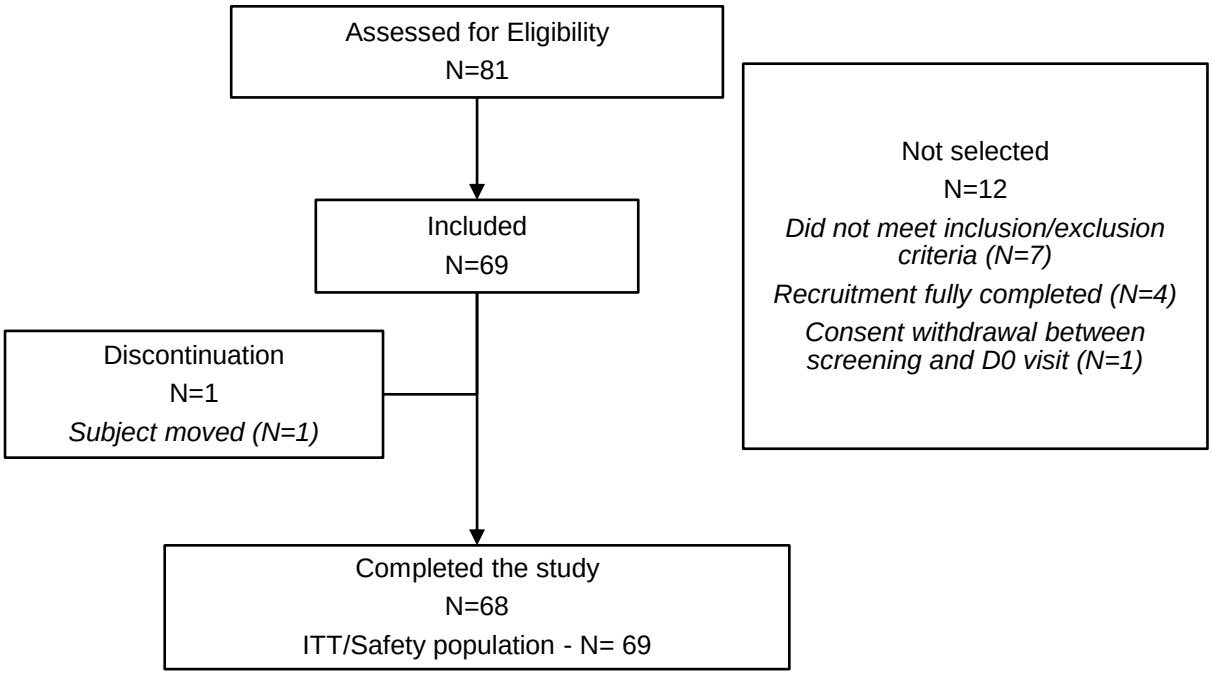
Basic result summary ISRCTN16392182

Clinical study of the safety and effectiveness of the use of a hyaluronic acid injectable product (Perfectha® Finelines Lidocaine) in the treatment of wrinkles around the eyes and mouth – summary information	
Full study title:	**Assessment of the safety and effectiveness of use of Perfectha® Finelines Lidocaine in the treatment of the periorbital and perioral wrinkles and tear troughs**
Dates of investigation:	Start date: 23 February 2023 End date: 25 March 2024
Single identification number:	French competent authority number: 2022-A01776-37

Results of the investigation

Participant flow:



Baseline characteristics:

	Total N=69	Treatment in periorbital lines (PLs) N=48	Treatment in tear troughs (TTs) N=34	Treatment in upper lip wrinkles (ULWs) N=32
Age :				
mean (SD)	52.7 (9.1)	53.4 (8.9)	48.9 (9.3)	56.7 (6.7)
min ; max	29.0 ; 65.0	32.0 ; 65.0	29.0 ; 65.0	42.0 ; 65.0
Sex:				
Female	63 (91%)	43 (90%)	32 (94%)	32 (100%)
Male	6 (9%)	5 (10%)	2 (6%)	0 (0%)

Outcome measures:

Endpoints	Number (%)			
	TOTAL N=69	Treatment in tear troughs (TTs) N=34	Treatment in periorbital lines (PLs) N=48	Treatment in upper lip wrinkles (ULWs) N=32
Primary endpoint				
GAIS responder rate (investigator evaluation) at M3				
% responder	93%	91%	88%	91%
95% CI	[84.1% ,96.9%]	[77.0% ,97.0%]	[75.3% ,94.1%]	[75.8% ,96.8%]

Endpoints	Number (%)		
	Treatment in tear troughs (TTs) N=34	Treatment in periorbital lines (PLs) N=48	Treatment in upper lip wrinkles (ULWs) N=32
Secondary endpoints			
GAIS responder rate (investigator evaluation):			
At M1			
% responder	91%	89%	87%
95% CI	[77.0% ,97.0%]	[77.4% ,95.4%]	[71.1% ,94.9%]
At M6			
% responder	85%	85%	94%
95% CI	[69.9% ,93.6%]	[72.3% ,92.6%]	[79.3% ,98.2%]
At M9			
% responder	82%	68%	87%
95% CI	[66.5% ,91.7%]	[53.8% ,79.6%]	[71.1% ,94.9%]
GAIS responder rate (subjects' evaluation):			
At M1			
% responder	74%	79%	81%
95% CI	[56.9% ,85.4%]	[65.1% ,88.0%]	[63.7% ,90.8%]
At M3			
% responder	85%	83%	69%
95% CI	[69.1% ,93.3%]	[70.4% ,91.3%]	[51.4% ,82.0%]
At M6			
% responder	68%	81%	61%
95% CI	[50.8% ,80.9%]	[67.5% ,89.6%]	[43.8% ,76.3%]
At M9			
% responder	53%	70%	58%
95% CI	[36.7% ,68.5%]	[56.0% ,81.3%]	[40.8% ,73.6%]

Endpoints	Number (%)
	Treatment in tear troughs (TTs) N=34
Secondary endpoints	
Proportion of subject with at least 1 grade of improvement on the Barton scale from baseline (blind evaluation on photographs):	
At M1	
% responder	11.8%
95% CI	[4.7% ,26.6%]
At M3	
% responder	14.7%
95% CI	[6.4% ,30.1%]
At M6	
% responder	20.6%
95% CI	[10.3% ,36.8%]
At M9	

% responder	15.2%
95% CI	[6.7% ,30.9%]
Change from baseline of the Barton scale	
At M1	
mean (SD)	0.18 (0.75)
median	0.25
At M3	
mean (SD)	0.13 (0.84)
median	0.00
At M6	
mean (SD)	-0.18 (0.78)
median	0.00
At M9	
mean (SD)	-0.23 (0.64)
median	0.00

Endpoints	**Number (%)** **Treatment in periorbital lines (PLs)** **N=48**
Secondary endpoints	
Proportion of subject with at least 1 grade of improvement on the Lemperle scale from baseline (blind evaluation on photographs):	
At M1	
% responder	15.9%
95% CI	[7.9% ,29.4%]
At M3	
% responder	15.2%
95% CI	[7.6% ,28.2%]
At M6	
% responder	20.0%
95% CI	[10.9% ,33.8%]
At M9	
% responder	17.4%
95% CI	[9.1% ,30.7%]
Change from baseline of the Lemperle scale	
At M1	
mean (SD)	0.17 (1.47)
median	0.00
At M3	
mean (SD)	0.41 (1.60)
median	0.00
At M6	
mean (SD)	0.07 (1.26)
median	0.00
At M9	
mean (SD)	-0.20 (0.67)
median	0.00

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Endpoints	Number (%) Treatment in upper lip wrinkles (ULWs) N=32
Secondary endpoints	
Proportion of subject with at least 2 grades of improvement on the Bazin scale from baseline (blind evaluation on photographs):	
At M1	
% responder	34.8%
95% CI	[18.8% ,55.1%]
At M3	
% responder	38.5%
95% CI	[22.4% ,57.5%]
At M6	
% responder	28.6%
95% CI	[15.3% ,47.1%]
At M9	
% responder	32.1%
95% CI	[17.9% ,50.7%]
Change from baseline of the Bazin scale	
At M1	
mean (SD)	-1.17 (1.19)
median	-1.00
At M3	
mean (SD)	-1.23 (1.39)
median	-1.00
At M6	
mean (SD)	-1.00 (1.19)
median	-1.00
At M9	
mean (SD)	-0.82 (1.28)
median	-1.00

Adverse events

Summary of reported AEs	Number (%)
Proportion of subjects:	
with at least one ADE	39/69 (57%)
with at least one AE	44/69 (64%)
with at least one SADE	0/69 (0%)
with at least one SAE	0/69 (0%)
System Organ Class (SOC) :	
Eye disorders	2/69 (3%)
Gastrointestinal disorders	1/69 (1%)
General disorders and administration site condition	39/69 (57%)
Infections and infestations	8/69 (12%)
Injury, poisoning and procedural complications	2/69 (3%)
Investigations	1/69 (1%)
Musculoskeletal and connective tissue disorders	1/69 (1%)
Nervous system disorders	6/69 (9%)
Respiratory, thoracic and mediastinal disorders	1/69 (1%)
Skin and subcutaneous tissue disorders	2/69 (3%)