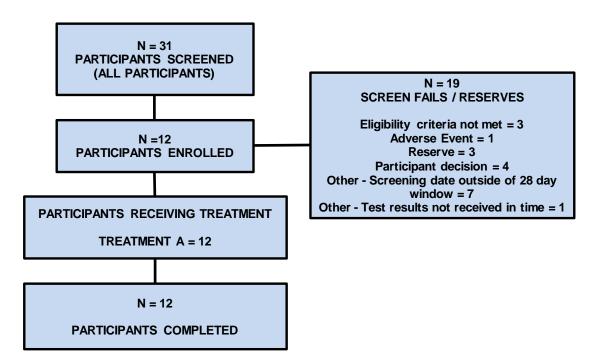
Title: Oral delivery of a vitamin formulation to the colon

ISRCTN: ISRCTN60502217

IRAS: 332044

Participant Flow Chart



Baseline Characteristics

Sex Male 7 (58.3%) Female 5 (41.7%) N 12 Race White 8 (66.7%) Asian or Asian British 2 (16.7%) White and Asian 1 (8.3%) Black, Black British, Caribbean, or African 1 (8.3%) Black, Black British, Caribbean, or African 1 (8.3%) N 12 Age 1.7 N 1.2 Mean 3.0 SD 12.78 Min 20 Max 5 Height (m) 12 Mean 1.7 SD 0.08 Median 1.70 Max 1.88 Weight(kg) 1.8 Weight(kg) 1.8 Median 7.9 Max 1.0 Modian 1.0 Min 5.0 Min 5.0 Min 5.0 Min 5.0 Min		Total
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SD 3.13 Median 26.30 Min 20.66		
Median 26.30 Min 20.66		
Min 20.66		
Max 30.07		30.07

Outcomes Measured (Primary)

Treatment	А
	Radiolabelled colon targeted vitamin tablet
Dosed	N = 12
Site of onset	
Stomach	0 (0%)
Small Intestine	5 (42%)
Small Intestine / Ileocecal Junction	1 (8%)
Ileocecal Junction	1 (8%)
Colon	4 (33%)
n	11
Not Observed	1 (8%)
Onset radiolabel release [hours]	
Mean	5.9
SD	2.2
Median	5.4
Min - Max	3.4 - 10.4
n	11

N = Number of observations; SD = Standard deviation; Min = Minimum; Max = Maximum

Adverse Events

	Total participants
	N = 12
Number of participants with at least one AE	6 (50%)
Total number of AEs	8
Number of participants with at least one TEAE	4 (33.3%)
Total number of TEAEs	5
Total number of participants with at least one SAE	0 (0%)
Total number of SAEs	0
	Total AEs
	N = 8
Total number of treatment related AEs	1 (12.5%)
Total number of AEs leading to death	0 (0%)
Total number of AEs leading to discontinuation	0 (0%)
	Intensity Grading
Mild	8 (100%)
Moderate	0 (0%)
Severe	0 (0%)