Clinical trial results:
A phase 3 clinical trial to evaluate efficacy and safety of twice daily applications of delgocitinib cream 20 mg/g compared with cream vehicle for a 16-week treatment period in adolescents 12-17 years of age with moderate to severe chronic hand eczema

Summary

EudraCT number	2021-006340-27
Trial protocol	FR ES BE PL
Global end of trial date	17 December 2024

Results information

Result version number	v1 (current)
This version publication date	03 July 2025
First version publication date	03 July 2025

Trial information

Trial identification

Sponsor protocol code	LP0133-1426

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT05355818
WHO universal trial number (UTN)	U1111-1284-2122

Notes:

Sponsors

Sponsor organisation name	LEO Pharma A/S
Sponsor organisation address	Industriparken 55, Ballerup, Denmark, 2750
Public contact	Clinical Disclosure, LEO Pharma A/S, +45 44945888, disclosure@leo-pharma.com
Scientific contact	Clinical Disclosure, LEO Pharma A/S, +45 44945888, disclosure@leo-pharma.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	Yes
EMA paediatric investigation plan number(s)	EMEA-002329-PIP02-20
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	Yes

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	15 January 2025
Is this the analysis of the primary completion data?	Yes
Primary completion date	05 December 2024
Global end of trial reached?	Yes
Global end of trial date	17 December 2024
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To evaluate the efficacy of twice daily applications of delgocitinib cream 20 mg/g compared with cream vehicle in the treatment of adolescents with moderate to severe CHE.

Protection of trial subjects:

The trial was conducted in accordance with the Declaration of Helsinki (2013) and ICH GCP (2016), including archiving of essential documents.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	14 July 2022
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Australia: 14
Country: Number of subjects enrolled	Canada: 7
Country: Number of subjects enrolled	United Kingdom: 7
Country: Number of subjects enrolled	Poland: 32
Country: Number of subjects enrolled	Spain: 20
Country: Number of subjects enrolled	Belgium: 2
Country: Number of subjects enrolled	France: 16
Worldwide total number of subjects	98
EEA total number of subjects	70

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	98

Adults (18-64 years)	0
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

This trial was conducted at sites in 7 countries (Australia, Belgium, Canada, Spain, France, United Kingdom, and Poland).

Pre-assignment

Screening details:

101 participants were screened; 3 were excluded prior to randomization.

Participants were randomized 3:1 to treatment with delgocitinib cream 20 mg/g or cream vehicle.

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Carer

Arms

Are arms mutually exclusive?	Yes
Arm title	Delgocitinib Cream 20 mg/g

Arm description:

Participants were randomized to twice-daily topical applications of delgocitinib cream 20 mg/g for a 16-week treatment period followed by a follow-up period of 2 weeks for assessment of safety.

Delgocitinib cream: Cream for topical application.

Arm type	Experimental
Investigational medicinal product name	Delgocitinib
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Cream
Routes of administration	Topical use

Dosage and administration details:

Twice-daily delgocitinib cream 20 mg/g for 16 weeks. Applied topically.

Arm title	Cream vehicle

Arm description:

Participants were randomized to twice-daily applications of cream vehicle for a 16-week treatment period followed by a follow-up period of 2 weeks for assessment of safety.

Cream vehicle: The cream vehicle is similar to the delgocitinib cream except that it does not contain any active medical ingredient.

Arm type	Placebo
Investigational medicinal product name	Cream vehicle
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Cream
Routes of administration	Topical

Dosage and administration details:

Twice-daily cream vehicle for 16 weeks. Applied topically.

Number of subjects in period 1	Delgocitinib Cream 20 mg/g	Cream vehicle
Started	74	24
Completed	71	21
Not completed	3	3
Adverse event, non-fatal	1	1
Lost to follow-up	-	1
Lack of efficacy	2	1

Baseline characteristics

Reporting groups	
Reporting group title	Delgocitinib Cream 20 mg/g

Reporting group description:

Participants were randomized to twice-daily topical applications of delgocitinib cream 20 mg/g for a 16-week treatment period followed by a follow-up period of 2 weeks for assessment of safety.

