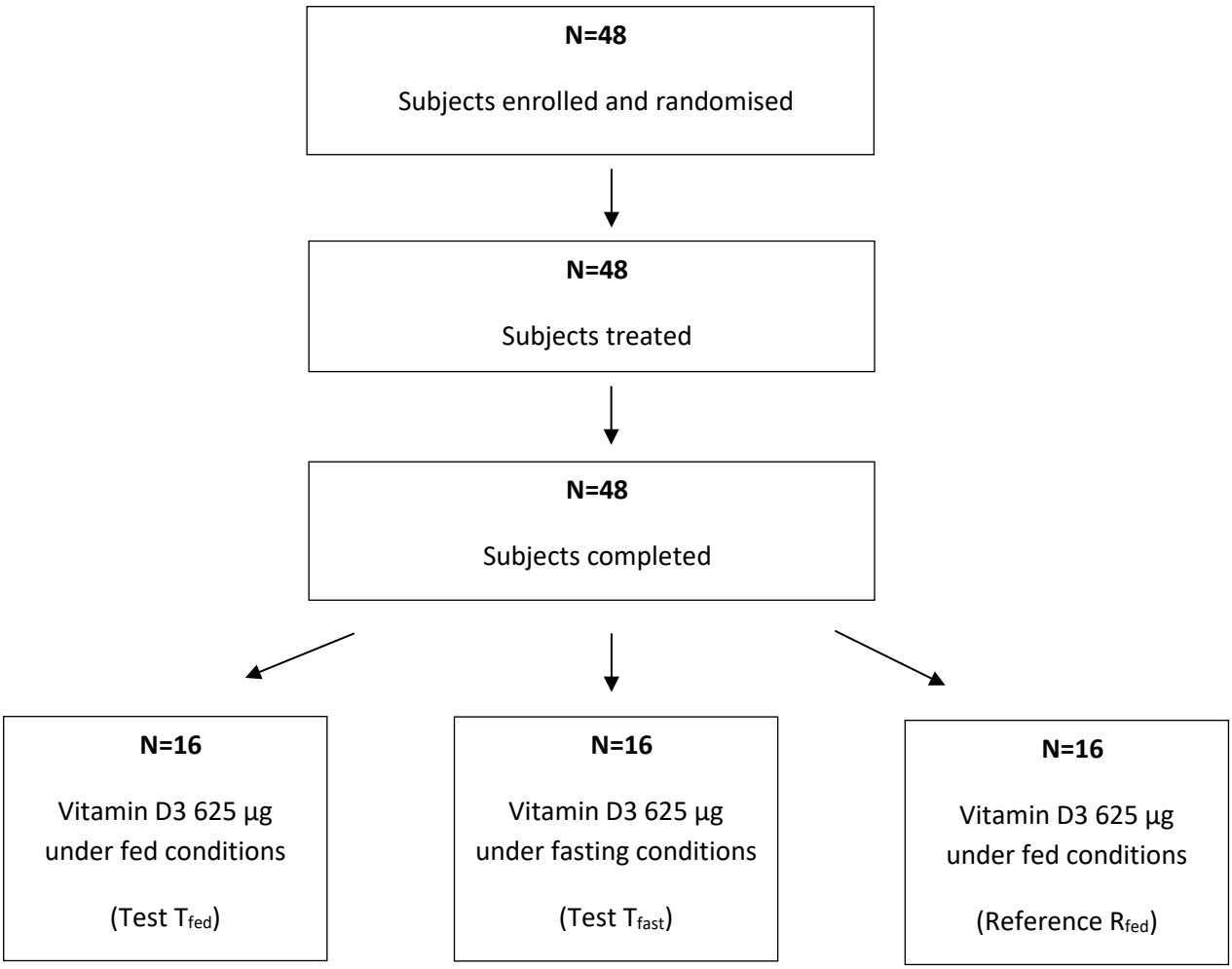
Participant flow



Baseline characteristics

Demographic data	**Enrolled and Safety set N=48**
Sex	
Female – n (%)	25 (52.1 %)
Male – n (%)	23 (47.9 %)
Age (years)	
Mean ± SD	51.1±6.6
Median (range)	52.0 (40 – 65)
Body weight (kg)	
Mean ± SD	69.19±9.91
Median (range)	68.90 (54.1 – 94.0)
Height (cm)	
Mean ± SD	168.3±9.4
Median (range)	167.0 (154 – 196)
Body Mass Index (kg/m^2)	
Mean ± SD	24.37±2.25
Median (range)	24.00 (20.4 – 28.9)
Race	
White – n (%)	47 (97.9)
Mulatto – n (%)	1 (2.1)

Outcome measures

Primary outcome

Vitamin D3 (25(OH)D3): outcome of the statistical analysis between test and reference administered under fed conditions (T_{fed} *vs*. R_{fed}). N=16

Treatment comparison	Parameter	PE%	90% CI
T_{fed} *vs.* R_{fed}	C_{max}	104.95%	83.91 – 131.25
	AUC_{0-t}	124.60%	84.84 – 183.00
	$AUC_{0-\infty}$	110.14%	55.39 – 218.98*

*PE: Point estimate, calculated as ratio of geometric means; CI: confidence interval; *: N=9*

Secondary outcome

Vitamin D3 (25(OH)D3): outcome of the statistical analysis between test administered under fed and test administered under fasting conditions (T_{fed} *vs*. T_{fast}). N=16

Treatment comparison	Parameter	PE%	90% CI
