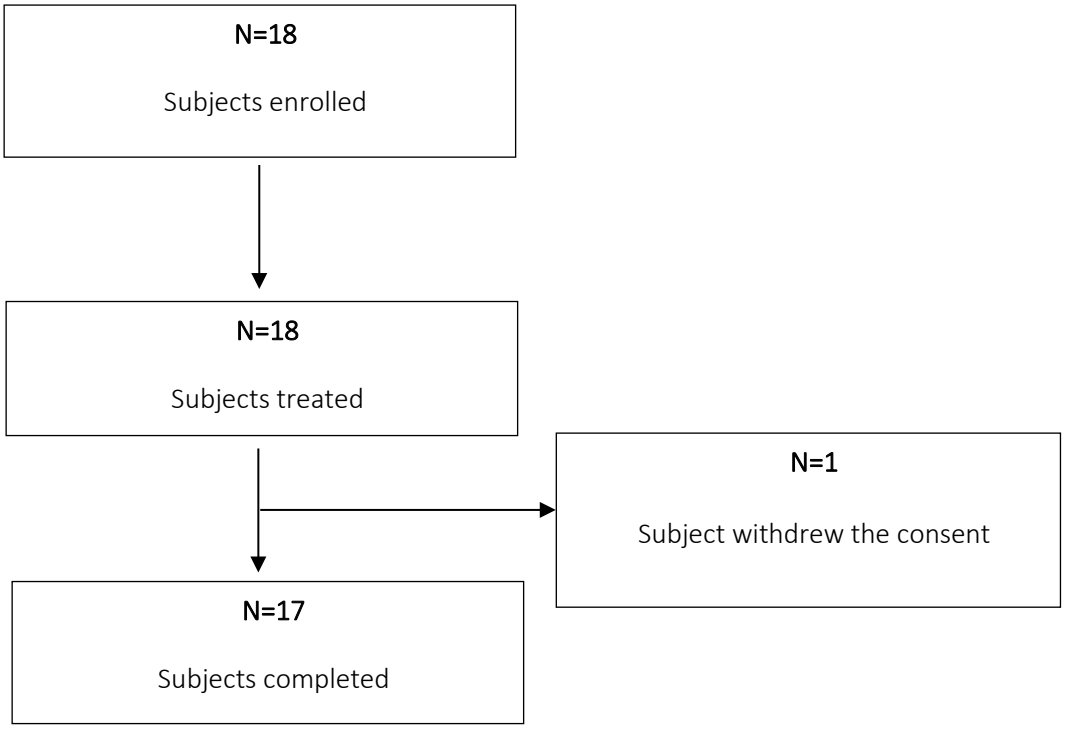
Participant flow



Baseline characteristics

Demographic data	**Safety set - N=18**	**PK set - N=17**
Sex		
Females – n (%)	9 (50%)	9 (52.9%)
Males – n (%)	9 (50%)	8 (47.1%)
Age (years)		
Mean ± SD	47.3±9.5	46.9±9.7
Median (range)	47.0 (32 – 60)	46.0 (32 – 60)
Body weight (kg)		
Mean ± SD	74.18±12.62	72.78±11.49
Range	68.65 (56.7 – 97.9)	68.60 (56.7 – 95.9)
Height (cm)		
Mean ± SD	171.5±11.0	170.1±9.4
Median (range)	171.5 (154 – 196)	171.0 (154 – 184)
BMI (kg/m^2)		
Mean ± SD	25.10±2.38	25.08±2.45
Median (range)	24.45 (21.9 – 29.3)	24.30 (21.9 – 29.3)
Race		
White – n (%)	17 (94.4%)	16 (94.1%)
Mestizo – n (%)	1 (5.6%)	1 (5.9%)

Outcome measures

Primary outcome

AUC_{0-t} of total plasma chondroitin sulfate (h*µM) measured and calculated after single dose of Condrosulf® under fed and fasting conditions is shown below.

AUC_{0-t} total chondroitin sulfate (h*µM)	
T_{fed}	T_{fast}
48.9376 ±30.5067	49.6133 ±28.5775

mean±SD is shown

Secondary outcomes

The elimination phase could not be defined for any subject. This means that the criteria for extrapolation to infinity established in the protocol were not met for any subjects and that λ_z, t1/2, $AUC_{0-\infty}$, Cl/F and V_d/F could not be calculated.

Mean peak levels (C_{max}) could not be calculated reliably due to the impossibility to define a clear curve peak.

Adverse events

No treatment-emergent adverse event, death, serious or other significant adverse event occurred throughout the study. No subject discontinued the study due to safety reasons. No significant change in laboratory assays, vital signs, body weight or ECG was observed.