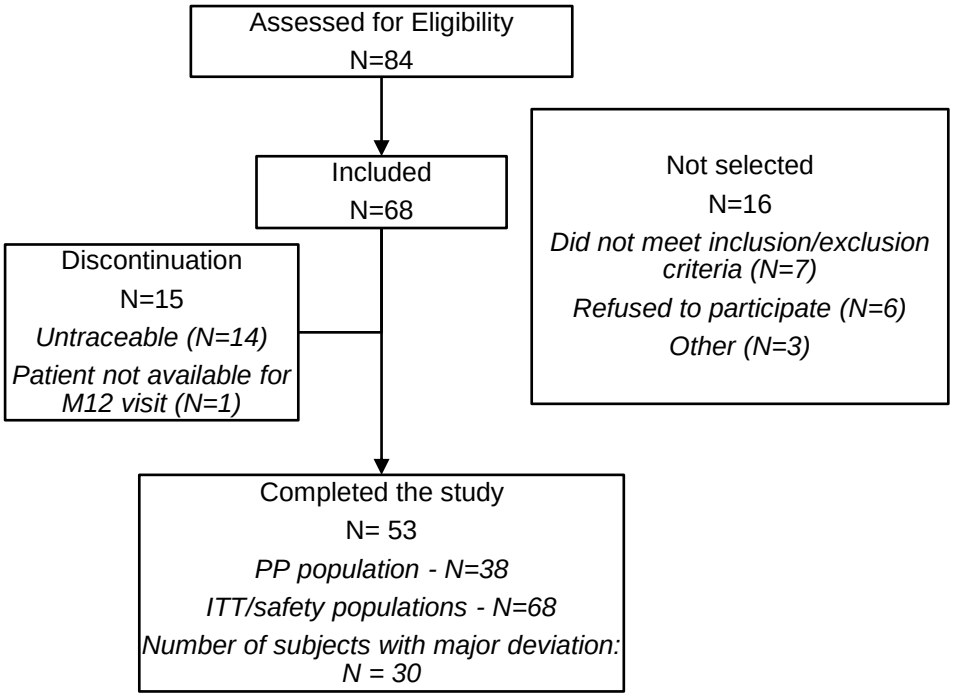
Basic result summary ISRCTN10761529

Clinical study of the safety and effectiveness of MaiLi Precise® and MaiLi Define® in the treatment of facial skin depressions – summary information	
Full study title:	**Clinical study of the safety and effectiveness of MaiLi Precise® and MaiLi Define® in the treatment of facial skin depressions**
Dates of investigation:	Start date: 18 July 2022 End date: 26 December 2023
Single identification number:	**PI_2021/151**

Results of the investigation

Participant flow:



Baseline characteristics:

	Total N=68	Group 1 (treatment with MaiLi Precise®) N=34	Group 2 (treatment with MaiLi Define®) N=34
Age :			
mean (SD)	47.8 (9.9)	43.9 (10.7)	51.8 (7.2)
min ; max	25.0 ; 64.0	25.0 ; 57.0	31.0 ; 64.0
Sex:			
Female	66 (97%)	32 (94%)	34 (100%)
Male	2 (3%)	2 (6%)	0 (0%)

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Outcome measures:

Endpoints	Number (%)				
	TOTAL N=68	Group 1 (NLFs) N=31	Group 1 (TTs) N=14	Group 2 (NLFs) N=30	Group 2 (MLs) N=22
Primary endpoint					
GAIS responder rate (investigator evaluation) at M6	45 (94%)	/	/	/	/
Secondary endpoints					
GAIS responder rate (investigator evaluation):					
At M1	/	28 (97%)	10 (83%)	27 (93%)	18 (86%)
At M6	/	24 (92%)	8 (89%)	20 (100%)	13 (100%)
At M12	/	17 (81%)	8 (80%)	22 (88%)	16 (94%)
GAIS responder rate (subjects' evaluation):					
At M1	/	25 (89%)	9 (82%)	26 (93%)	20 (100%)
At M6	/	24 (92%)	8 (89%)	18 (90%)	11 (85%)
At M12	/	14 (67%)	9 (90%)	16 (64%)	12 (71%)
Proportion of subject with at least 1 grade of improvement on the WSRS scale from baseline (blind evaluation on photographs):					
At M1	/	10 (39%)	/	16 (62%)	/
At M6	/	7 (29%)	/	9 (53%)	/
At M12	/	4 (31%)	/	10 (56%)	/

NLFs= Nasolabial folds TTs= Tear troughs MLs= Marionette lines

Endpoints	Number (%)							
	Group 1 (NLFs) N=31		Group 1 (TTs) N=14		Group 2 (NLFs) N=30		Group 2 (MLs) N=22	
	Right side	Left side	Right side	Left side	Right side	Left side	Right side	Left side
GAIS scores (investigator evaluation)								
At M1								
Very much improved	15 (52%)	15 (52%)	0 (0%)	0 (0%)	15 (52%)	14 (48%)	8 (38%)	7 (33%)
Much improved	10 (34%)	8 (28%)	6 (50%)	5 (42%)	6 (21%)	10 (34%)	4 (19%)	6 (29%)
Improved	3 (10%)	6 (21%)	4 (33%)	6 (50%)	7 (24%)	4 (14%)	7 (33%)	5 (24%)
No change	1 (3%)	0 (0%)	1 (8%)	1 (8%)	1 (3%)	1 (3%)	2 (10%)	3 (14%)
Worse	0 (0%)	0 (0%)	1 (8%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
At M6								
Very much improved	10 (38%)	9 (35%)	0 (0%)	0 (0%)	12 (60%)	9 (45%)	7 (54%)	4 (31%)
Much improved	6 (23%)	7 (27%)	2 (22%)	3 (33%)	3 (15%)	8 (40%)	3 (23%)	6 (46%)
Improved	9 (35%)	8 (31%)	6 (67%)	5 (56%)	5 (25%)	3 (15%)	3 (23%)	3 (23%)
No change	1 (4%)	2 (8%)	1 (11%)	1 (11%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Worse	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
At M12								
Very much improved	5 (24%)	4 (19%)	0 (0%)	0 (0%)	11 (44%)	7 (28%)	6 (35%)	2 (12%)
Much improved	4 (19%)	3 (14%)	1 (10%)	1 (10%)	1 (4%)	6 (24%)	3 (18%)	7 (41%)
Improved	8 (38%)	11 (52%)	8 (80%)	7 (70%)	10 (40%)	10 (40%)	7 (41%)	7 (41%)
No change	4 (19%)	3 (14%)	1 (10%)	2 (20%)	3 (12%)	2 (8%)	1 (6%)	1 (6%)
Worse	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
GAIS scores (subjects' evaluation):								
At M1								
Very much improved	6 (21%)	4 (14%)	2 (18%)	2 (18%)	13 (46%)	14 (50%)	7 (35%)	8 (40%)
Much improved	8 (29%)	10 (36%)	3 (27%)	3 (27%)	4 (14%)	3 (11%)	3 (15%)	2 (10%)
Improved	13 (46%)	12 (43%)	4 (36%)	5 (45%)	9 (32%)	9 (32%)	10 (50%)	10 (50%)
No change	0 (0%)	2 (7%)	1 (9%)	1 (9%)	2 (7%)	2 (7%)	0 (0%)	0 (0%)
Worse	1 (4%)	0 (0%)	1 (9%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
At M6								
Very much improved	9 (35%)	9 (35%)	1 (11%)	1 (11%)	8 (40%)	8 (40%)	3 (23%)	3 (23%)
Much improved	8 (31%)	6 (23%)	2 (22%)	2 (22%)	3 (15%)	3 (15%)	1 (8%)	1 (8%)
Improved	7 (27%)	9 (35%)	5 (56%)	5 (56%)	7 (35%)	7 (35%)	7 (54%)	7 (54%)

No change	2 (8%)	2 (8%)	1 (11%)	1 (11%)	2 (10%)	2 (10%)	2 (15%)	2 (15%)
Worse	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
At M12								
Very much improved	2 (10%)	1 (5%)	1 (11%)	1 (11%)	8 (32%)	8 (32%)	3 (18%)	3 (18%)
Much improved	6 (29%)	6 (29%)	2 (22%)	2 (22%)	4 (16%)	3 (12%)	2 (12%)	2 (12%)
Improved	7 (33%)	8 (38%)	5 (56%)	5 (56%)	4 (16%)	5 (20%)	7 (41%)	7 (41%)
No change	6 (29%)	6 (29%)	1 (11%)	1 (11%)	8 (32%)	9 (36%)	4 (24%)	4 (24%)
Worse	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)	0 (0%)	1 (6%)	1 (6%)

NLFs= Nasolabial folds TTs= Tear troughs MLs= Marionette lines

Adverse events

Summary of reported AEs	Number (%) Group 1 (treatment with MaiLi Precise®) N==34	Number (%) Group 2 (treatment with MaiLi Define®) N=34
Proportion of subjects:		
with at least one ADE	11 (32%)	11 (32%)
with at least one AE	17 (50%)	14 (41%)
with at least one SADE	0 (0%)	0 (0%)
with at least one SAE	1 (3%)	0 (0%)
System Organ Class (SOC) :		
Gastrointestinal disorders	1 (3%)	0 (0%)
General disorders and administration site conditions	18 (55%)	21 (84%)
Infections and infestations	2 (6%)	1 (4%)
Injury, poisoning and procedural complications	1 (3%)	0 (0%)
Musculoskeletal and connective tissue disorders	4 (12%)	2 (8%)
Nervous system disorders	4 (12%)	0 (0%)
Psychiatric disorders	1 (3%)	1 (4%)
Respiratory, thoracic and mediastinal disorders	1 (3%)	0 (0%)
Surgical and medical procedures	1 (3%)	0 (0%)