

Participant flow

Consented:	182
Screen Failure/Disqualified:	17
Randomized to treatment:	165
Withdrawal/Dropped:	24
Completed:	141

Baseline characteristics

Demographics Summary All Subjects Treated					
Demographic/ Statistic or Category	Placebo (n=55)	Retinol low conc. & Pal-KTTKS (n=55)	Retinol high conc. & Pal-KTTKS (n=55)	Overall (n=165)	P-value
Age (Years)					
Mean (SD)	38.93 (13.215)	40.71 (14.381)	41.65 (14.189)	40.43 (13.899)	0.582
Min.-Max.	19 - 61	21 - 65	20 - 63	19 - 65	
Brush type					
Manual	18 (33%)	20 (36%)	19 (35%)	57 (35%)	0.923
Power	37 (67%)	35 (64%)	36 (65%)	108 (65%)	
Hand					
Left	6 (11%)	4 (7%)	3 (5%)	13 (8%)	0.557
Right	49 (89%)	51 (93%)	52 (95%)	152 (92%)	
Race					
Asian	0 (0%)	2 (4%)	0 (0%)	2 (1%)	0.130
Caucasian	54 (98%)	50 (91%)	55 (100%)	159 (96%)	
Asian Occidental	1 (2%)	2 (4%)	0 (0%)	3 (2%)	
North African	0 (0%)	1 (2%)	0 (0%)	1 (1%)	
Sex					
Female	37 (67%)	43 (78%)	43 (78%)	123 (75%)	0.317
Male	18 (33%)	12 (22%)	12 (22%)	42 (25%)	

Outcome measures

Efficacy Results Analysis of Covariance Summary Gingival Recession Evaluable Subjects					
				p-value (95% CI)	
Treatment	N	Adjusted Mean (SE)	% Reduction from Placebo	Retinol low conc. & Pal-KTTKS	Retinol high conc. & Pal-KTTKS
Month 6 (Overall Baseline Mean=1.56, Error Variance=0.152)					
Placebo	50	1.44 (0.055)		0.533 (-0.20, 0.10)	0.505 (-0.21, 0.10)
Retinol low conc. & Pal-KTTKS	52	1.49 (0.054)	-3.4%		0.961 (-0.16, 0.15)
Retinol high conc. & Pal-KTTKS	52	1.49 (0.055)	-3.6%		
Month 12 (Overall Baseline Mean=1.56, Error Variance=0.217)					
Placebo	46	1.48 (0.069)		0.705 (-0.15, 0.23)	0.456 (-0.12, 0.26)
Retinol low conc. & Pal-KTTKS	49	1.44 (0.067)	2.5%		0.712 (-0.15, 0.22)
Retinol high conc. & Pal-KTTKS	51	1.40 (0.066)	4.9%		
Month 18 (Overall Baseline Mean=1.55, Error Variance=0.238)					
Placebo	44	1.52 (0.074)		0.267 (-0.31, 0.09)	0.247 (-0.32, 0.08)
Retinol low conc. & Pal-KTTKS	49	1.63 (0.070)	-7.4%		0.946 (-0.21, 0.19)
Retinol high conc. & Pal-KTTKS	49	1.64 (0.071)	-7.9%		
Month 24 (Overall Baseline Mean=1.56, Error Variance=0.202)					
Placebo	45	1.54 (0.067)		0.076 (-0.35, 0.02)	0.568 (-0.24, 0.13)
Retinol low conc. & Pal-KTTKS	48	1.71 (0.065)	-10.8%		0.231 (-0.07, 0.30)
Retinol high conc. & Pal-KTTKS	48	1.60 (0.066)	-3.5%		

Efficacy Results Analysis of Covariance Summary Clinical Attachment Level Evaluable Subjects					
				p-value (95% CI)	
Treatment	N	Adjusted Mean (SE)	% Reduction from Placebo	Retinol low conc. & Pal-KTTKS	Retinol high conc. & Pal-KTTKS
Month 6 (Overall Baseline Mean=3.04, Error Variance=0.328)					
Placebo	50	3.07 (0.081)		0.399 (-0.32, 0.13)	0.321 (-0.34, 0.11)
Retinol low conc. & Pal-KTTKS	52	3.17 (0.080)	-3.1%		0.874 (-0.24, 0.21)
Retinol high conc. & Pal-KTTKS	52	3.19 (0.080)	-3.7%		
Month 12 (Overall Baseline Mean=3.05, Error Variance=0.375)					
Placebo	46	3.21 (0.090)		0.248 (-0.10, 0.39)	0.349 (-0.13, 0.37)
Retinol low conc. & Pal-KTTKS	49	3.07 (0.088)	4.5%		0.822 (-0.27, 0.22)
Retinol high conc. & Pal-KTTKS	51	3.10 (0.086)	3.7%		
Month 18 (Overall Baseline Mean=3.05, Error Variance=0.462)					
Placebo	44	3.33 (0.103)		0.743 (-0.33, 0.23)	0.974 (-0.28, 0.29)
Retinol low conc. & Pal-KTTKS	49	3.38 (0.097)	-1.4%		0.714 (-0.22, 0.33)
Retinol high conc. & Pal-KTTKS	49	3.33 (0.098)	0.1%		
Month 24 (Overall Baseline Mean=3.05, Error Variance=0.246)					
Placebo	45	3.34 (0.074)		0.141 (-0.36, 0.05)	0.973 (-0.20, 0.21)
Retinol low conc. & Pal-KTTKS	48	3.49 (0.072)	-4.6%		0.131 (-0.05, 0.36)
Retinol high conc. & Pal-KTTKS	48	3.34 (0.072)	0.1%		

Adverse events

Study No. 2021041								
EOT Table12 Listing of Adverse Events								
Subject	MedDRA LLT Term	Onset Date	Resolve Date	Serious (Yes/No)	Severity	Related To Treatment?	Reported/ Observed	Drop due to AE (Yes/No)
Placebo								
1101	ILL-DEFINED DISORDER	16AUG22	16AUG22	No	Mild	Doubtful	Reported by Subject	Yes
1177	TYPE I DIABETES MELLITUS	10JAN23	10JAN23	No	Moderate	Not Related	Reported by Subject	Yes
Retinol low conc. & Pal-KTTKS								
1022	HYPERAESTHESIA TEETH	09AUG22	12OCT23	No	Mild	Possible	Reported by Subject	No
1093	HYPERAESTHESIA TEETH	11OCT22	24JUN24	No	Mild	Possible	Reported by Subject	No
1159	HAIR LOSS	17AUG22	17AUG22	No	Mild	Doubtful	Reported by Subject	Yes
	GUM BLEEDING	17AUG22	17AUG22	No	Mild	Doubtful	Reported by Subject	Yes
Retinol high conc. & Pal-KTTKS								
1089	NUMBNESS GINGIVAL	04OCT22	19APR24	No	Mild	Possible	Reported by Subject	No
1135	HYPERAESTHESIA TEETH	04JAN23	24JUN24	No	Mild	Possible	Reported by Subject	No
1157	ORAL HOT FEELING	28JUL22	28JUL22	No	Mild	Possible	Reported by Subject	Yes
1166	CHEMICAL BURN OF ORAL CAVITY	08DEC22	08JUN23	No	Mild	Not Related	Observed by Examiner	No
1182	HYPERAESTHESIA TEETH	16AUG22	19JUN24	No	Mild	Possible	Reported by Subject	No