Delgocitinib cream: Cream for topical application.

Reporting group title	Cream vehicle

Reporting group description:

Participants were randomized to twice-daily applications of cream vehicle for a 16-week treatment period followed by a follow-up period of 2 weeks for assessment of safety.

Cream vehicle: The cream vehicle is similar to the delgocitinib cream except that it does not contain any active medical ingredient.

Reporting group values	Delgocitinib Cream 20 mg/g	Cream vehicle	Total
Number of subjects	74	24	98
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	74	24	98
Adults (18-64 years)	0	0	0
From 65-84 years	0	0	0
85 years and over	0	0	0
Age continuous Units: years			
arithmetic mean	14.6	14.7	
standard deviation	± 1.7	± 1.6	-
Gender categorical Units: Subjects			
Female	46	12	58
Male	28	12	40
Ethnicity Units: Subjects			
Hispanic or Latino	8	0	8
Not Hispanic or Latino	62	21	83
Not reported	4	3	7
Race Units: Subjects			
White	69	20	89
Black or African American	2	0	2
Asian	1	2	3
American Indian or Alaska Native	0	0	0

Native Hawaiian or Other Pacific Islander	0	0	0
Not reported	2	2	4
IGA-CHE score			
The Investigator's Global Assessment for chronic hand eczema (IGA-CHE) is an instrument used in clinical trials to rate the severity of the participant's global chronic hand eczema (CHE) and is based on a 5-point scale ranging from 0 (clear) to 4 (severe).			
Units: Subjects			
Clear	0	0	0
Almost clear	0	0	0
Mild	0	0	0
Moderate	56	18	74
Severe	18	6	24
HECSI score			
The Hand Eczema Severity Index (HECSI) is an instrument used in clinical trials to rate the severity of 6 clinical signs (erythema, infiltration/papulation, vesicles, fissures, scaling, and oedema) and the extent of the lesions in each of the 5 hand regions (fingertips, fingers [except fingertips], palm of hands, back of hands, and wrists) by use of standard scales. The HECSI score will range from 0 (lowest possible score) to 360 (highest possible score), with a higher score indicating greater severity.			
Units: scores on a scale			
arithmetic mean	70.9	76.2	
standard deviation	± 37.8	± 39.7	-
HESD itch score (weekly average)			
The Hand Eczema Symptom Diary (HESD) itch score is one component of the HESD eDiary. In the HESD eDiary, participants will assess the worst severity of 6 individual signs and symptoms of CHE over the past 24 hours using an 11-point numeric rating scale with anchors of 0 ='no (symptom)' and 10 ='severe (symptom)' throughout the trial on a daily basis. Data is missing for 1 participant in the delgocitinib cream group.			
Units: scores on a scale			
arithmetic mean	5.56	5.91	
standard deviation	± 2.59	± 3.01	-
HESD pain score (weekly average)			
The Hand Eczema Symptom Diary (HESD) pain score is one component of the HESD eDiary. In the HESD eDiary, participants will assess the worst severity of 6 individual signs and symptoms of CHE over the past 24 hours using an 11-point numeric rating scale with anchors of 0 ='no (symptom)' and 10 ='severe (symptom)' throughout the trial on a daily basis. Data is missing for 1 participant in the delgocitinib cream group.			
Units: scores on a scale			
arithmetic mean	5.20	5.65	
standard deviation	± 2.75	± 3.49	-
HESD score (weekly average)			
The Hand Eczema Symptom Diary (HESD) is an eDiary in which participants will assess the worst severity of 6 individual signs and symptoms of CHE over the past 24 hours using an 11-point numeric rating scale with anchors of 0 ='no (symptom)' and 10 ='severe (symptom)' throughout the trial on a daily basis. The HESD score is derived as the average of the 6 signs and symptoms. Data is missing for 1 participant in the delgocitinib cream group.			
Units: scores on a scale			
arithmetic mean	5.63	5.75	
standard deviation	± 2.26	± 3.00	-
CDLQI score			
The Children's Dermatology Life Quality Index (CDLQI) is a validated questionnaire consisting of 10 items addressing the participant's perception of the impact of their skin disease on different aspects of their quality of life over the last week. Each question is scored from 0 (no impact) to 3 (high impact). The CDLQI score is the sum of the 10 items (score ranging from 0 to 30).			
Units: scores on a scale			

arithmetic mean	8.5	9.6	
standard deviation	± 5.5	± 6.8	-

End points

End points reporting groups

Reporting group title	Delgocitinib Cream 20 mg/g

Reporting group description:

