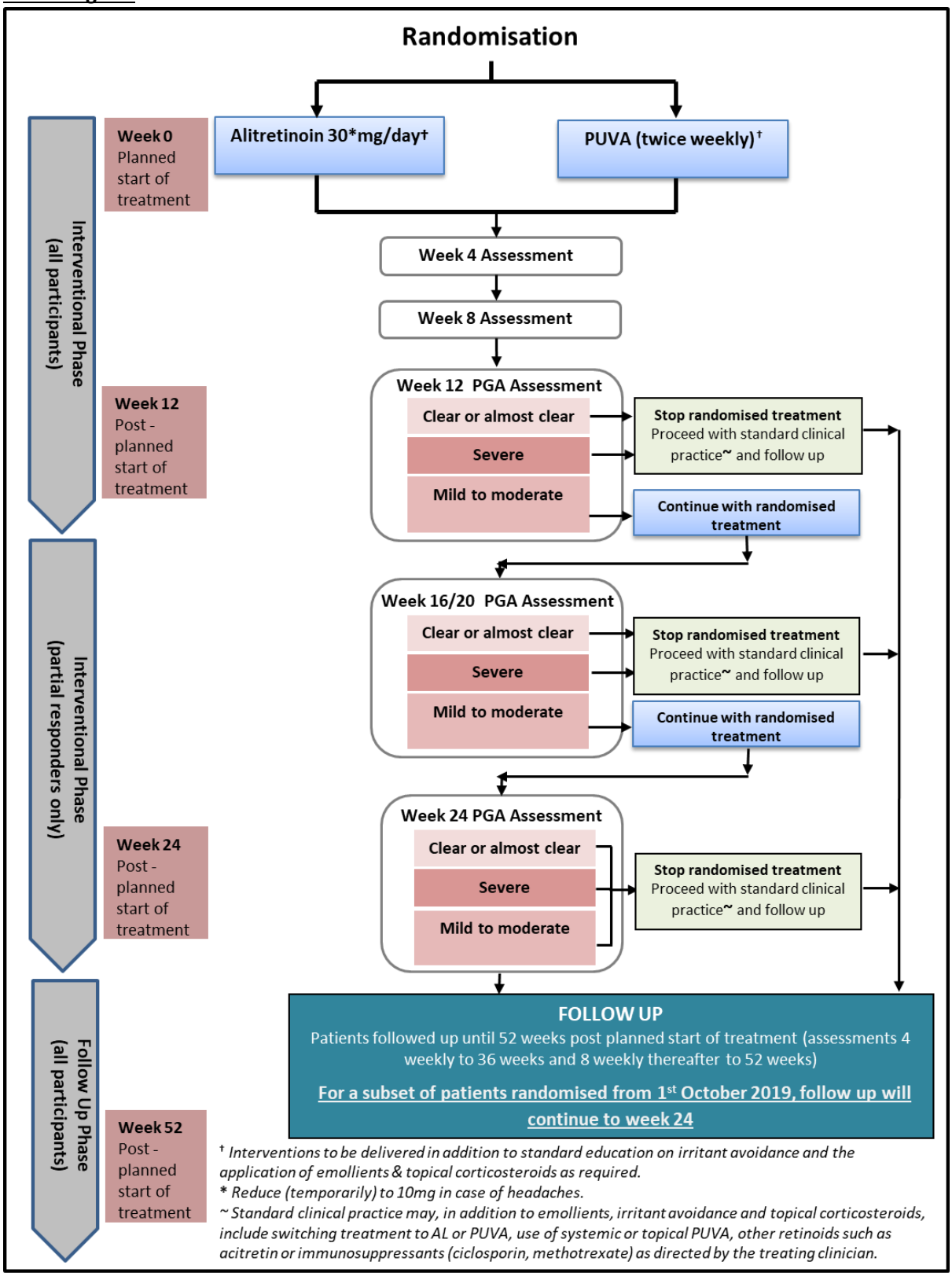
ALPHA
Comparing treatments for severe chronic hand eczema

Flow Diagram



† *Interventions to be delivered in addition to standard education on irritant avoidance and the application of emollients & topical corticosteroids as required.*

* *Reduce (temporarily) to 10mg in case of headaches.*

~ *Standard clinical practice may, in addition to emollients, irritant avoidance and topical corticosteroids, include switching treatment to AL or PUVA, use of systemic or topical PUVA, other retinoids such as acitretin or immunosuppressants (ciclosporin, methotrexate) as directed by the treating clinician.*

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Baseline characteristics

	Alitretinoin	Immersion PUVA	Total
Age (years)			
Mean (s.d.)	46.5 (14.9)	45.1 (15.2)	45.8 (15.1)
Median (range)	47.7 (20, 81)	44.6 (18, 79)	46.0 (18, 81)
IQR	33.5, 58.7	31.9, 56.8	32.9, 58.0
Missing	0	0	0
N	220	221	441
Gender			
Male	85 (38.6%)	77 (34.8%)	162 (36.7%)
Female	132 (60.0%)	141 (63.8%)	273 (61.9%)
Missing	3 (1.4%)	3 (1.4%)	6 (1.4%)
Total	220 (100%)	221 (100%)	441 (100%)
BMI (kg/m)			
Mean (s.d.)	30.1 (6.6)	28.9 (5.8)	29.5 (6.2)
Median (range)	29.3 (18, 69)	28.5 (17, 50)	28.7 (17, 69)
IQR	25.5, 34.0	24.9, 32.3	25.2, 33.2
Missing	9	8	17
N	211	213	424
Participant's smoking status			
Non smoking	89 (40.5%)	85 (38.5%)	174 (39.5%)
Past smoker	79 (35.9%)	93 (42.1%)	172 (39.0%)
Current smoker	52 (23.6%)	42 (19.0%)	94 (21.3%)
Missing	0 (0.0%)	1 (0.5%)	1 (0.2%)
Total	220 (100%)	221 (100%)	441 (100%)
Are the feet involved as well?			
Yes	57 (25.9%)	60 (27.1%)	117 (26.5%)
No	163 (74.1%)	160 (72.4%)	323 (73.2%)
Missing	0 (0.0%)	1 (0.5%)	1 (0.2%)
Total	220 (100%)	221 (100%)	441 (100%)
Filaggrin loss-of-function mutation			
No mutation	141 (64.1%)	126 (57.0%)	267 (60.5%)
Mutation	27 (12.3%)	24 (10.9%)	51 (11.6%)
Samples taken but mutation status could not be determined	0 (0.0%)	2 (0.9%)	2 (0.5%)
No sample available for analysis	52 (23.6%)	69 (31.2%)	121 (27.4%)
Skin type			
White	193 (87.7%)	199 (90.0%)	392 (88.9%)
Fair	5 (2.3%)	2 (0.9%)	7 (1.6%)
Dark	22 (10.0%)	20 (9.0%)	42 (9.5%)
Total	220 (100%)	221 (100%)	441 (100%)
Duration of disease			
Less than 6 months	6 (2.7%)	4 (1.8%)	10 (2.3%)
6 - 24 months	57 (25.9%)	63 (28.5%)	120 (27.2%)
Greater than 24 months	157 (71.4%)	154 (69.7%)	311 (70.5%)
Total	220 (100%)	221 (100%)	441 (100%)
Clinical Phenotype			
Predominantly hyperkeratotic	143 (65.0%)	143 (64.7%)	286 (64.9%)
Predominantly vesicular	62 (28.2%)	62 (28.1%)	124 (28.1%)
Fingertip dermatitis	15 (6.8%)	16 (7.2%)	31 (7.0%)
Total	220 (100%)	221 (100%)	441 (100%)

	Alitretinoin	Immersion PUVA	Total
Presence of specific IgE			
Yes	114 (51.8%)	113 (51.1%)	227 (51.5%)
No	106 (48.2%)	107 (48.4%)	213 (48.3%)
Missing	0 (0.0%)	1 (0.5%)	1 (0.2%)
Total	220 (100%)	221 (100%)	441 (100%)
Baseline DLQI (Categorised)[a]			
Less than 15	121 (55.0%)	129 (58.4%)	250 (56.7%)
Greater than or equal to 15	99 (45.0%)	92 (41.6%)	191 (43.3%)
Total	220 (100%)	221 (100%)	441 (100%)
Baseline DLQI (Continuous)			
Mean (s.d.)	13.9 (6.8)	13.6 (6.0)	13.8 (6.4)
Median (range)	13.0 (2, 30)	13.0 (2, 30)	13.0 (2, 30)
IQR	8.0, 20.0	9.0, 17.0	9.0, 18.0
Missing	1	2	3
N	219	219	438

Primary outcome measure – disease activity of the index hand, quantified using the HECSI tool, at 12 weeks post planned start of treatment

	Alitretinoin	Immersion PUVA	Total
Baseline			
Mean (s.d.)	68.2 (47.5)	62.2 (42.0)	65.2 (44.9)
Coefficient of variation	0.7	0.7	0.7
Median (range)	57.0 (2, 243)	52.5 (2, 206)	55.0 (2, 243)
IQR	34.0, 97.0	30.0, 86.0	31.5, 91.0
Missing	6	7	13
N	214	214	428
12 weeks			
Mean (s.d.)	30.4 (33.5)	35.8 (38.4)	32.9 (35.9)
Coefficient of variation	1.1	1.1	1.1
Median (range)	19.0 (0, 196)	25.0 (0, 230)	20.0 (0, 230)
IQR	6.0, 44.0	8.0, 53.0	7.0, 44.0
Missing	51	74	125
N	169	147	316

Safety

Reportable adverse events

	Alitretinoin	Immersion PUVA	Total
Participant received any randomised treatment			
Yes	96 (89.7%)	26 (92.9%)	122 (90.4%)
No	9 (8.4%)	2 (7.1%)	11 (8.1%)
Missing	2 (1.9%)	0 (0.0%)	2 (1.5%)
Total	107 (100%)	28 (100%)	135 (100%)
Intensity Grade			
Mild	67 (62.6%)	11 (39.3%)	78 (57.8%)
Moderate	33 (30.8%)	9 (32.1%)	42 (31.1%)

	Alitretinoin	Immersion PUVA	Total
Severe	7 (6.5%)	8 (28.6%)	15 (11.1%)
Life-threatening	0 (0.0%)	0 (0.0%)	0 (0.0%)
Total	107 (100%)	28 (100%)	135 (100%)
Does the event meet the criteria of an SAE			
Yes	2 (1.9%)	2 (7.1%)	4 (3.0%)
No	105 (98.1%)	26 (92.9%)	131 (97.0%)
Total	107 (100%)	28 (100%)	135 (100%)
Action taken			
None	67 (62.6%)	10 (35.7%)	77 (57.0%)
Delayed, modified or stopped	14 (13.1%)	9 (32.1%)	23 (17.0%)
Permanently stopped	26 (24.3%)	9 (32.1%)	35 (25.9%)
Total	107 (100%)	28 (100%)	135 (100%)