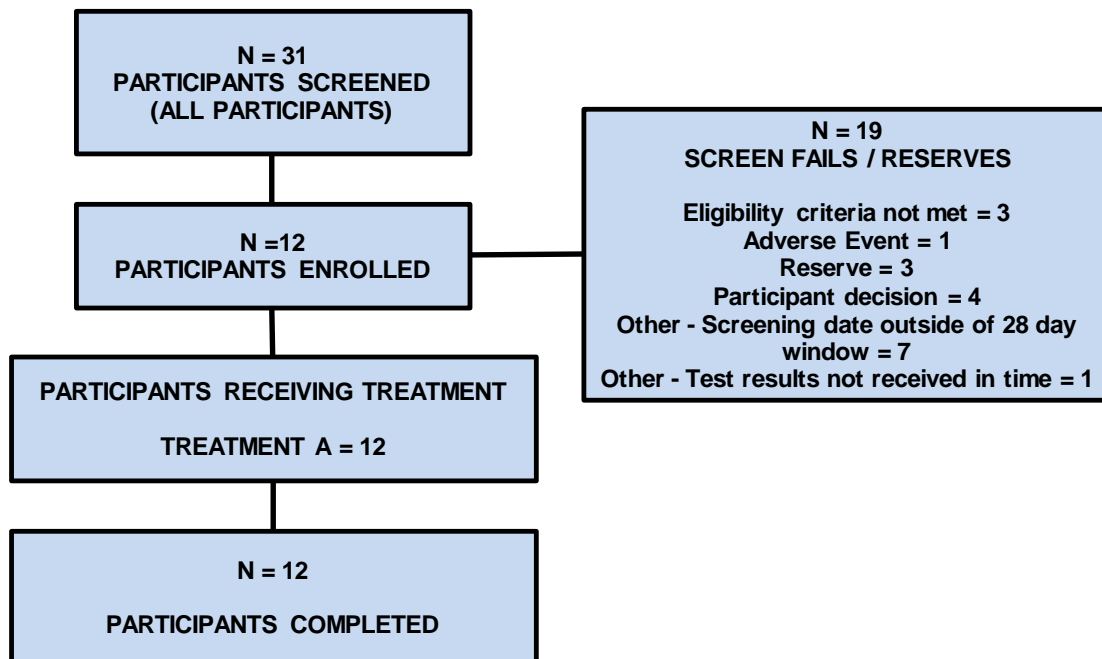


Title:	Oral delivery of a vitamin formulation to the colon
ISRCTN:	ISRCTN60502217
IRAS:	332044

Participant Flow Chart



Baseline Characteristics

	Total (N=12)
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%)
N	12
Age	
N	12
Mean	32.0
SD	12.78
Median	27.5
Min	20
Max	56
Height (m)	
N	12
Mean	1.70
SD	0.08
Median	1.74
Min	1.60
Max	1.88
Weight(kg)	
N	12
Mean	79.9
SD	13.38
Median	79.9
Min	52.9
Max	102.3
BMI (kg/m2)	
N	12
Mean	26.2
SD	3.13
Median	26.30
Min	20.66
Max	30.07

Outcomes Measured (Primary)

Treatment	A
	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%)