Participants were randomized to twice-daily topical applications of delgocitinib cream 20 mg/g for a 16-week treatment period followed by a follow-up period of 2 weeks for assessment of safety.

Delgocitinib cream: Cream for topical application.

Reporting group title	Cream vehicle

Reporting group description:

Participants were randomized to twice-daily applications of cream vehicle for a 16-week treatment period followed by a follow-up period of 2 weeks for assessment of safety.

Cream vehicle: The cream vehicle is similar to the delgocitinib cream except that it does not contain any active medical ingredient.

Primary: IGA-CHE treatment success at Week 16

End point title	IGA-CHE treatment success at Week 16[1]

End point description:

The Investigator's Global Assessment for chronic hand eczema© (IGA-CHE) is a 5 point scale used in clinical trials to rate the severity of the subject's CHE from 0 (clear) to 4 (severe). Treatment success means a score of 0 (clear) or 1 (almost clear) with a ≥2 step improvement from baseline.

End point type	Primary

End point timeframe:

Week 16

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The statistical analysis used was the Bayesian method with neither a p-value nor a confidence interval to report.

End point values	Delgocitinib Cream 20 mg/g	Cream vehicle		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	74	24		
Units: count of participants	47	7		

Statistical analyses

No statistical analyses for this end point

Secondary: HECSI-90 at Week 16

End point title	HECSI-90 at Week 16

End point description:

The Hand Eczema Severity Index (HECSI) is an instrument used in clinical trials to rate the severity of 6 clinical signs (erythema, infiltration/papulation, vesicles, fissures, scaling, and oedema) and the extent of the lesions in each of the 5 hand regions (fingertips, fingers [except fingertips], palm of hands, back of hands, and wrists) by use of standard scales. The HECSI score will range from 0 (lowest possible

score) to 360 (highest possible score), with a higher score indicating greater severity. HECSI-90 is defined as at least 90% improvement in HECSI score from baseline.

The statistical analysis used was the Bayesian method with neither a p-value nor a confidence interval to report.

End point type	Secondary
End point timeframe:	
Week 16	

End point values	Delgocitinib Cream 20 mg/g	Cream vehicle		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	74	24		
Units: count of participants	53	9		

Statistical analyses

No statistical analyses for this end point

Secondary: Reduction of HESD itch score (weekly average) of ≥4 points from baseline at Week 16

End point title	Reduction of HESD itch score (weekly average) of ≥4 points from baseline at Week 16

End point description:

The Hand Eczema Symptom Diary© (HESD) is an instrument designed to assess severity of CHE signs and symptoms. The participants will assess the worst severity of 6 individual signs and symptoms of CHE from 0 (none) to 10 (severe) over the past 24 hours. The participants will complete the HESD on a daily basis in an eDiary.' This endpoint will only assess the 'itch' component for participants with a baseline HESD itch score (weekly average) of ≥4 points.

The statistical analysis used was the Bayesian method with neither a p-value nor a confidence interval to report.

End point type	Secondary
End point timeframe:	
Week 16	

End point values	Delgocitinib Cream 20 mg/g	Cream vehicle		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	54	19		
Units: count of participants	35	7		

Statistical analyses

No statistical analyses for this end point

Secondary: Reduction of HESD pain score (weekly average) of ≥4 points from baseline at Week 16

End point title	Reduction of HESD pain score (weekly average) of ≥4 points from baseline at Week 16

End point description:

The Hand Eczema Symptom Diary© (HESD) is an instrument designed to assess severity of CHE signs and symptoms. The participants will assess the worst severity of 6 individual signs and symptoms of CHE from 0 (none) to 10 (severe) over the past 24 hours. The participants will complete the HESD on a daily basis in an eDiary.' This endpoint will only assess the 'pain' component for participants with a baseline HESD pain score (weekly average) of ≥4 points.

