Basic result summary ISRCTN20356582

CLINICAL STUDY FOR THE SAFETY AND EFFECTIVENESS OF USE OF PERFECTHA® DERM LIDOCAINE IN THE TREATMENT OF MEDIUM LINES AND DEPRESSIONS – summary information	
Full study title:	**CLINICAL STUDY FOR THE SAFETY AND EFFECTIVENESS OF USE OF PERFECTHA® DERM LIDOCAINE IN THE TREATMENT OF MEDIUM LINES AND DEPRESSIONS**
Dates of investigation:	Start date: 16 November 2022 End date: 08 November 2023
Single identification number:	**2022-A01654-39**
Results of the investigation	
Participant flow:	

Participant flow diagram:

- Screened* N = 94
  - Screening failure N = 16
- Selected** N = 78
  - Selected but not included N = 8
- Randomized*** N = 70
  - Dropped-Out subjects N = 2
    - S50036 / R-028 (Dropped out subject – Subject is untraceable since 28 December 2022)
    - S50068 / R-065 (Last visit not done)
- Completed the study N=68

Basic result summary ISRCTN20356582

Baseline characteristics:

	Global N=70	NLF N=63	ML N=56
Sex:			
Female	63 (90.0%)	57 (90.5%)	49 (87.5%)
Male	7 (10.0%)	6 (9.5%)	7 (12.5%)
Age (years)	50.13 (8.01)	49.38 (7.91)	52.04 (6.94)
Origin (White)	70 (100.0%)	63 (100.0%)	56 (100.0%)
Phototype:			
II	24 (34.3%)	22 (34.9%)	20 (35.7%)
III	35 (50.0%)	30 (47.6%)	26 (46.4%)
IV	11 (15.7%)	11 (17.5%)	10 (17.9%)
NLF= Nasolabial folds			
ML= Marionette lines			

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<table>
<tr><td rowspan="3">Outcome measures:</td><td rowspan="3"></td><td rowspan="2">Endpoints</td><td colspan="3" align="center">Number (%)</td></tr>
<tr><td>Global
N=70</td><td>NLF
N=63</td><td>ML
N=56</td></tr>
<tr><td colspan="4">

Primary endpoint

Endpoint	Global N=70	NLF N=63	ML N=56
GAIS responder rate (investigator evaluation) at M3	67 (97.10%)	/	/

Secondary endpoints
GAIS responder rate (investigator evaluation):

	Global	NLF N=63	ML N=56
At M1 (before touch-up)	/	61 (100.00%)	53 (98.15%)
At M3	/	62 (100.00%)	53 (96.36%)
At M6	/	58 (98.31%)	51 (94.44%)
At M9	/	60 (98.36%)	49 (90.74%)

GAIS responder rate (subjects' evaluation):

	NLF	ML
At M1 (before touch-up)	56 (91.80%)	50 (94.34%)
At M3	59 (95.16%)	52 (94.55%)
At M6	59 (98.33%)	52 (96.30%)
At M9	58 (95.08%)	50 (94.34%)

Proportion of subject with at least 1 WSRS grade of improvement from baseline (investigator live evaluation):

	Global	NLF	ML
At M1 (before touch-up)	/	27 (44%)	/
At M3	/	33 (53%)	/
At M6	/	31 (53%)	/
At M9	/	31 (51%)	/

Proportion of subject with at least 1 WSRS grade of improvement from baseline (blind evaluation on photographs):

	Global	NLF	ML
At M1 (before touch-up)	/	20 (32.8%)	/
At M3	/	22 (35.5%)	/
At M6	/	16 (28.1%)	/
At M9	/	15 (24.6%)	/

Proportion of subject with at least 1 MLGS grade of improvement from baseline (investigator live evaluation):

	Global	NLF	ML
At M1 (before touch-up)	/	/	29 (54%)
At M3	/	/	31 (56%)
At M6	/	/	29 (54%)
At M9	/	/	27 (51%)

Proportion of subject with at least 1 MLGS grade of improvement from baseline (blind evaluation on photographs):

	Global	NLF	ML
At M1 (before touch-up)	/	/	5 (9.3%)
At M3	/	/	7 (12.7%)
At M6	/	/	2 (3.7%)
At M9	/	/	2 (3.7%)

NLF= Nasolabial folds

ML= Marionette lines

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</table>

Basic result summary ISRCTN20356582

Endpoints	Number (%)			
	NLF N=63		ML N=56	
	Left side	Right side	Left side	Right side
GAIS scores (investigator evaluation)				
At M1 (before touch-up)				
Very much improved	24 (39.34%)	22 (36.07%)	19 (35.19%)	18 (33.33%)
Much improved	20 (32.79%)	25 (40.98%)	17 (31.48%)	14 (25.93%)
Improved	17 (27.87%)	14 (22.95%)	17 (31.48%)	21 (38.89%)
No change	0 (0.00%)	0 (0.00%)	1 (1.85%)	1 (1.85%)
Worse	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
At M3				
Very much improved	35 (56.45%)	33 (53.23%)	29 (52.73%)	26 (47.27%)
Much improved	21 (33.87%)	23 (37.10%)	14 (25.45%)	15 (27.27%)
Improved	6 (9.68%)	6 (9.68%)	10 (18.18%)	13 (23.64%)
No change	0 (0.00%)	0 (0.00%)	2 (3.64%)	1 (1.82%)
Worse	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
At M6				
Very much improved	25 (42.37%)	30 (50.85%)	20 (37.04%)	19 (35.19%)
Much improved	22 (37.29%)	20 (33.90%)	13 (24.07%)	14 (25.93%)
Improved	12 (20.34%)	8 (13.56%)	18 (33.33%)	20 (37.04%)
No change	0 (0.00%)	1 (1.69%)	3 (5.56%)	1 (1.85%)
Worse	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
At M9				
Very much improved	25 (40.98%)	28 (45.90%)	18 (33.33%)	22 (40.74%)
Much improved	18 (29.51%)	19 (31.15%)	12 (22.22%)	11 (20.37%)
Improved	17 (27.87%)	13 (21.31%)	19 (35.19%)	18 (33.33%)
No change	1 (1.64%)	1 (1.64%)	4 (7.41%)	3 (5.56%)
Worse	0 (0.00%)	0 (0.00%)	1 (1.85%)	0 (0.00%)
GAIS scores (subjects' evaluation):				
At M1 (before touch-up)				
Very much improved	25 (40.98%)	30 (49.18%)	20 (37.04%)	22 (41.51%)
Much improved	18 (29.51%)	16 (26.23%)	24 (44.44%)	23 (43.40%)
Improved	14 (22.95%)	13 (21.31%)	7 (12.96%)	7 (13.21%)
No change	3 (4.92%)	2 (3.28%)	2 (3.70%)	1 (1.89%)
Worse	1 (1.64%)	0 (0.00%)	1 (1.85%)	0 (0.00%)
At M3				
Very much improved	28 (45.16%)	31 (50.00%)	18 (32.73%)	25 (45.45%)
Much improved	20 (32.26%)	18 (29.03%)	21 (38.18%)	20 (36.36%)
Improved	11 (17.74%)	11 (17.74%)	14 (25.45%)	8 (14.55%)
No change	3 (4.84%)	2 (3.23%)	2 (3.64%)	2 (3.64%)
Worse	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
At M6				
Very much improved	28 (46.67%)	32 (53.33%)	17 (31.48%)	22 (40.74%)
Much improved	24 (40.00%)	23 (38.33%)	25 (46.30%)	23 (42.59%)
Improved	7 (11.67%)	4 (6.67%)	10 (18.52%)	7 (12.96%)
No change	1 (1.67%)	1 (1.67%)	2 (3.70%)	2 (3.70%)
Worse	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
At M9				
Very much improved	20 (32.79%)	29 (47.54%)	15 (27.78%)	22 (41.51%)
Much improved	28 (45.90%)	24 (39.34%)	20 (37.04%)	19 (35.85%)
Improved	10 (16.39%)	6 (9.84%)	15 (27.78%)	12 (22.64%)
No change	3 (4.92%)	2 (3.28%)	4 (7.41%)	0 (0.00%)
Worse	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
NLF= Nasolabial folds				
ML= Marionette lines				

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<table>
<tr><td rowspan="2">Adverse events</td><td rowspan="2"></td><td rowspan="2">Summary of reported AEs</td><td>Number (%)</td><td rowspan="2"></td></tr>
<tr><td>Global
N=70</td></tr>
<tr><td></td><td></td><td>Proportion of subjects:</td><td></td><td></td></tr>
<tr><td></td><td></td><td>with at least one ADE</td><td>20 (29%)</td><td></td></tr>
<tr><td></td><td></td><td>with at least one AE</td><td>44 (63%)</td><td></td></tr>
<tr><td></td><td></td><td>with at least one SADE</td><td>0 (0%)</td><td></td></tr>
<tr><td></td><td></td><td>with at least one SAE</td><td>0 (0%)</td><td></td></tr>
<tr><td></td><td></td><td>System Organ Class (SOC) :</td><td></td><td></td></tr>
<tr><td></td><td></td><td>Eye disorders</td><td>1 (1%)</td><td></td></tr>
<tr><td></td><td></td><td>Gastrointestinal disorders</td><td>2 (3%)</td><td></td></tr>
<tr><td></td><td></td><td>General disorders and administration site conditions</td><td>23 (33%)</td><td></td></tr>
<tr><td></td><td></td><td>Immune system disorders</td><td>1 (1%)</td><td></td></tr>
<tr><td></td><td></td><td>Infections and infestations</td><td>17 (24%)</td><td></td></tr>
<tr><td></td><td></td><td>Injury, poisoning and procedural complications</td><td>2 (3%)</td><td></td></tr>
<tr><td></td><td></td><td>Musculoskeletal and connective tissue disorders</td><td>4 (6%)</td><td></td></tr>
<tr><td></td><td></td><td>Nervous system disorders</td><td>15 (21%)</td><td></td></tr>
<tr><td></td><td></td><td>Reproductive system and breast disorders</td><td>2 (3%)</td><td></td></tr>
<tr><td></td><td></td><td>Respiratory, thoracic and mediastinal disorders</td><td>2 (3%)</td><td></td></tr>
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