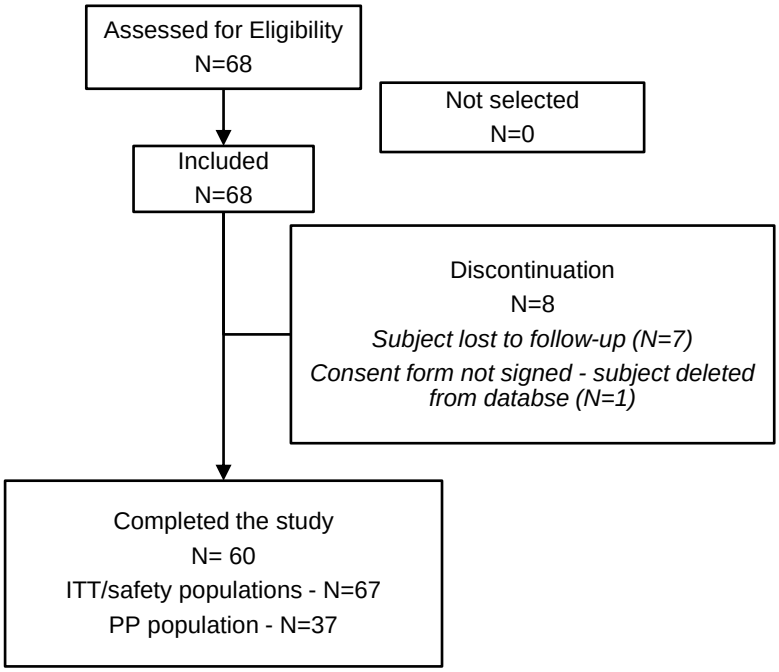
Basic result summary ISRCTN72858148

Clinical study to evaluate the safety and effectiveness of the use of two hyaluronic acid injectable products (Perfectha® Derm Lidocaine and Perfectha® Deep Lidocaine) in the treatment of lips – summary information	
Full study title:	**Assessment of the safety and effectiveness of use of Perfectha® Derm Lidocaine and Perfectha® Deep Lidocaine in the treatment of lips**
Dates of investigation:	Start date: 20 November 2022 End date: 24 April 2024
Single identification number:	French competent authority number: 2022-A01589-34

Results of the investigation

Participant flow:



Baseline characteristics:

	Group 1 (treatment with Perfectha® Derm Lidocaine) N=34	Group 2 (treatment with Perfectha® Deep Lidocaine) N=33
Age :		
mean (SD)	50.56 (13.83)	43.55 (11.82)
min ; max	25.0 ; 71.0	24.0 ; 65.0
Sex:		
Female	32 (94.1%)	33 (100.0%)
Male	2 (5.9%)	0 (0.0%)

Outcome measures:

Endpoints	Number (%)		
	TOTAL N=67	Group 1 (treatment with Perfectha® Derm Lidocaine) N=34	Group 2 (treatment with Perfectha® Deep Lidocaine) N=33
Primary endpoint			
GAIS responder rate (investigator evaluation) at M3			
% responder	91%	97%	85%
95% CI	[81.4% ,96.3%]	[83.8% ,99.4%]	[67.5% ,94.1%]

Endpoints	Number (%)		
	Group 1 (treatment with Perfectha® Derm Lidocaine) N=34	Group 2 (treatment with Perfectha® Deep Lidocaine) N=33	TOTAL N=67
Secondary endpoints			
GAIS responder rate (investigator evaluation):			
At M1			
% responder	97%	90%	94%
95% CI	[84.3% ,99.4%]	[75.1% ,96.7%]	[84.8% ,97.5%]
At M6			
% responder	94%	90%	92%
95% CI	[79.9% ,98.3%]	[73.6% ,96.4%]	[82.2% ,96.4%]
At M9			
% responder	87%	83%	85%
95% CI	[70.3% ,94.7%]	[66.4% ,92.7%]	[73.9% ,91.9%]
GAIS responder rate (subjects' evaluation):			
At M1			
% responder	100%	92%	96%
95% CI	[87.5% ,100.0%]	[75.0% ,97.8%]	[87.0% ,98.9%]
At M3			
% responder	97%	100%	98%
95% CI	[82.8% ,99.4%]	[84.5% ,100.0%]	[89.5% ,99.6%]
At M6			
% responder	97%	92%	94%
95% CI	[82.8% ,99.4%]	[75.0% ,97.8%]	[84.9% ,98.1%]
At M9			
% responder	90%	85%	88%
95% CI	[73.6% ,96.4%]	[67.5% ,94.1%]	[76.4% ,93.8%]

