subjects affected / exposed	0 / 16 (0.00%)	1 / 13 (7.69%)	
occurrences (all)	0	1	
Gastritis			
subjects affected / exposed	1 / 16 (6.25%)	1 / 13 (7.69%)	
occurrences (all)	1	1	
Nausea			
subjects affected / exposed	8 / 16 (50.00%)	6 / 13 (46.15%)	
occurrences (all)	8	6	
Rectal haemorrhage			
subjects affected / exposed	0 / 16 (0.00%)	1 / 13 (7.69%)	
occurrences (all)	0	1	
Vomiting			
subjects affected / exposed	2 / 16 (12.50%)	2 / 13 (15.38%)	
occurrences (all)	2	3	

Reproductive system and breast disorders Dysmenorrhoea subjects affected / exposed occurrences (all)	 0 / 16 (0.00%) 0	 1 / 13 (7.69%) 1	
Respiratory, thoracic and mediastinal disorders Oropharyngeal pain subjects affected / exposed occurrences (all)	 0 / 16 (0.00%) 0	 1 / 13 (7.69%) 1	
Skin and subcutaneous tissue disorders Eczema subjects affected / exposed occurrences (all)	 0 / 16 (0.00%) 0	 1 / 13 (7.69%) 1	
Psychiatric disorders Anxiety subjects affected / exposed occurrences (all)	 0 / 16 (0.00%) 0	 1 / 13 (7.69%) 2	
Infections and infestations Helicobacter infection subjects affected / exposed occurrences (all)	 1 / 16 (6.25%) 1	 0 / 13 (0.00%) 0	
Metabolism and nutrition disorders Metabolic acidosis subjects affected / exposed occurrences (all)	 0 / 16 (0.00%) 0	 1 / 13 (7.69%) 1	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
23 July 2014	Increased screening visit from within 6 days of colonoscopy to between 30 and 6 days prior to colonoscopy and amended study duration from up to 39 days to up to 60 days.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported