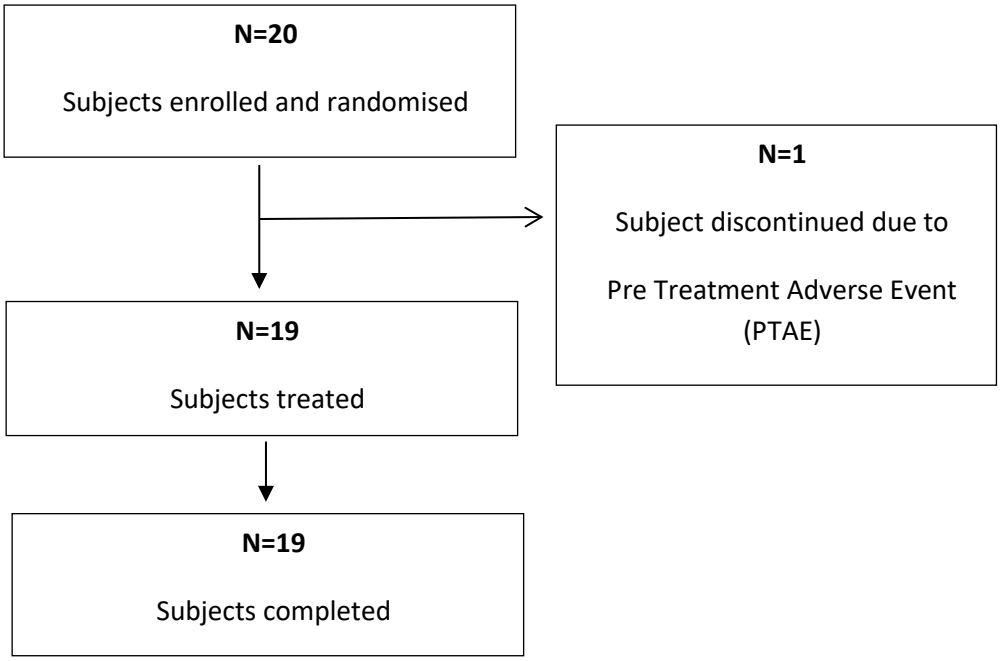
Participant flow



Baseline characteristics

Demographic data	**Safety and PK set - N=19**
Gender	
Female – n (%)	9 (47.4%)
Male – n (%)	10 (52.6%)
Age (years)	
Mean ± SD	33.1±10.8
Median (range)	33.0 (18 – 55)
Body weight (kg)	
Mean ± SD	71.66±11.64
Range	71.10 (50.4 – 91.1)
Height (cm)	
Mean ± SD	171.3±8.2
Median (range)	170.0 (157 – 190)
BMI (kg/m^2)	
Mean ± SD	24.34±2.87
Median (range)	23.90 (20.0 – 28.8)
Race	
White – n (%)	18 (94.7%)
Mulatto – n (%)	1 (5.3%)

Outcome measures

Primary outcome

Diclofenac – Outcome of the statistical test of food effect. N = 19

		Geometric mean ratio	
Treatment comparison	**Parameter**	**PE%**	**90% CI**
T vs. R	C_{max}	31.05%	24.27 – 39.74
	AUC_{0-t}	81.16%	75.34 – 87.42
	$AUC_{0-\infty}$	85.23%	78.60 – 92.42*

*PE: Point estimate, calculated as ratio of geometric means; CV%: within-subject variability; *: N=16*

Secondary outcome

Main diclofenac plasma PK parameters after single dose of DHEP tablets administered under fed conditions (Test treatment) and fasting conditions (Reference treatment). N = 19

Diclofenac PK parameters	**DHEP 65 mg tablets** **Fed conditions**	**DHEP 65 mg tablets** **Fasting conditions**
C_{max} (ng/mL)	577.16±266.09	1835.11±845.72
AUC_{0-t} (ng/mL×h)	1281.33±392.30	1584.74±562.38
$AUC_{0-\infty}$ (ng/mL×h)	1386.38±433.64*	1650.19±562.66**
t_{max} (h)	0.50 (0.25–6.00)	0.35 (0.25–1.00)
$t_{½}$ (h)	2.02±0.62*	1.43±0.46**
λ_z (1/h)	0.37±0.11*	0.54±0.19**

*Values are arithmetic means ± SD, except for t_{max}: median (min-max); *: N=16; **: N=18*

Adverse events

Overview of TEAEs: number of TEAEs and number of subjects with TEAEs. Safety set N=19

Category	DHEP 65 mg tablets Fed conditions		DHEP 65 mg tablets Fasting conditions		Overall	
	N AEs	n (%) subjects	N AEs	n (%) subjects	N AEs	n (%) subjects
All TEAEs	1	1 (5.3)	1	1 (5.3)	2	2 (10.5)
Related	1	1 (5.3)	0	0 (0.0)	1	1 (5.3)
Not related	0	0 (0.0)	1	1 (5.3)	1	1 (5.3)
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)

Number of subjects reporting and number of reported TEAEs by treatment, system organ class (SOC) and preferred term (PT) (Safety set; N=19)

MedDRA description SOC and PT term	DHEP 65 mg tablets Fed conditions		DHEP 65 mg tablets Fasting conditions	
	AEs n	Subjects n (%)	AEs n	Subjects n (%)
Total number of AEs and of subjects with at least one AE	**1**	**1 (5.3)**	**1**	**1 (5.3)**
Gastrointestinal disorders	**1**	**1 (5.3)**	**0**	**0**
Abdominal pain upper	1	1 (5.3)	0	0
Nervous system disorders	**0**	**0**	**1**	**1 (5.3)**
Headache	0	0	1	1 (5.3)