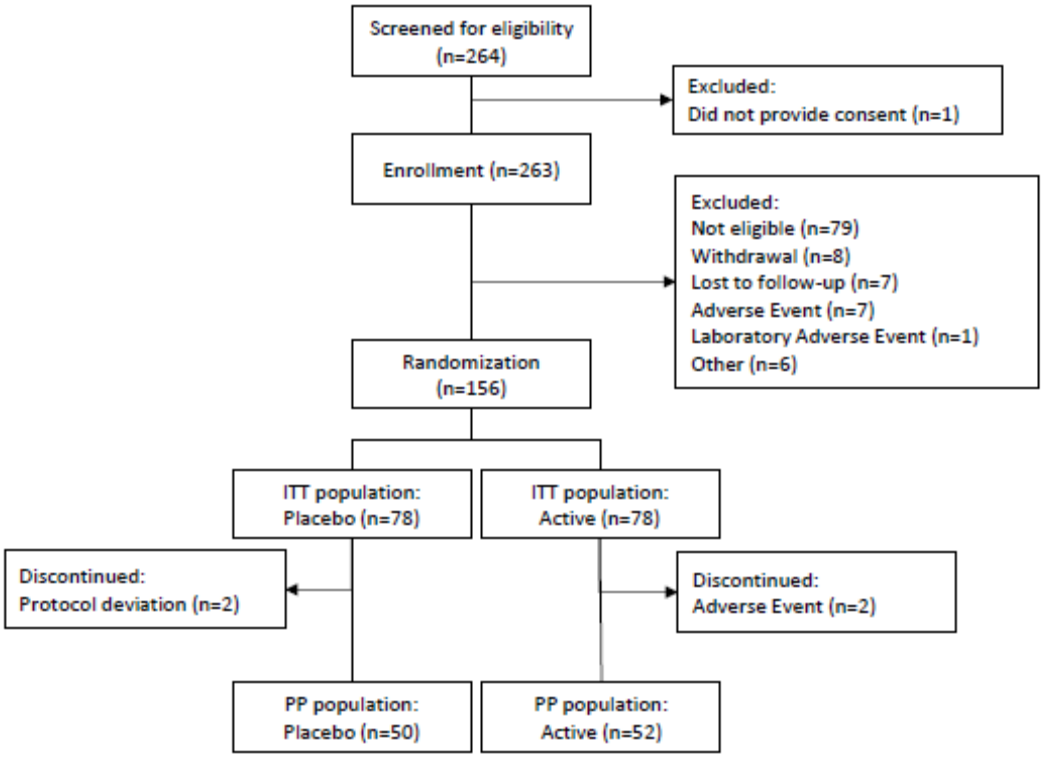
Participant flow



Baseline characteristics

Demographic and Physical Characteristics (ITT Population)

		Active (N = 78)	Placebo (N = 78)	Total (N = 156)
Age (years)	Mean	42.15	40.95	41.55
	(range)	(18–66)	(19–67)	(18–67)
Sex	Female n (%)	71 (91)	68 (87.2)	139 (89.1)
	Male n (%)	7 (9)	10 (12.8)	17 (10.9)
Ethnicity	Caucasian n (%)	78 (100)	73 (93.6)	151 (96.8)
	Asian n (%)	0 (0)	1 (1.3)	1 (0.6)
	Afro-Caribbean n (%)	0 (0)	4 (2.6)	4 (2.6)
Physical characteristics (mean [SD])	Body temperature °C	36.17 (0.41)	36.23 (0.38)	36.20 (0.39)
	Systolic blood pressure (mmHg)	124 (14.46)	125.6 (17.11)	124.8 (15.81)
	Diastolic blood pressure (mmHg)	78.26 (10.71)	77.17 (10.68)	77.71 (10.67)
	Pulse rate (bpm)	72.33 (11.2)	71 (10.92)	71.67 (11.05)
	BMI (kg/m^2)	26.00 (3.89)	27.74 (5.26)	26.87 (4.69)

Source: Table 1.1 in Appendix 16.4 (Note: Table 1.1 has no units for temperature, blood pressure, pulse rate, height, etc.)

BMI – body mass index; ITT – intent-to-treat; SD – standard deviation

Outcome measures

Average VAS score for abdominal bloating (baseline and treatment) – ITT population

	Baseline: Day -7 to Day -1 (V2 to V3)			Change from Baseline to Treatment		
	Placebo (N=78)	**Active (N=78)**	**Total (N=156)**	**Placebo (N=78)**	**Active (N=78)**	**Total (N=156)**
Minimum	2.857	5.143	2.857	-54.429	-53.143	-54.429
25%	27.667	26.929	27.429	-19	-18.089	-19
Median	39.167	39.214	39.167	-6.643	-7.5	-7.143
75%	51.143	51.071	51.143	0	0	0
Maximum	100	83.429	100	18	27.714	27.714
Mean	39.961	39.683	39.823	-9.311	-9.199	-9.255
SD	18.742	17.558	18.104	15.511	16.364	15.888
Missing	1	2	3	1	2	3

Source: Table 8.ITT in Appendix 16.4

SD – standard deviation

Results of the primary efficacy analysis – ITT, PP and PP cohort populations

Population	Shapiro-Wilks test on residuals†	Difference	95% CI	p-value
ITT	0.957	-0.039	4.796, -4.875	0.987
PP	0.368	-0.834	4.641, -6.309	0.766
PP Cohort 1*	0.471	-2.044	5.294, -9.383	0.587
PP Cohort 2*	0.988	1.011	9.463, -7.441	0.816

Source: Table 8.ITT, Table 8.PP, Table 8.PP C1, Table 8.PP C2 in Appendix 16.4; Table 1 in Statistical Study Report

* Cohort 1 up to and including 25 December 2015, Cohort 2 is after 25 December 2015.

† A p-value of greater than 0.05 in the Shapiro-Wilks test shows that the data are normally distributed

Adverse events

Summary of Adverse Events

Population	Active (N = 78) n (%)	Placebo (N = 78) n (%)	Total (N = 156) n (%)
At least one AE	30 (38.5)	36 (46.2)	66 (42.3)
Intensity of AE			
Any severe AE	0	0	0
Any moderate AE	6 (7.7)	2 (2.6)	8 (5.1)
Any mild AE	26 (33.3)	35 (44.9)	61 (39.1)
Any event leading to death	0	0	0
Any event leading to treatment discontinuation*	2 (2.6)	0	2 (1.3)
Any SAE	0	0	0
Relationship to study medication			
Any definitely related AE	0	0	0
Any probably related AE	0	0	0
Any possibly related AE	12 (15.4)	13 (16.7)	25 (16.0)
Any unlikely related AE	13 (16.7)	14 (17.9)	27 (17.3)
Any unrelated AE	14 (17.9)	15 (19.2)	29 (18.6)

Source: Table 12 in Appendix 16.2.7 and Table 13 in Appendix 16.4

*Treatment was discontinued because of use of antibiotics to treat the AE