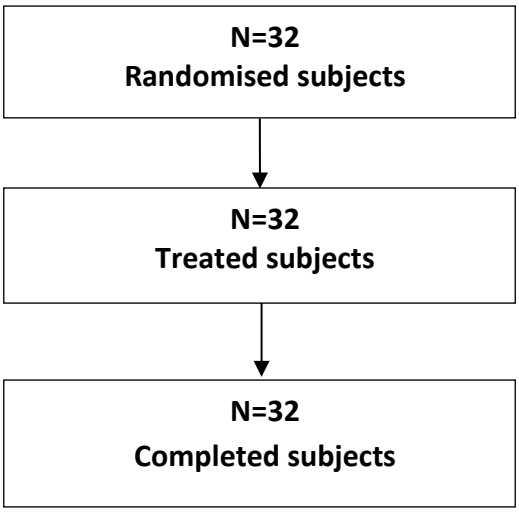
Participant flow



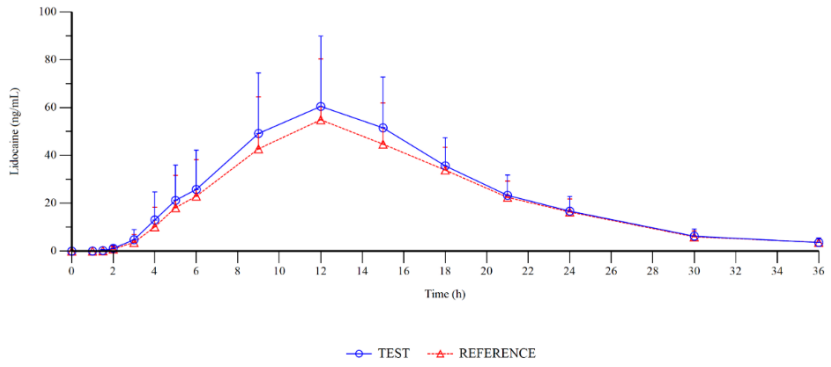
Baseline characteristics

Demographic data	**Randomised, safety, pharmacokinetic and adhesion set - N=32**
Gender	
Female – n (%)	16 (50%)
Male – n (%)	16 (50%)
Age (years)	
Mean ± SD	50.4±8.3
Median (range)	51.0 (34 – 64)
Body weight (kg)	
Mean ± SD	69.20±11.71
Range	68.65 (49.6 – 94.3)
Height (cm)	
Mean ± SD	169.3±10.9
Median (range)	170.0 (150 – 196)
BMI (kg/m^2)	
Mean ± SD	24.07±2.91
Median (range)	24.45 (18.7 – 30.0)
n (%): number and percentage of subjects are shown for qualitative measures; mean±SD are shown for quantitative measures	

Outcome measures

Pharmacokinetics results

Mean (+SD) plasma lidocaine concentrations (ng/mL) vs. time profiles after single application of test and reference plaster are shown below in linear scale (N=32):



Main plasma lidocaine pharmacokinetic parameters after single application of test and reference plaster. N = 32:

PK parameters	**Test**	**Reference**
C_{max} (ng/mL)	62.399±28.550	56.414±24.743
AUC_{0-t} (ng/mL×h)	875.119±347.193	794.964±283.739
$AUC_{0-\infty}$ (ng/mL×h)	905.172±348.789	827.353±279.592
t_{max} (h)	12 (9–18)	12 (9–18)
$t_{½}$ (h)	5.359±1.187	5.575±1.506
λ_z (1/h)	0.136±0.029	0.132±0.028

Values are arithmetic means ± SD, except for t_{max}: median (min-max)

Comparison	**Parameter**	**Point estimate (%)**	**90% confidence intervals (%)**
Test vs. reference	**AUC_{0-t}**	108.33	101.93-115.13
	$AUC_{0-\infty}$	107.44	101.22-114.03
	C_{max}	108.70	101.03-116.95

Adhesion results

Frequency of adhesion scores and of adhesion scores representing the highest degree of detachment given by the Investigator after single dose application of Test and Reference plaster on Day 3 (N=32):

Time	Score	Test n (%)	Reference n (%)
0 h	**0**	32 (100)	32 (100)
2 h	**0**	32 (100)	30 (93.8)
	1	0	2 (6.3)
4 h	**0**	32 (100)	29 (90.6)
	1	0	3 (9.4)
8 h	**0**	32 (100)	24 (75.0)
	1	0	6 (18.8)
	2	0	1 (3.1)
	3	0	1 (3.1)
12 h	**0**	29 (90.6)	19 (59.4)
	1	2 (6.3)	9 (28.1)
	2	1 (3.1)	2 (6.3)
	3	0	1 (3.1)
	4	0	1 (3.1)

n (%): number and percentage of subjects are shown, lidocaine 700 mg medicated plasters; scores: 0: ≥ 90% adhered, 1: ≥ 80% to < 90% adhered, 2: ≥ 70% to < 80% adhered, 3: ≥ 60% to < 70% adhered, 4: ≥ 50% to < 60% adhered

Presence of residual adhesive paste or cold-flow and movement, displacement or wrinkling of the plaster during the application time

On Day 3, no plaster moved or was displaced or wrinkled during the application. No cold-flow was observed. Residual adhesive paste was observed on the release liner surface only for one participant (3.1%) with the reference plaster, but it was never present on the skin after removal.

Adverse events

Number of treatment-emergent adverse events (TEAEs) and number and percentage of subjects with TEAEs by treatment, system organ class (SOC) and preferred term (PT). Safety set

MedDRA description **SOC and PT term**	**Test** **N=32**		**Reference** **N=32**	
	AEs **n**	**Subjects** **n (%)**	**AEs** **n**	**Subjects** **n (%)**
Total number of AEs and of subjects with at least one AE	**6**	**4 (12.5)**	**8**	**6 (18.8)**
General disorders and administration site conditions	**5**	**3 (9.4)**	**5**	**4 (12.5)**
Application site erythema	5	3 (9.4)	5	4 (12.5)
Investigations	**0**	**0**	**3**	**2 (6.3)**
Alanine aminotransferase increased	0	0	1	1 (3.1)
Aspartate aminotransferase increased	0	0	1	1 (3.1)
Haemoglobin decreased	0	0	1	1 (3.1)
Infections and infestations	**1**	**1 (3.1)**	**0**	**0**
Nasopharyngitis	1	1 (3.1)	0	0

AEs n – n (%): number of treatment-emergent adverse events and number and percentage of subjects with treatment-emergent adverse events are shown