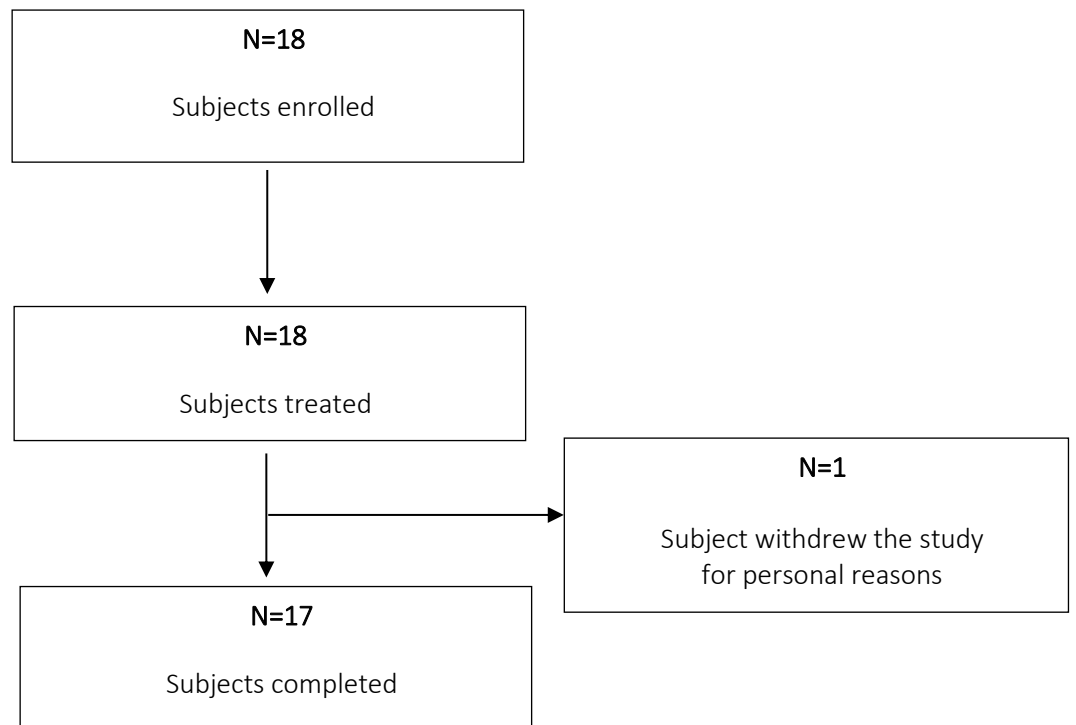


## Participant flow



### Baseline characteristics

Demographic data	Safety set – N=18	PK sets 1 and 2 – N=17
<b>Sex</b>		
Women – n (%)	9 (50%)	8 (47.1%)
Men – n (%)	9 (50%)	9 (52.9%)
<b>Age (years)</b>		
Mean ± SD	43.4±7.1	44.1±6.5
Median (range)	46.5 (31 – 53)	47.0 (32 – 53)
<b>Body weight (kg)</b>		
Mean ± SD	68.79±10.59	69.12±10.82
Range	67.75 (51.5 – 81.9)	68.20 (51.5 – 81.9)
<b>Height (cm)</b>		
Mean ± SD	168.9±9.0	169.0±9.2
Median (range)	169.0 (155 – 184)	171.0 (155 – 184)
<b>BMI (kg/m<sup>2</sup>)</b>		
Mean ± SD	24.02±2.33	24.09±2.38
Median (range)	23.40 (19.1 – 28.0)	23.50 (19.1 – 28.0)
<b>Race</b>		
White – n (%)	17 (94.4%)	16 (94.1%)
Other, mulatto – n (%)	1 (5.6%)	1 (5.9%)

## Outcome measures

### Primary outcome

PK parameters of total chondroitin sulfate measured and calculated on Days 1 and 14-16 after single and multiple doses of Condrosulf® 800 mg q.d. for 14 days (N=17)

Total N=16	Total N=17
AUC <sub>0-t</sub> (μMxh)	AUC <sub>t,ss</sub> (μMxh)
17.0928	16.4405
±23.9766	±14.0535

*mean±SD is shown*

### Secondary outcome

Total amount of total chondroitin sulfate excreted in urine measured and calculated on Days 1 and 14-16 after single and multiple doses of Condrosulf® 800 mg q.d. for 14 days (N=17)

Total – Day1	Total – Day14
Ae <sub>0-t</sub> (nmol)	Ae <sub>0-t,ss</sub> (nmol)
5054.3812	5834.8082

*mean±SD is shown*

## Adverse events

Overview of TEAEs: number of TEAEs and number of subjects with TEAEs. Safety set

Category	Overall N=18	
	N AEs	n (%) subjects
All TEAEs	3	3 (16.7)
Related	1	1 (5.6)
Not related	2	2 (11.1)
Leading to discontinuation	0	0 (0.0)
SAEs	0	0 (0.0)

Number of subjects with TEAEs and number of TEAEs by treatment, system organ class (SOC) and preferred term (PT) (Safety set)

MedDRA description SOC and PT term	Safety set N=18	
	AEs n	Subjects n (%)
<b>Total number of AEs and of subjects with at least one AE</b>	<b>3</b>	<b>3 (16.7)</b>
<b>Investigations</b>	<b>2</b>	<b>2 (11.1)</b>
Transaminases increased	2	2 (11.1)
<b>Gastrointestinal disorders</b>	<b>1</b>	<b>1 (5.6)</b>
Nausea	1	1 (5.6)

*N – n (%): number of TEAEs and number and percentage of subjects with TEAEs are shown*