Clinical trial results:
A Phase III, multicentre, parallel-group, randomized, placebo-controlled, double-blind clinical trial
to study the efficacy and safety of desloratadine in Japanese subjects with chronic urticaria

Summary

EudraCT number	2017-000608-13
Trial protocol	Outside EU/EEA
Global end of trial date	13 March 2014

Results information

Result version number	v1 (current)
This version publication date	09 April 2017
First version publication date	09 April 2017

Trial information

Trial identification

Sponsor protocol code	4117-201

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01916967
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Merck Sharp & Dohme Corp.
Sponsor organisation address	2000 Galloping Hill Road, Kenilworth, NJ, United States, 07033
Public contact	Clinical Trials Disclosure, Merck Sharp & Dohme Corp., ClinicalTrialsDisclosure@merck.com
Scientific contact	Clinical Trials Disclosure, Merck Sharp & Dohme Corp., ClinicalTrialsDisclosure@merck.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
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	13 March 2014
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	13 March 2014
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

This is a study to evaluate the efficacy and safety of desloratadine (MK-4117) in Japanese participants with chronic urticaria. The primary hypothesis is that the efficacy of desloratadine 10 mg and 5 mg is superior to placebo as based on the change from Baseline in the sum score of pruritus/itch and rash as assessed by the Investigator at Week 2.

Protection of trial subjects:

This study was conducted in conformance with Good Clinical Practice standards and applicable country and/or local statutes and regulations regarding ethical committee review, informed consent, and the protection of human subjects participating in biomedical research.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	27 August 2013
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Japan: 239
Worldwide total number of subjects	239
EEA total number of subjects	0

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)	11
Adults (18-64 years)	205
From 65 to 84 years	23
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Participants with chronic urticaria of at least 12 years of age were enrolled in this trial.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Desloratadine 5 mg

Arm description:

Participants received desloratadine 5 mg, as one 5 mg tablet and one placebo tablet, orally, once daily in the evening for 2 weeks

Arm type	Experimental
Investigational medicinal product name	Desloratadine
Investigational medicinal product code	
Other name	MK-4117
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

5 mg Desloratadine administered orally once daily for 2 weeks

Arm title	Desloratadine 10 mg

Arm description:

Participants received desloratadine 10 mg, as two 5 mg tablets, orally, once daily in the evening for 2 weeks

Arm type	Experimental
Investigational medicinal product name	Desloratadine
Investigational medicinal product code	
Other name	MK-4117
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

10 mg Desloratadine administered orally once daily for 2 weeks

Arm title	Placebo

Arm description:

Participants received placebo, as two tablets, orally, once daily in the evening for 2 weeks

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:
Placebo for Desloratadine administered orally once daily for 2 weeks

Number of subjects in period 1	Desloratadine 5 mg	Desloratadine 10 mg	Placebo
Started	80	79	80
Completed	80	78	71
Not completed	0	1	9
Physician decision	-	-	1
Adverse event, non-fatal	-	-	2
Protocol deviation	-	1	-
Lack of efficacy	-	-	6

Baseline characteristics

Reporting groups	
Reporting group title	Desloratadine 5 mg
Reporting group description:	
Participants received desloratadine 5 mg, as one 5 mg tablet and one placebo tablet, orally, once daily in the evening for 2 weeks	
Reporting group title	Desloratadine 10 mg
Reporting group description:	
Participants received desloratadine 10 mg, as two 5 mg tablets, orally, once daily in the evening for 2 weeks	
Reporting group title	Placebo
Reporting group description:	
Participants received placebo, as two tablets, orally, once daily in the evening for 2 weeks	

Reporting group values	Desloratadine 5 mg	Desloratadine 10 mg	Placebo
Number of subjects	80	79	80
Age Categorical Units: Subjects			
Adolescents (12-17 years)	4	3	4
Adults (18-64 years)	67	66	72
From 65-84 years	9	10	4
Age Continuous Units: years			
arithmetic mean	38.4	40.6	39.3
standard deviation	± 16.3	± 15.8	± 15.2
Gender Categorical Units: Subjects			
Female	59	48	45
Male	21	31	35

Reporting group values	Total		
Number of subjects	239		
Age Categorical Units: Subjects			
Adolescents (12-17 years)	11		
Adults (18-64 years)	205		
From 65-84 years	23		
Age Continuous Units: years			
arithmetic mean			
standard deviation	-		
Gender Categorical Units: Subjects			
Female	152		
Male	87		

End points

End points reporting groups

Reporting group title	Desloratadine 5 mg
Reporting group description:	
Participants received desloratadine 5 mg, as one 5 mg tablet and one placebo tablet, orally, once daily in the evening for 2 weeks	
Reporting group title	Desloratadine 10 mg
Reporting group description:	
Participants received desloratadine 10 mg, as two 5 mg tablets, orally, once daily in the evening for 2 weeks	
Reporting group title	Placebo
Reporting group description:	
Participants received placebo, as two tablets, orally, once daily in the evening for 2 weeks	
Subject analysis set title	Desloratadine 5 mg
Subject analysis set type	Safety analysis
Subject analysis set description:	
Participants received desloratadine 5 mg, as one 5 mg tablet and one placebo tablet, orally, once daily in the evening for 2 weeks	
Subject analysis set title	Desloratadine 10 mg
Subject analysis set type	Safety analysis
Subject analysis set description:	
Participants received desloratadine 10 mg, as two 5 mg tablets, orally, once daily in the evening for 2 weeks	
Subject analysis set title	Placebo
Subject analysis set type	Safety analysis
Subject analysis set description:	
Participants received placebo, as two tablets, orally, once daily in the evening for 2 weeks	
Subject analysis set title	Desloratadine 5 mgPlacebo
Subject analysis set type	Safety analysis
Subject analysis set description:	
Participant received desloratadine 5 mg, as one 5 mg tablet and one placebo tablet, orally, once daily for 1 week and then received placebo, as two tablets, orally, once daily for 1 week	

Primary: Change from baseline in the sum score of pruritus/itch and rash assessed by investigator at Week 2

End point title	Change from baseline in the sum score of pruritus/itch and rash assessed by investigator at Week 2
End point description:	
The Investigator assessed the severity of participant pruritus/itch during the daytime (0=Virtually no itching to 4=Cannot relax because of constant itching) and nighttime (0=Virtually no itching to 4=Cannot sleep because of itching). The score used for pruritus/itch was the higher of the day or night scores (0=Asymptomatic to 4=Severe). The Investigator also assessed the severity of participant rash using the overall rash score (0=No rash to 3=Looks very bad). The sum of the pruritus/itch score (0-4) and rash score (0-3) could range from 0 to 7, with a higher sum score indicating greater severity. The change from Baseline in the sum of the pruritus/itch and overall rash scores at the Week 2 clinic visit was calculated. The population analyzed consisted of all randomized participants who took at least one dose of study drug, had a Baseline assessment and a Week 2 assessment for this outcome measure.	
End point type	Primary
End point timeframe:	
Baseline Visit and Week 2 Visit	

End point values	Desloratadine 5 mg	Desloratadine 10 mg	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	80	79	80	
Units: Score on a scale				
least squares mean (confidence interval 95%)	-3.19 (-3.56 to -2.83)	-3.16 (-3.52 to -2.79)	-2.02 (-2.4 to -1.65)	

Statistical analyses

Statistical analysis title	Difference LS means: Desloratadine 5 mg vs Placebo

Statistical analysis description:

Model with terms of visit, visit by treatment, visit by age strata, visit by severity interactions; visit treated as a categorical variable

Comparison groups	Desloratadine 5 mg v Placebo
Number of subjects included in analysis	160
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Constrained Longitudinal Data Analysis
Parameter estimate	Difference in LS means
Point estimate	-1.17
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.69
upper limit	-0.65

Statistical analysis title	Difference LS means: Desloratadine 5 mg vs Placebo

Statistical analysis description:

Model with terms of visit, visit by treatment, visit by age strata, visit by severity interactions; visit treated as a categorical variable

Comparison groups	Desloratadine 10 mg v Placebo
Number of subjects included in analysis	159
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Constrained Longitudinal Data Analysis
Parameter estimate	Difference in LS means
Point estimate	-1.13
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.66
upper limit	-0.61

Primary: Number of participants who experienced at least one adverse event (AE)

End point title	Number of participants who experienced at least one adverse event (AE)[1]

End point description:

An AE is any unfavourable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a study drug or protocol specified procedure, whether or not considered related to the study drug or protocol specified procedure. Any worsening (i.e., any clinically significant adverse change in frequency and/or intensity) of a preexisting condition that is temporally associated with the use of the study drug, is also an AE. The population analyzed consisted of all participants who received at least one dose of study drug. One Placebo group participant took the wrong study drug. This participant was analyzed separately.

