

Kinetics of intestinal presence of spores following oral administration of Bacillus clausii formulations:

Three single centre, crossover, randomised, open label studies

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Short title: Kinetics of Bacillus clausii formulations over three studies

Supplementary Information

Table S1. Treatment emergent adverse events by system organ class and preferred term.

Table S2. Spore counts (in millions). Standard deviation within data and coefficient of variation of the three studies.

Table S1. Treatment emergent adverse events by system organ class and preferred term.

	2012 EGKINETIC4	
	E2 BID	E4 OD
	N=22	N=22
	N (%)	N (%)
Gastrointestinal disorders		
Abdominal pain	3 (13.6 %)	3 (13.6 %)
Infections and infestations		
Dysentery	1 (4.5 %)	1 (4.5 %)
Foot and mouth disease	1 (4.5 %)	0
Nasopharyngitis	1 (4.5 %)	1 (4.5 %)
Injury, poisoning and procedural complications		
Arthropod sting	1 (4.5 %)	1 (4.5 %)
Nervous system disorders		
Headache	1 (4.5 %)	1 (4.5 %)
Reproductive system and breast disorders		
Menstrual discomfort	1 (4.5 %)	2 (9.1 %)
Prostatitis	1 (4.5 %)	1 (4.5 %)
Respiratory, thoracic and mediastinal disorders		
Oropharyngeal pain	1 (4.5 %)	1 (4.5 %)
	2012 EGKINETIC6	
	EC 2 TID	ES 6 OD
	N=22	N=22
	N (%)	N (%)
Endocrine disorders		
Goitre	1 (4.5 %)	0
Gastrointestinal disorders		
Abdominal pain	1 (4.5 %)	1 (4.5 %)
General disorders and administration site conditions		
Pain	2 (9.1 %)	1 (4.5 %)
Metabolism and nutrition disorders		
Hypertriglyceridaemia	1 (4.5 %)	0
Nervous system disorders		
Headache	2 (9.1 %)	3 (13.6 %)
Reproductive system and breast disorders		
Menstrual discomfort	1 (4.5 %)	1 (4.5 %)
Respiratory, thoracic and mediastinal disorders		
Nasopharyngitis	0	3 (13.6 %)
Oropharyngeal pain	0	1 (4.5 %)
	EGKINETIC 6OP	
	ES6 OD	E6 OD
	N=30	N=29
	N (%)	N (%)
Gastrointestinal disorders		
Toothache	0	1 (3.4%)
Infections and infestations		
Influenza	0	1 (3.4%)
Nervous system disorders		
Headache	1 (3.3%)	3 (10.3%)

Table S2. Spore counts (in millions). Standard deviation within data and coefficient of variation of the three studies.

	Formulation	SD within	Coefficient of variation (%)
Summary AUC, spore counts			
2012 EGKINETIC4	E2 BID vs E4 OD	0.21	21.15
2012 EGKINETIC6	E2 TID vs E6 OD	0.57	61.60
2016 EGKINETIC6OP	E6 OD vs ES6 OD	0.37	38.70
Summary AUC, vegetative counts			
2012 EGKINETIC4	E2 BID vs E4 OD	0.23	23.24
2012 EGKINETIC6	E2 TID vs E6 OD	0.57	61.92
Summary AUC, C_{max}			
2016 EGKINETIC6OP	E6 OD vs ES6 OD	0.34	35.1