Endpoints	Number (%)	
	Group 1 (treatment with Perfectha® Derm Lidocaine) N=34	Group 2 (treatment with Perfectha® Deep Lidocaine) N=33
Secondary endpoints		
Proportion of subject with at least 1 grade of improvement in superior and/or inferior lip from baseline on the Rossi scale (blind evaluation on photographs):		
At M1		
% responder	37.9%	53.6%
95% CI	[22.7% ,56.0%]	[35.8% ,70.5%]
At M3		
% responder	29.6%	21.7%
95% CI	[15.9% ,48.5%]	[9.7% ,41.9%]
At M6		
% responder	20.7%	18.5%
95% CI	[9.8% ,38.4%]	[8.2% ,36.7%]
At M9		
% responder	11.5%	4.0%
95% CI	[4.0% ,29.0%]	[0.7% ,19.5%]

		Change from baseline of the Rossi scale:		
		At M1		
		mean (SD)	0.47 (0.42)	0.52 (0.44)
		median	0.50	0.50
		At M3		
		mean (SD)	0.35 (0.41)	0.27 (0.41)
		median	0.50	0.25
		At M6		
		mean (SD)	0.27 (0.34)	0.19 (0.32)
		median	0.25	0.00
		At M9		
		mean (SD)	0.23 (0.28)	0.13 (0.24)
		median	0.25	0.25

Endpoints		Number (%) Group 1 (treatment with Perfectha® Derm Lidocaine) N=34
Secondary endpoints		
Proportion of subject with at least 1 grade of improvement on the Draelos scale from baseline (blind evaluation on photographs):		
At M1		
	% responder	42.9%
	95% CI	[26.5% ,60.9%]
At M3		
	% responder	34.8%
	95% CI	[18.8% ,55.1%]
At M6		
	% responder	39.3%
	95% CI	[23.6% ,57.6%]
At M9		
	% responder	40.0%
	95% CI	[23.4% ,59.3%]
Change from baseline on the Draelos scale:		
At M1		
	mean (SD)	-0.36 (0.87)
	median	0.00
At M3		
	mean (SD)	-0.22 (0.80)
	median	0.00
At M6		
	mean (SD)	-0.25 (0.75)
	median	0.00
At M9		
	mean (SD)	-0.28 (0.68)
	median	0.00

Adverse events

Summary of reported AEs		Number (%) Group 1 (treatment with Perfectha® Derm Lidocaine) N=34	Group 2 (treatment with Perfectha® Deep Lidocaine) N=33
Proportion of subjects:			
	with at least one ADE	18/34 (53%)	17/33 (52%)
	with at least one AE	20/34 (59%)	20/33 (61%)
	with at least one SADE	0/34 (0%)	0/33 (0%)

		with at least one SAE	1/34 (3%)	1/33 (3%)	
		System Organ Class (SOC) :			
		Gastrointestinal disorders	0/34 (0%)	1/33 (3%)	
		General disorders and administration site conditions	18/34 (53%)	16/33 (48%)	
		Infections and infestations	0/34 (0%)	3/33 (9%)	
		Injury, poisoning and procedural complications	1/34 (3%)	0/33 (0%)	
		Musculoskeletal and connective tissue disorders	0/34 (0%)	1/33 (3%)	
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1/34 (3%)	0/33 (0%)	
		Nervous system disorders	2/34 (6%)	2/33 (6%)	
		Skin and subcutaneous tissue disorders	0/34 (0%)	1/33 (3%)	