T_{fed} *vs.* T_{fast}	C_{max}	90.11%	77.21 – 105.17
	AUC_{0-t}	106.34%	76.78 – 147.28
	$AUC_{0-\infty}$	101.60%	56.55 – 182.53*

*PE: Point estimate, calculated as ratio of geometric means; CI: confidence interval; *: N=9*

Main baseline-corrected Vitamin D3 (25(OH)D3) plasma PK parameters after single dose of three treatments: test administered under fed conditions (T_{fed}), test administered under fast conditions (T_{fast}), and reference administered under fed conditions (R_{fed}).

Baseline-corrected 25(OH)D3 PK parameters	**T_{fed} N=16**	**T_{fast} N=16**	**R_{fed} N=16**
C_{max} (ng/mL)	6.68±2.03	7.23±1.48	6.61±2.62
AUC_{0-t} (ng/mL×h)	2364.80±1336.97	2244.38±1144.26	2150.52±1622.76
$AUC_{0-\infty}$ (ng/mL×h)	4247.21±3903.59*	3328.43±1778.46°	3582.27±3144.33**
t_{max} (h)	144 (36–312)	42 (2-480)	48 (12–312)
$t_{½}$ (h)	231.75±199.59*	236.35±127.62°	205.80±142.39**
λ_z (1/h)	0.01±0.00*	0±0°	0.01±0**

*Values are arithmetic means ± SD, except for tmax: median (min-max); *: N=9; °: N=11; **: N=10*

Vitamin D3: palatability and ease of use of test evaluated by the subjects after administration under fed (T_{fed}) and fasting conditions (T_{fast}) (Safety set)

