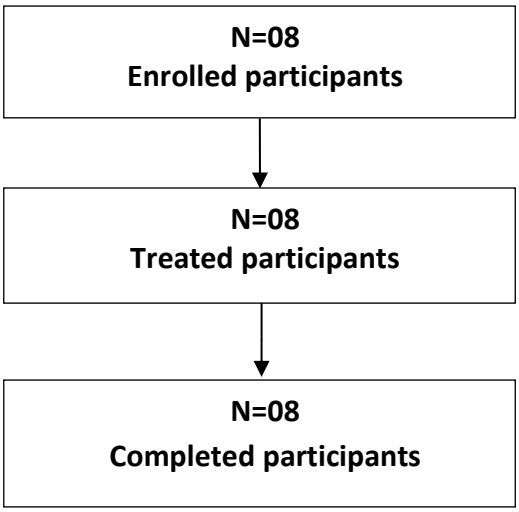
Participant flow



Baseline characteristics

Demographic data	**N=8**
Sex	
Women – n (%)	4 (50.0%)
Men – n (%)	4 (50.0%)
Age (years)	
Mean ± SD	37.6±12.0
Median (range)	41.0 (19 – 50)
Body weight (kg)	
Mean ± SD	71.90±10.12
Median (range)	72.10 (60.0 – 85.8)
Height (cm)	
Mean ± SD	172.8±9.0
Median (range)	171.0 (160 – 185)
Body mass index (kg/m^2)	
Mean ± SD	24.08±2.78
Median (range)	23.55 (20.2 – 29.7)

Abbreviations: N = numerosity; n (%) = number and percentage of subjects presented for qualitative data; mean±SD: presented for quantitative data; SD: standard deviation.

Outcome measures

The concentration of DFL24498 in both blood and plasma was below the lower quantification limit in all the samples. Therefore, no mean concentrations or pharmacokinetic parameters could be calculated.

Adverse events

Overview of Treatment-Emergent Adverse Events. Safety set

Category	N=8	
	No. Events	n (%) No. of Subjects
Total number of TEAEs and of subjects with TEAEs	1	1 (12.5)
Related	0	0
Not related	1	1 (12.5)
Leading to discontinuation	0	0 (0.0)
SAEs	0	0 (0.0)

Abbreviations: N = number of subjects; n = number of subjects who reported an event of that category; No. = number; SAE = serious adverse events; TEAE = treatment-emergent adverse event.

Only 1 treatment-emergent adverse event was reported during the study; 1 participant (12.5%) experienced an event of dizziness.

No treatment-related adverse events and no serious adverse events occurred during the study, and no participant discontinued the study or the study treatment due to an adverse event.

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term - Safety Set

System Organ Class [1] Preferred Term [1]	Safety Set N=8 n (%) [n AE]
Treatment-emergent Adverse Events	1 (12.5) [1]
Nervous system disorders	1 (12.5) [1]
Dizziness	1 (12.5) [1]

Note: The number and the proportion of subjects with any adverse event and the number of adverse events for each classification level are reported

The denominator for calculating the proportions is the number of subjects in the safety set

Abbreviations: N = numerosity; n (%) = number and percentage of subjects; n AE = number of adverse events

Subjects with Treatment-Emergent Adverse Events Related to the IMP By System Organ Class and Preferred Term - Safety Set

No treatment-emergent adverse events related to the IMP occurred during the study

Abbreviations: IMP = investigational medicinal product