The statistical analysis used was the Bayesian method with neither a p-value nor a confidence interval to report.

End point type	Secondary

End point timeframe:

Week 16

End point values	Delgocitinib Cream 20 mg/g	Cream vehicle		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	49	15		
Units: count of participants	31	5		

Statistical analyses

No statistical analyses for this end point

Secondary: Reduction of HESD score (weekly average) of ≥4 points from baseline at Week 16

End point title	Reduction of HESD score (weekly average) of ≥4 points from baseline at Week 16

End point description:

The Hand Eczema Symptom Diary© (HESD) is an instrument designed to assess severity of CHE signs and symptoms. The participants will assess the worst severity of 6 individual signs and symptoms of CHE from 0 (none) to 10 (severe) over the past 24 hours. The participants will complete the HESD on a daily basis in an eDiary.' This endpoint will only assess the score for participants with a baseline HESD itch score (weekly average) of ≥4 points.

The statistical analysis used was the Bayesian method with neither a p-value nor a confidence interval to report.

End point type	Secondary

End point timeframe:

Week 16

End point values	Delgocitinib Cream 20 mg/g	Cream vehicle		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	54	16		
Units: count of participants	30	5		

Statistical analyses

No statistical analyses for this end point

Secondary: IGA-CHE treatment success at Weeks 2, 4, 8, and 12

End point title	IGA-CHE treatment success at Weeks 2, 4, 8, and 12

End point description:

The Investigator’s Global Assessment for chronic hand eczema (IGA-CHE) is a 5 point scale used in clinical trials to rate the severity of the subject’s CHE from 0 (clear) to 4 (severe). Treatment success means a score of 0 (clear) or 1 (almost clear) with a ≥2 step improvement from baseline.

End point type	Secondary

End point timeframe:

Week 2, week 4, week 8, and week 12

End point values	Delgocitinib Cream 20 mg/g	Cream vehicle		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	74	24		
Units: count of participants				
Week 2	16	1		
Week 4	28	4		
Week 8	36	9		
Week 12	43	6		

Statistical analyses

Statistical analysis title	Statistical analysis - week 2

Statistical analysis description:

The primary estimand using the composite strategy is used for the analysis. Data is considered non response after initiation of rescue treatment or after permanent discontinuation of IMP. Missing data is imputed as non-response.

Comparison groups	Cream vehicle v Delgocitinib Cream 20 mg/g

Number of subjects included in analysis	98
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0054
Method	Regression, Logistic
Parameter estimate	Risk difference (RD)
Point estimate	17.47
Confidence interval	
level	95 %
sides	2-sided
lower limit	5.16
upper limit	29.78

Statistical analysis title	Statistical analysis - week 4

Statistical analysis description:

The primary estimand using the composite strategy is used for the analysis. Data is considered non response after initiation of rescue treatment or after permanent discontinuation of IMP. Missing data is imputed as non-response.

Comparison groups	Delgocitinib Cream 20 mg/g v Cream vehicle
Number of subjects included in analysis	98
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0248
Method	Regression, Logistic
Parameter estimate	Risk difference (RD)
Point estimate	21.21
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.69
upper limit	39.72

Statistical analysis title	Statistical analysis - week 8

Statistical analysis description:

The primary estimand using the composite strategy is used for the analysis. Data is considered non response after initiation of rescue treatment or after permanent discontinuation of IMP. Missing data is imputed as non-response.

Comparison groups	Delgocitinib Cream 20 mg/g v Cream vehicle
Number of subjects included in analysis	98
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.332
Method	Regression, Logistic
Parameter estimate	Risk difference (RD)
Point estimate	11.08

Confidence interval	
level	95 %
sides	2-sided
lower limit	-11.3
upper limit	33.46

Statistical analysis title	Statistical analysis - week 12

Statistical analysis description:

The primary estimand using the composite strategy is used for the analysis. Data is considered non response after initiation of rescue treatment or after permanent discontinuation of IMP. Missing data is imputed as non-response.

