



Clinical trial results:

A Multicenter, Double-blind, Randomized, Placebo-controlled, Parallel-group, Prospective Study to Evaluate the Safety and Efficacy of Domperidone in 6-month-old to 12-year-old Pediatric Subjects With Nausea and Vomiting Due to Acute Gastroenteritis

Summary

EudraCT number	2015-002923-24
Trial protocol	GB PT BE ES AT IT
Global end of trial date	03 August 2017

Results information

Result version number	v1 (current)
This version publication date	16 February 2018
First version publication date	16 February 2018

Trial information

Trial identification

Sponsor protocol code	R033812GTS3001
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02699385
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Janssen-Cilag International NV
Sponsor organisation address	Archimedesweg 29, Leiden, Netherlands, 2333 CM
Public contact	Clinical Registry Group, Janssen-Cilag International NV, ClinicalTrialsEU@its.jnj.com
Scientific contact	Clinical Registry Group, Janssen-Cilag International NV, ClinicalTrialsEU@its.jnj.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	03 August 2017
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	03 August 2017
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

The main objective of the study was to demonstrate that domperidone suspension (1 milligram per milliliter [mg/mL]) plus oral rehydration treatment (ORT) was more effective than placebo plus ORT at reducing the symptoms of vomiting associated with acute gastroenteritis (AG) within the first 48 hours of treatment administration in pediatric subjects aged 6 months to 12 years with AG and mild-to-moderate dehydration.

Protection of trial subjects:

This study was conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki and that are consistent with Good Clinical Practice and applicable regulatory requirements and also known instances of nonconformance were documented and are not considered to have had an impact on the overall conclusions of this study. Safety included incidence, and assessment of adverse events (AEs) vital sign measurements, physical examinations, adverse events of special interest (AESIs) that were referred to as adverse events (AEs) of clinical interest in the data outputs.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	07 July 2016
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Austria: 11
Country: Number of subjects enrolled	Belgium: 15
Country: Number of subjects enrolled	Spain: 16
Country: Number of subjects enrolled	United Kingdom: 10
Country: Number of subjects enrolled	Italy: 5
Country: Number of subjects enrolled	Russian Federation: 200
Country: Number of subjects enrolled	South Africa: 35
Worldwide total number of subjects	292
EEA total number of subjects	57

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37	0

wk	
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	36
Children (2-11 years)	256
Adolescents (12-17 years)	0
Adults (18-64 years)	0
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

A total of 480 pediatric subjects planned for the study, 240 subjects were to be randomly assigned in 1:1 ratio to each treatment group (domperidone and placebo). Screening for eligible subjects was performed on the same day as administration of the study agent.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Placebo

Arm description:

Subjects received placebo oral suspension plus Oral rehydration therapy (ORT) if needed (day 2 to 7 thrice daily for up to 7 days).

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Oral suspension
Routes of administration	Oral use

Dosage and administration details:

Subjects received placebo oral suspension plus Oral rehydration therapy (ORT) if needed (day 2 to 7) thrice daily for up to 7 days.

Investigational medicinal product name	Oral rehydration therapy
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Oral solution
Routes of administration	Oral use

Dosage and administration details:

Subjects received Oral rehydration therapy (ORT) thrice daily for up to 7 days.

Arm title	Domperidone
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Arm description:

Subjects received domperidone suspension (1 milligram(s) per milliliter (mg/mL)) plus ORT if needed (day 2 to 7) thrice daily for up to 7 day.

Arm type	Experimental
Investigational medicinal product name	Oral rehydration therapy (ORT)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Oral solution
Routes of administration	Oral use

Dosage and administration details:

Subjects received ORT if needed (day 2 to 7) thrice daily for up to 7 days.

Investigational medicinal product name	Domperidone
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Oral suspension
Routes of administration	Oral use

Dosage and administration details:

Subjects received domperidone suspension (1 milligram(s) per milliliter [mg/mL]) plus ORT if needed (day 2 to day 7) thrice daily for up to 7 days.

Number of subjects in period 1	Placebo	Domperidone
Started	145	147
Completed	141	146
Not completed	4	1
Adverse event, non-fatal	2	1
Non- specified	2	-

Baseline characteristics

Reporting groups

Reporting group title	Placebo
Reporting group description: Subjects received placebo oral suspension plus Oral rehydration therapy (ORT) if needed (day 2 to 7 thrice daily for up to 7 days).	
Reporting group title	Domperidone
Reporting group description: Subjects received domperidone suspension (1 milligram(s) per milliliter (mg/mL)) plus ORT if needed (day 2 to 7) thrice daily for up to 7 day.	

Reporting group values	Placebo	Domperidone	Total
Number of subjects	145	147	292
Title for AgeCategorical Units: subjects			
infants and toddlers(6 Months to <4 Years)	18	18	36
Children (4 to 12 Years)	127	129	256
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	0	0	0
From 65 to 84 years	0	0	0
85 years and over	0	0	0
Title for AgeContinuous Units: years			
arithmetic mean	6.766	6.964	
standard deviation	± 2.7868	± 2.5318	-
Title for Gender Units: subjects			
Female	62	74	136
Male	83	73	156

End points

End points reporting groups

Reporting group title	Placebo
Reporting group description: Subjects received placebo oral suspension plus Oral rehydration therapy (ORT) if needed (day 2 to 7 thrice daily for up to 7 days.	
Reporting group title	Domperidone
Reporting group description: Subjects received domperidone suspension (1 milligram(s) per milliliter (mg/mL)) plus ORT if needed (day 2 to 7) thrice daily for up to 7 day.	

Primary: Percentage of Subjects With No Vomiting Episodes Within the First 48 Hours of the First Treatment Administration

End point title	Percentage of Subjects With No Vomiting Episodes Within the First 48 Hours of the First Treatment Administration
End point description: The vomiting episodes were recorded for each subjects in the eDiary. The Intent-to-Treat (ITT) Analysis Set population included all the randomized subjects.	
End point type	Primary
End point timeframe: 48 hours	

End point values	Placebo	Domperidone		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	145	147		
Units: Percentage of subjects				
number (not applicable)	33.8	32.0		

Statistical analyses

Statistical analysis title	Statistical Analysis
Comparison groups	Placebo v Domperidone
Number of subjects included in analysis	292
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.732
Method	Cochran-Mantel-Haenszel

Secondary: Percentage of Subjects 4 Years of Age or Older With No Episode of Nausea Within the First 48 Hours of the First Treatment Administration.

End point title	Percentage of Subjects 4 Years of Age or Older With No
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End point description:

The nausea episodes were recorded in the eDiary. The ITT population included all the randomized subjects. Here 'N' signifies number of subjects who were analyzed for this endpoint.

End point type	Secondary
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End point timeframe:

48 hours

End point values	Placebo	Domperidone		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	127	129		
Units: Percentage of subjects				
number (not applicable)	38.6	35.7		

Statistical analyses

Statistical analysis title	Statistical Analysis
Comparison groups	Placebo v Domperidone
Number of subjects included in analysis	256
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.617
Method	Cochran-Mantel-Haenszel

Secondary: Mean Number of Vomiting Episodes for All Subjects Within the 0 to 24 Hour, Greater Than (>) 24 to 48 Hour, and >48 Hour to 7 Day Periods After the First Treatment Administration

End point title	Mean Number of Vomiting Episodes for All Subjects Within the 0 to 24 Hour, Greater Than (>) 24 to 48 Hour, and >48 Hour to 7 Day Periods After the First Treatment Administration
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End point description:

The vomiting episodes were recorded for each subjects in the eDiary. The ITT population included all the randomized subjects.

End point type	Secondary
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End point timeframe:

Up to Day 7

End point values	Placebo	Domperidone		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	145	147		
Units: Vomiting episodes				
arithmetic mean (standard deviation)				
0 - <= 24 Hours	1.6 (± 1.64)	1.4 (± 1.35)		
> 24 - <= 48 Hours	0.2 (± 0.55)	0.1 (± 0.45)		
> 48 Hours - <= 7 Days	0.0 (± 0.25)	0.1 (± 0.26)		

Statistical analyses

Statistical analysis title	Statistical analysis
Comparison groups	Placebo v Domperidone
Number of subjects included in analysis	292
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.835
Method	Generalized linear model

Secondary: Mean Number of Episodes of Nausea for Subjects 4 Years of age or Older Within the 0 to 24 Hour, >24 to 48 Hour, and >48 Hour to 7 Day Periods After the First Treatment Administration

End point title	Mean Number of Episodes of Nausea for Subjects 4 Years of age or Older Within the 0 to 24 Hour, >24 to 48 Hour, and >48 Hour to 7 Day Periods After the First Treatment Administration
End point description: The nausea episodes were recorded in the eDiary. The ITT population included all the randomized subjects. Here 'N' signifies number of subjects who were analyzed for this endpoint.	
End point type	Secondary
End point timeframe: Up to Day 7	

End point values	Placebo	Domperidone		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	127	129		
Units: Nausea episodes				
arithmetic mean (standard deviation)				
0 - <= 24 Hours	1.8 (± 2.02)	1.5 (± 1.72)		
> 24 - <= 48 Hours	0.2 (± 0.58)	0.2 (± 0.69)		
> 48 Hours - <= 7 Days	0.1 (± 0.67)	0.1 (± 0.44)		

Statistical analyses

Statistical analysis title	Statistical analysis
Comparison groups	Placebo v Domperidone
Number of subjects included in analysis	256
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.413
Method	Generalized linear model

Secondary: Percentage of Subjects who had No Episode of Vomiting Within the 0- to 24-hour, >24 to 48-Hour, and >48-Hour to 7 Day Periods After the First Treatment Administration

End point title	Percentage of Subjects who had No Episode of Vomiting Within the 0- to 24-hour, >24 to 48-Hour, and >48-Hour to 7 Day Periods After the First Treatment Administration
End point description: The vomiting episodes were recorded for each subjects in the eDiary. The ITT population included as all the randomized subjects.	
End point type	Secondary
End point timeframe: Up to Day 7	

End point values	Placebo	Domperidone		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	145	147		
Units: Percentage of Subjects				
number (not applicable)				
<= 24 Hours	35.9	32.7		
> 24 - <= 48 Hours	86.2	89.1		
48 Hours - <= 7 Days	95.2	95.2		

Statistical analyses

Statistical analysis title	Statistical analysis
Comparison groups	Placebo v Domperidone
Number of subjects included in analysis	292
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.807
Method	Generalized linear model

Secondary: Percentage of Subjects 4 Years of age or Older who had No Episode of Nausea Within the 0- to 24-Hour, >24 to 48-Hour, and >48-Hour to 7 Day Periods After the First Treatment Administration

End point title	Percentage of Subjects 4 Years of age or Older who had No Episode of Nausea Within the 0- to 24-Hour, >24 to 48-Hour, and >48-Hour to 7 Day Periods After the First Treatment Administration
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End point description:

The nausea episodes were recorded in the eDiary. The ITT population included all the randomized subjects. Here 'N' signifies number of subjects who were analyzed for this endpoint.

End point type	Secondary
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End point timeframe:

Up to Day 7

End point values	Placebo	Domperidone		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	127	129		
Units: Percentage of Subjects				
number (not applicable)				
0 - <= 24 Hours;	40.2	38.0		
> 24 - <= 48 Hours	85.8	85.3		
> 48 Hours - <= 7 Days	92.9	96.9		

Statistical analyses

Statistical analysis title	Statistical analysis
Comparison groups	Placebo v Domperidone
Number of subjects included in analysis	256
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.235
Method	Generalized linear model

Secondary: Percentage of Subjects who had No Episode of Vomiting Within the 7 day Treatment Period After the First Treatment Administration

End point title	Percentage of Subjects who had No Episode of Vomiting Within the 7 day Treatment Period After the First Treatment Administration
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End point description:

The vomiting episodes were recorded for each subjects in the eDiary. The ITT population included as all the randomized subjects.

End point type	Secondary
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End point timeframe:

Day 1 up to Day 7

End point values	Placebo	Domperidone		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	145	147		
Units: Percentage of subjects				
number (not applicable)	32.4	30.6		

Statistical analyses

Statistical analysis title	Statistical Analysis
Comparison groups	Placebo v Domperidone
Number of subjects included in analysis	292
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.707
Method	Cochran-Mantel-Haenszel

Secondary: Percentage of Subjects 4 Years of age or Older who had no Episode of Nausea Within the 7 day Treatment Period After the First Treatment Administration

End point title	Percentage of Subjects 4 Years of age or Older who had no Episode of Nausea Within the 7 day Treatment Period After the First Treatment Administration
End point description: The nausea episodes were recorded in the eDiary. The ITT population included all the randomized subjects. Here 'N' signifies number of subjects who were analyzed for this endpoint.	
End point type	Secondary
End point timeframe: Day 1 up to Day 7	

End point values	Placebo	Domperidone		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	127	129		
Units: Percentage of subjects				
number (not applicable)	37.8	35.7		

Statistical analyses

Statistical analysis title	Statistical Analysis
Comparison groups	Placebo v Domperidone
Number of subjects included in analysis	256
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.68
Method	Cochran-Mantel-Haenszel

Secondary: Percentage of Subjects Taking a Rescue Medication Within the 7-day Treatment Period

End point title	Percentage of Subjects Taking a Rescue Medication Within the 7-day Treatment Period
End point description: If nausea, vomiting, or diarrhea worsens during the study and the investigator initiate rescue medication, the study medication discontinued. The ITT population included all the randomized subjects.	
End point type	Secondary
End point timeframe: Day 1 up to Day 7	

End point values	Placebo	Domperidone		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	145	147		
Units: Percentage of subjects				
number (not applicable)	1.4	0.7		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Stopping Study Agent Early due to Vomiting-Free for 24 Hours Within the 7-day Treatment Period

End point title	Percentage of Subjects Stopping Study Agent Early due to Vomiting-Free for 24 Hours Within the 7-day Treatment Period
End point description: The vomiting episodes were recorded for each subjects in the eDiary. The ITT population included all the randomized subjects.	
End point type	Secondary
End point timeframe: Day 1 up to Day 7	

End point values	Placebo	Domperidone		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	145	147		
Units: Percentage of subjects				
number (not applicable)	97.2	99.3		

Statistical analyses

Statistical analysis title	Statistical Analysis
Comparison groups	Placebo v Domperidone
Number of subjects included in analysis	292
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.169
Method	Cochran-Mantel-Haenszel

Secondary: Mean Time to Last Study Agent Within the 7-day Treatment Period

End point title	Mean Time to Last Study Agent Within the 7-day Treatment Period
End point description: Time taken to administer last study medication were observed. The ITT population included all the randomized subjects.	
End point type	Secondary
End point timeframe: Day 1 up to Day 7	

End point values	Placebo	Domperidone		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	145	147		
Units: Hours				
arithmetic mean (standard deviation)	48.302 (± 25.6233)	46.440 (± 20.0828)		

Statistical analyses

Statistical analysis title	Statistical Analysis
Comparison groups	Placebo v Domperidone

Number of subjects included in analysis	292
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.382
Method	ANCOVA

Secondary: Percentage of Subjects Referred to an Emergency Room/Hospital for Treatment Within the 7 day Treatment Period.

End point title	Percentage of Subjects Referred to an Emergency Room/Hospital for Treatment Within the 7 day Treatment Period.
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End point description:

If nausea, vomiting, or diarrhea worsened during the study and admitted the subject to the hospital for IV fluids, the study medication discontinued. The ITT population included all the randomized subjects.

End point type	Secondary
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End point timeframe:

Day 1 up to Day 7

End point values	Placebo	Domperidone		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	145	147		
Units: Percentage of subjects				
number (not applicable)	0.7	0.7		

Statistical analyses

No statistical analyses for this end point

Secondary: Mean Time-to-Last Vomiting Within the 7-day Period After the First Treatment Administration

End point title	Mean Time-to-Last Vomiting Within the 7-day Period After the First Treatment Administration
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End point description:

The vomiting episodes were recorded for each subjects in the eDiary. The ITT population included all the randomized subjects. Here 'N' signifies number of subjects who were analyzed for this endpoint.

End point type	Secondary
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End point timeframe:

Day 1 up to Day 7

End point values	Placebo	Domperidone		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	97	102		
Units: Hours				
arithmetic mean (standard deviation)	16.88 ($\pm$ 20.739)	16.87 ($\pm$ 25.388)		

Statistical analyses

Statistical analysis title	Statistical Analysis
Comparison groups	Placebo v Domperidone
Number of subjects included in analysis	199
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.837
Method	ANCOVA

Secondary: Change in Hydration Score From Day 1 (Baseline) to day 2

End point title	Change in Hydration Score From Day 1 (Baseline) to day 2
End point description:	
The severity of dehydration were assessed using the Dehydration Score Assessment. a Children under 24 month of age with a score range 7 to 10 points have mild dehydration and children with a score range of 11 to 17 points have moderate dehydration (only children under 24 months of age are evaluated for tears). b) Children 24 months of age or older with a score range of 6 to 9 points have mild dehydration and children with a score range of 10 to 15 points have moderate dehydration. and c) Children under 24 months of age with scores of 18 or more and children 24 months of age or older with scores of 16 or more are considered to be severely dehydrated and were excluded from the study. Here 'N' signifies number of subjects who were analyzed for this endpoint. The ITT population included all the randomized subjects.	
End point type	Secondary
End point timeframe:	
Baseline (Day 1) and Day 2	

End point values	Placebo	Domperidone		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	145	146		
Units: Units on a scale				
arithmetic mean (standard deviation)	-1.1 ($\pm$ 1.24)	-1.1 ($\pm$ 1.42)		

Statistical analyses

Statistical analysis title	Statistical Analysis
Comparison groups	Placebo v Domperidone
Number of subjects included in analysis	291
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.972
Method	ANCOVA

Secondary: Change From Baseline in Weight at day 2

End point title	Change From Baseline in Weight at day 2
End point description: Weight was measured to the nearest 100 grams in underwear (no diaper/nappy/training pants). The ITT population included all the randomized subjects. Here 'N' signifies number of subjects who were analyzed for this endpoint.	
End point type	Secondary
End point timeframe: Baseline and Day 2	

End point values	Placebo	Domperidone		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	142	146		
Units: Kilogram				
arithmetic mean (standard deviation)	-0.03 (± 0.227)	-0.01 (± 0.197)		

Statistical analyses

Statistical analysis title	Statistical Analysis
Comparison groups	Placebo v Domperidone
Number of subjects included in analysis	288
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.372
Method	ANCOVA

Secondary: Percentage of Subjects With Diarrhea Within 0- to 24-Hour, >24- to 48-Hour, >48-Hour to 7 day After the First Successful Treatment Administration

End point title	Percentage of Subjects With Diarrhea Within 0- to 24-Hour, >24- to 48-Hour, >48-Hour to 7 day After the First Successful Treatment Administration
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End point description:

The diarrhea episodes were recorded for each subject in the eDiary. The ITT population included all the

randomized subjects.

End point type	Secondary
End point timeframe:	
Up to Day 7	

End point values	Placebo	Domperidone		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	145	147		
Units: Percentage of subjects				
number (not applicable)				
0 - <= 24 Hours	72.4	68.7		
> 24 - <= 48 Hours	30.3	30.6		
> 48 Hours - <= 7 Days	20.0	17.7		

Statistical analyses

Statistical analysis title	Statistical Analysis
Comparison groups	Placebo v Domperidone
Number of subjects included in analysis	292
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.555
Method	Generalized linear model

Secondary: Percentage of Subjects With Diarrhea Within 0-Hour to 7-day After the First Successful Treatment Administration

End point title	Percentage of Subjects With Diarrhea Within 0-Hour to 7-day After the First Successful Treatment Administration
End point description:	
The diarrhea episodes were recorded for each subject in the eDiary. The ITT population included all the randomized subjects.	
End point type	Secondary
End point timeframe:	
Up to Day 7	

End point values	Placebo	Domperidone		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	145	147		
Units: Percentage of subjects				
number (not applicable)	76.6	74.1		

Statistical analyses

Statistical analysis title	Statistical analysis
Comparison groups	Placebo v Domperidone
Number of subjects included in analysis	292
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.562
Method	Cochran-Mantel-Haenszel

Adverse events

Adverse events information^[1]

Timeframe for reporting adverse events:

Up to Day 15

Assessment type	Non-systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	20.0
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Reporting groups

Reporting group title	Domperidone
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Reporting group description:

Subjects received domperidone suspension (1 milligram(s) per milliliter (mg/mL)) plus ORT if needed (day 2 to 7) thrice daily for up to 7 day.

Reporting group title	Placebo
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Reporting group description:

Subjects received placebo oral suspension plus Oral rehydration therapy (ORT) if needed (day 2 to 7 thrice daily for up to 7 days).

Notes:

[1] - There are no non-serious adverse events recorded for these results. It is expected that there will be at least one non-serious adverse event reported.

Justification: No non-serious adverse events were observed above frequency threshold of 5 % for any arm.

Serious adverse events	Domperidone	Placebo	
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 147 (0.68%)	1 / 145 (0.69%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events			
Infections and infestations			
Gastroenteritis Salmonella			
subjects affected / exposed	1 / 147 (0.68%)	0 / 145 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 147 (0.00%)	1 / 145 (0.69%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	Domperidone	Placebo	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 147 (0.00%)	0 / 145 (0.00%)	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? Yes

Date	Interruption	Restart date
03 August 2017	The study was terminated early for futility based on the recommendations of the Independent Data Monitoring Committee following a planned interim analysis performed when half of the planned subjects to be randomized had either completed or dropped out from the study.	-

Notes:

Limitations and caveats

None reported