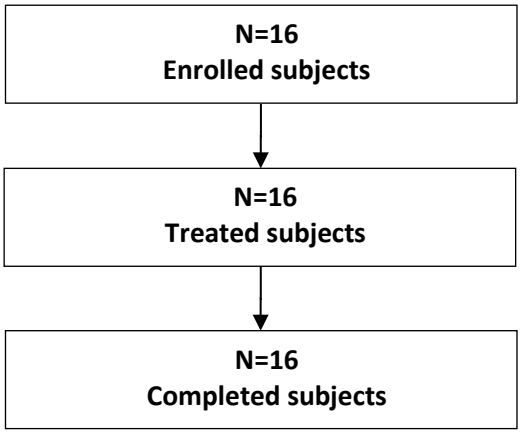
Participant flow



All 16 completed subjects received the two study treatments (Mesalazine 1200 mg gastro-resistant prolonged release tablets [T] and Mesavancol® 1200 mg gastro-resistant prolonged release tablets [R]) in two consecutive study periods according to a randomised, cross-over design.

Baseline characteristics

Demographic data	Randomised, safety and PK set N=16
Sex	
Female - n (%)	9 (56.3%)
Male – n (%)	7 (43.8%)
Age (years)	
Mean ± SD	39.4±10.4
Median (min-max)	41.0 (25-52)
Body weight (kg)	
Mean ± SD	65.86±8.59
Median (min-max)	63.55 (54.9-83.1)
Height (cm)	
Mean ± SD	167.9±8.6
Median (min-max)	166.5 (155-182)
Body Mass Index (kg/m^2)	
Mean ± SD	23.39±2.69
Median (range)	23.05 (20.1-29.8)
Race	
White – n (%)	14 (87.5%)
Other, Mestizo – n (%)	1 (6.3%)
Other, Mulatto – n (%)	1 (6.3%)

Outcome measures

Descriptive statistics of mesalazine (5-ASA) plasma pharmacokinetic parameters are presented in the table below:

Pharmacokinetic parameters	**T N=16**	**R N=16**
C_{max} (ng/mL)	8540.358±6323.043	2097.469±2104.860
AUC_{0-t} (ng/mL×h)	22830.013±12340.774	10665.911±8816.940
t_{max} (h)	6 (4–36)	24 (7-48)

T: Mesalazine 1200 mg; R: Mesavancol® 1200 mg; values are arithmetic means ± SD, except for t_{max}: median (min-max).

A very large intra and inter-subject variability was observed for both study treatments. The statistical analysis was not completed.

Adverse events

Number of treatment-emergent adverse events (TEAEs) and number and percentage of subjects with TEAEs by treatment, system organ class (SOC) and preferred term (PT) after single dose of Mesalazine 1200 mg gastro-resistant prolonged release tablets (T) and Mesavancol® 1200 mg gastro-resistant prolonged release tablets (R). Safety set

SOC	**T N=16**		**R N=16**		**Overall N=16**	
PT	**n AEs**	**n (%) subjects**	**n AEs**	**n (%) subjects**	**n AEs**	**n (%) subjects**
All TEAEs – all SOCs	1	1 (6.3)	4	3 (18.8)	5	4 (25.0)
Gastrointestinal disorders	0	0 (0.0)	2	2 (12.5)	2	2 (12.5)
Abdominal discomfort	0	0 (0.0)	1	1 (6.3)	1	1 (6.3)
Diarrhoea	0	0 (0.0)	1	1 (6.3)	1	1 (6.3)
Investigations	0	0 (0.0)	2	1 (6.3)	2	1 (6.3)
ALT increased	0	0 (0.0)	1	1 (6.3)	1	1 (6.3)
AST increased	0	0 (0.0)	1	1 (6.3)	1	1 (6.3)
Musculoskeletal and connective tissue disorders	1	1 (6.3)	0	0 (0.0)	1	1 (6.3)
Back pain	1	1 (6.3)	0	0 (0.0)	1	1 (6.3)

T: Mesalazine 1200 mg; R: Mesavancol® 1200 mg

Number of TEAEs and number of subjects with TEAEs after single dose of Mesalazine 1200 mg gastro-resistant prolonged release tablets (T) and Mesavancol® 1200 mg gastro-resistant prolonged release tablets (R). Safety set

Category	**T N=16**		**R N=16**		**Overall N=16**	
	n AEs	**n (%) subjects**	**n AEs**	**n (%) subjects**	**n AEs**	**n (%) subjects**
All TEAEs	1	1 (6.3)	4	3 (18.8)	5	4 (25.0)
Related	0	0 (0.0)	4	3 (18.8)	4	3 (18.8)
Not related	1	1 (6.3)	0	0 (0.0)	1	1 (6.3)
Leading to discontinuation	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
SAEs	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)