Comparison groups	Delgocitinib Cream 20 mg/g v Cream vehicle
Number of subjects included in analysis	98
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0016
Method	Regression, Logistic
Parameter estimate	Risk difference (RD)
Point estimate	33.02
Confidence interval	
level	95 %
sides	2-sided
lower limit	12.51
upper limit	53.52

Secondary: Change in CDLQI score from baseline to Week 16

End point title	Change in CDLQI score from baseline to Week 16

End point description:

The Children's Dermatology Life Quality Index (DDLQI) is a validated questionnaire consisting of 10 items addressing the participant's perception of the impact of their skin disease on different aspects of their quality of life over the last week. Each question is scored from 0 (no impact) to 3 (high impact). The CDLQI score is the sum of the 10 items (score ranging from 0 to 30); a high score is indicative of a poor quality of life.

End point type	Secondary

End point timeframe:

Week 16

End point values	Delgocitinib Cream 20 mg/g	Cream vehicle		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	74	24		
Units: score on a scale				
least squares mean (standard error)	-5.57 (± 0.44)	-2.92 (± 0.78)		

Statistical analyses

Statistical analysis title	Statistical analysis 1

Statistical analysis description:

Primary estimand: Composite. Data considered non-response by using WOCF (including the baseline value) after initiation of rescue treatment or after permanent discontinuation of IMP. Missing data imputed using WOCF (including the baseline value).

Comparison groups	Delgocitinib Cream 20 mg/g v Cream vehicle
Number of subjects included in analysis	98
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0038
Method	ANCOVA
Parameter estimate	Mean difference (net)
Point estimate	-2.65
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.42
upper limit	-0.88

Secondary: Number of treatment emergent AEs from baseline up to Week 18

End point title	Number of treatment emergent AEs from baseline up to Week 18

End point description:

An adverse event (AE) will be considered treatment emergent if started after the first application of treatment, or started before the first application of treatment and worsened in severity after treatment.

End point type	Secondary

End point timeframe:

Week 18

End point values	Delgocitinib Cream 20 mg/g	Cream vehicle		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	74	24		
Units: events	77	19		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Treatment emergent adverse events were collected during the 16 weeks of treatment + 2 weeks of follow-up.

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	24.0

Reporting groups

Reporting group title	Delgocitinib Cream 20 mg/g

Reporting group description:

Participants were randomized to twice-daily topical applications of delgocitinib cream 20 mg/g for a 16-week treatment period followed by a follow-up period of 2 weeks for assessment of safety.

Delgocitinib cream: Cream for topical application.

Reporting group title	Cream vehicle

Reporting group description:

Participants were randomized to twice-daily applications of cream vehicle for a 16-week treatment period followed by a follow-up period of 2 weeks for assessment of safety.

Cream vehicle: The cream vehicle is similar to the delgocitinib cream except that it does not contain any active medical ingredient.

Serious adverse events	Delgocitinib Cream 20 mg/g	Cream vehicle	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 74 (0.00%)	0 / 24 (0.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	

Frequency threshold for reporting non-serious adverse events: 5 %

Non-serious adverse events	Delgocitinib Cream 20 mg/g	Cream vehicle	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	17 / 74 (22.97%)	4 / 24 (16.67%)	
Nervous system disorders			
Headache			
subjects affected / exposed	4 / 74 (5.41%)	1 / 24 (4.17%)	
occurrences (all)	4	1	
Infections and infestations			

Nasopharyngitis subjects affected / exposed occurrences (all)	10 / 74 (13.51%) 12	4 / 24 (16.67%) 4	
Upper respiratory tract infection subjects affected / exposed occurrences (all)	5 / 74 (6.76%) 5	0 / 24 (0.00%) 0	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
11 December 2023	This amendment was mainly written to change the statistical methodology. Minor clarifications and editorial changes have been made throughout the document.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported