Basic result summary ISRCTN30768206

Clinical study of the safety and effectiveness of two hyaluronic acid injectable products (MaiLi Precise® and MaiLi Define®) as fillers in the treatment of lip thinness and wrinkles around the mouth – summary information	
Full study title:	Clinical study of the safety and effectiveness of use of MaiLi Precise® and MaiLi Define® in the treatment of lips and perioral area
Dates of investigation:	Start date: 10 August 2022 End date: 20 April 2024
Single identification number:	French competent authority number: 2021-A02544-37

Results of the investigation	
Participant flow:	Assessed for Eligibility N=68 Not selected N=0 (no screening failure) Included N=68 Discontinuation N=13 *Untraceable: N=11* *Refused the follow-up: N=1* *Other reasons: N=1* Completed the study up to Month 12 - N=55 *PP population - N=24* *ITT/Safety population - N=68* *Number of subjects with major deviation: N = 44*

Baseline characteristics:

	Total N=68	Group 1 (treatment with MaiLi Precise®) N=34	Group 2 (treatment with MaiLi Define®) N=34
Age :			
mean (SD)	40.76 (13.97)	48.79 (13.89)	32.74 (8.37)
min ; max	21.0 ; 65.0	22.0 ; 65.0	21.0 ; 50.0
Sex:			
Female	68 (100%)	34 (100%)	34 (100%)

Basic result summary ISRCTN30768206

Outcome measures:

Endpoints	Number (%)			
	TOTAL N=68	Group 1 (Lips) N=24	Group 1 (Perioral wrinkles) N=18	Group 2 (Lips) N=34
Primary endpoint				
GAIS responder rate (investigator evaluation) at M6	96%	/	/	/
Secondary endpoints				
GAIS responder rate (investigator evaluation):				
At M1	/	100%	100%	100%
At M6	/	95%	100%	96%
At M12	/	95%	100%	100%
GAIS responder rate (subjects' evaluation):				
At M1	/	96%	100%	100%
At M6	/	95%	100%	100%
At M12	/	86%	100%	100%
Proportion of subject with at least 1 grade of improvement on the Rossi scale (superior and/or inferior lip) from baseline (blind evaluation on photographs):				
At M1	/	26%	/	23%
At M6	/	43%	/	29%
At M12	/	33%	/	21%
Change from baseline of the Rossi scale (mean superior and inferior lip)				
At M1				
Mean ± SEM	/	0.38 ± 0.09	/	0.48 ± 0.04
95% CI	/	[0.20 ,0.56]	/	[0.40 ,0.57]
At M6				
Mean ± SEM	/	0.31 ± 0.13	/	0.33 ± 0.08
95% CI	/	[0.03 ,0.59]	/	[0.16 ,0.50]
At M12				
Mean ± SEM	/	0.24 ± 0.10	/	0.24 ± 0.08
95% CI	/	[0.03 ,0.45]	/	[0.07 ,0.41]
Proportion of subject with at least 2 grades of improvement on the Bazin upper lip scale from baseline (blind evaluation on photographs):				
At M1	/	/	35%	/
At M6	/	/	27%	/
At M12	/	/	31%	/
Change from baseline of the Bazin upper lip scale				
At M1				
Mean ± SEM	/	/	-1.29 ± 0.28	/
95% CI	/	/	[-1.89 ; -0.70]	/
At M6				
Mean ± SEM	/	/	-1.13 ± 0.38	/
95% CI	/	/	[-1.94 ; -0.33]	/
At M12				
Mean ± SEM	/	/	-1.00 ± 0.47	/
95% CI	/	/	[-2.02 ; 0.02]	/

Endpoints	Number (%)		
	Group 1 (Lips) N=24	Group 1 (Perioral wrinkles) N=18	Group 2 (Lips) N=34
GAIS investigator evaluation:			
At M1			
Very much improved	21 (88%)	16 (94%)	24 (92%)
Much improved	2 (8%)	1 (6%)	1 (4%)
Improved	1 (4%)	0 (0%)	1 (4%)
No change	0 (0%)	0 (0%)	0 (0%)
Worse	0 (0%)	0 (0%)	0 (0%)
At M6			
Very much improved	14 (67%)	13 (87%)	24 (86%)
Much improved	6 (29%)	2 (13%)	3 (11%)

Improved	0 (0%)	0 (0%)	0 (0%)
No change	1 (5%)	0 (0%)	1 (4%)
Worse	0 (0%)	0 (0%)	0 (0%)
At M12			
Very much improved	15 (68%)	12 (80%)	19 (76%)
Much improved	6 (27%)	3 (20%)	6 (24%)
Improved	0 (0%)	0 (0%)	0 (0%)
No change	1 (5%)	0 (0%)	0 (0%)
Worse	0 (0%)	0 (0%)	0 (0%)
GAIS subjects' evaluation:			
At M1			
Very much improved	17 (71%)	15 (94%)	18 (69%)
Much improved	3 (13%)	0 (0%)	8 (31%)
Improved	2 (8%)	1 (6%)	0 (0%)
No change	2 (8%)	0 (0%)	0 (0%)
Worse	0 (0%)	0 (0%)	0 (0%)
At M6			
Very much improved	12 (57%)	10 (67%)	18 (64%)
Much improved	5 (24%)	5 (33%)	10 (36%)
Improved	3 (14%)	0 (0%)	0 (0%)
No change	1 (5%)	0 (0%)	0 (0%)
Worse	0 (0%)	0 (0%)	0 (0%)
At M12			
Very much improved	6 (27%)	9 (60%)	11 (44%)
Much improved	7 (32%)	3 (20%)	10 (40%)
Improved	6 (27%)	3 (20%)	4 (16%)
No change	3 (14%)	0 (0%)	0 (0%)
Worse	0 (0%)	0 (0%)	0 (0%)

Adverse events

	Number (%)	
Summary of reported AEs	**Group 1 (treatment with MaiLi Precise®)** **N==34**	**Group 2 (treatment with MaiLi Define®)** **N=34**
Proportion of subjects:		
with at least one ADE	12 (35%)	14 (41%)
with at least one AE	12 (35%)	15 (44%)
with at least one SADE	0 (0%)	0 (0%)
with at least one SAE	0 (0%)	0 (0%)
System Organ Class (SOC) :		
General disorders and administration site conditions	12 (35%)	14 (41%)
Injury, poisoning and procedural complications	0 (0%)	1 (3%)
Nervous system disorders	0 (0%)	2 (6%)
Respiratory, thoracic and mediastinal disorders	0 (0%)	1 (3%)