Parameter	**Evaluation**	**T_{fed} N=16**	**T_{fast} N=16**
Taste	**Very likable**	3 (18.8 %)	2 (12.5 %)
	Likable	12 (75.0 %)	13 (81.3 %)
	Neither likable nor dislikeable	1 (6.3 %)	1 (6.3 %)
	Dislikeable	0	0
	Very dislikeable	0	0
Intensity of taste	**Very mild**	0	0
	Mild	12 (75.0 %)	12 (75.0 %)
	Neither mild nor strong	4 (25.0 %)	4 (25.0 %)
	Strong	0	0
	Very strong	0	0
Aftertaste	**Yes**	12 (75.0 %)	10 (62.5 %)
	No	4 (25.0 %)	6 (37.5 %)
Mouthfeel	**Very pleasant**	1 (6.3 %)	1 (6.3 %)
	Pleasant	13 (81.3 %)	11 (68.8 %)
	Neither pleasant nor unpleasant	2 (12.5 %)	4 (25.0 %)
	Unpleasant	0	0
	Very unpleasant	0	0
Ease of use	**Very easy**	10 (62.5 %)	7 (43.8 %)
	Easy	6 (37.5 %)	8 (50.0 %)
	Neither easy nor hard	0	1 (6.3 %)
	Hard	0	0
	Too hard	0	0

Adverse events

Vitamin D3: number of subjects reporting and number of reported TEAEs by treatment, system organ class (SOC) and preferred term (PT) after single dose of three treatments: test administered under fed conditions (T_{fed}), test administered under fast conditions (T_{fast}), and reference administered under fed conditions (R_{fed}). Safety set

MedDRA description SOC and PT term	T_{fed} N=16		T_{fast} N=16		R_{fed} N=16	
	AEs n	Subjects n (%)	AEs n	Subjects n (%)	AEs n	Subjects n (%)
Total number of AEs and of subjects with at least one AE	**9**	**5 (31.3)**	**3**	**3 (18.8)**	**4**	**4 (25.0)**
Nervous system disorders	**2**	**2 (12.5)**	**2**	**2 (12.5)**	**2**	**2 (12.5)**
Headache	2	2 (12.5)	1	1 (6.3)	2	2 (12.5)
Dizziness	0	0	1	1 (6.3)	0	0
General disorders and administration site conditions	**2**	**2 (12.5)**	**1**	**1 (6.3)**	**0**	**0**
Influenza like illness	1	1 (6.3)	1	1 (6.3)	0	0
Pyrexia	1	1 (6.3)	0	0	0	0
Musculoskeletal and connective tissue disorders	**1**	**1 (6.3)**	**0**	**0**	**1**	**1 (6.3)**
Neck pain	1	1 (6.3)	0	0	0	0
Pain in extremity	0	0	0	0	1	1 (6.3)
Gastrointestinal disorders	**1**	**1 (6.3)**	**0**	**0**	**0**	**0**
Diarrhoea	1	1 (6.3)	0	0	0	0
Infections and infestations	**1**	**1 (6.3)**	**0**	**0**	**0**	**0**
Tonsillitis	1	1 (6.3)	0	0	0	0
Renal and urinary disorders	**0**	**0**	**0**	**0**	**1**	**1 (6.3)**
Proteinuria	0	0	0	0	1	1 (6.3)
Reproductive system and breast disorders	**1**	**1 (6.3)**	**0**	**0**	**0**	**0**
Dysmenorrhoea	1	1 (6.3)	0	0	0	0
Respiratory, thoracic and mediastinal disorders	**1**	**1 (6.3)**	**0**	**0**	**0**	**0**
Oropharyngeal pain	1	1 (6.3)	0	0	0	0

Vitamin D3: number of TEAEs and number of subjects with TEAEs after single dose of three treatments: test administered under fed conditions (T_{fed}), test administered under fast conditions (T_{fast}), and reference administered under fed conditions (R_{fed}). Safety set

Category	T_{fed} N=16		T_{fast} N=16		R_{fed} N=16		Overall N=48	
	N AEs	n (%) subjects	N AEs	n (%) subjects	N AEs	n (%) subjects	N AEs	n (%) subjects
All TEAEs	9	5 (31.3)	3	3 (18.8)	4	4 (25.0)	16	12 (25.0)
Related	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Not related	9	5 (31.3)	3	3 (18.8)	4	4 (25.0)	16	12 (25.0)
Leading to discontinuation	0	0 (0.0)	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)	0	0 (0.0)