End point type	Primary

End point timeframe:

Up to 4 weeks (Up to 2 weeks after last dose of study drug)

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: Statistical comparisons between treatment groups were neither planned nor performed for this primary endpoint.

End point values	Desloratadine 5 mg	Desloratadine 10 mg	Placebo	Desloratadine 5 mgPlacebo
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	80	79	79	1
Units: Participants				
number (not applicable)	24	18	16	0

Statistical analyses

No statistical analyses for this end point

Primary: Number of participants who discontinued study drug due to an AE

End point title	Number of participants who discontinued study drug due to an AE[2]

End point description:

An AE is any unfavourable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a study drug or protocol specified procedure, whether or not considered related to the study drug or protocol specified procedure. Any worsening (i.e., any clinically significant adverse change in frequency and/or intensity) of a preexisting condition that is temporally associated with the use of the study drug, is also an AE. The population analyzed consisted of all participants who received at least one dose of study drug. One Placebo group participant took the wrong study drug. This participant was analyzed separately.

End point type	Primary

End point timeframe:

Up to 2 weeks

Notes:

[2] - 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: Statistical comparisons between treatment groups were neither planned nor performed for this primary endpoint.

End point values	Desloratadine 5 mg	Desloratadine 10 mg	Placebo	Desloratadine 5 mgPlacebo
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	80	79	79	1
Units: Participants				
number (not applicable)	0	0	2	0

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in the Sum Score of Pruritus/Itch and Rash Assessed by Investigator at Day 3 and Week 1

End point title	Change From Baseline in the Sum Score of Pruritus/Itch and Rash Assessed by Investigator at Day 3 and Week 1

End point description:

The Investigator assessed the severity of participant pruritus/itch during the daytime (0=Virtually no itching to 4=Cannot relax because of constant itching) and nighttime (0=Virtually no itching to 4=Cannot sleep because of itching). The score used for pruritus/itch was the higher of the day or night scores (0=Asymptomatic to 4=Severe). The Investigator also assessed the severity of participant rash using the overall rash score (0=No rash to 3=Looks very bad). The sum of the pruritus/itch score (0-4) and rash score (0-3) could range from 0 to 7, with a higher sum score indicating greater severity. The changes from Baseline in the sum of the pruritus/itch and overall rash scores at the Day 3 and Week 1 clinic visits were calculated. The population analyzed consisted of all randomized participants who took at least one dose of study drug, had a Baseline assessment and at least one post Baseline assessment for this outcome measure.

End point type	Secondary

End point timeframe:

Baseline Visit and Day 3 Visit, Week 1 Visit

End point values	Desloratadine 5 mg	Desloratadine 10 mg	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	80	79	80	
Units: Score on a scale				
least squares mean (confidence interval 95%)				
Change from Baseline at Day 3	-2.57 (-2.91 to -2.23)	-2.75 (-3.09 to -2.41)	-0.8 (-1.14 to -0.46)	
Change from Baseline at Week 1	-3.01 (-3.34 to -2.68)	-3.16 (-3.5 to -2.83)	-1.39 (-1.72 to -1.06)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in the Pruritus/Itch Score Assessed by Investigator at Day 3, Week 1 and Week 2

End point title	Change From Baseline in the Pruritus/Itch Score Assessed by

	Investigator at Day 3, Week 1 and Week 2

End point description:

The Investigator assessed the severity of participant pruritus/itch during the daytime and nighttime (0=Asymptomatic to 4=Severe). The sum of the daytime and nighttime pruritus/itch scores could range from 0 to 8, with a higher score indicating greater severity. The changes from Baseline in the sum of the daytime and nighttime scores at the Day 3, Week 1 and Week 2 clinic visits were calculated. The population analyzed consisted of all randomized participants who took at least one dose of study drug, had a Baseline assessment and at least one post Baseline assessment for this outcome measure.

End point type	Secondary

End point timeframe:

Baseline Visit and Day 3 Visit, Week 1 Visit, Week 2 Visit

End point values	Desloratadine 5 mg	Desloratadine 10 mg	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	80	79	80	
Units: Score on a scale				
least squares mean (confidence interval 95%)				
Change from Baseline at Day 3	-2.62 (-2.97 to -2.27)	-2.72 (-3.07 to -2.37)	-0.61 (-0.95 to -0.26)	
Change from Baseline at Week 1	-2.98 (-3.35 to -2.61)	-3.13 (-3.5 to -2.76)	-1.38 (-1.75 to -1.01)	
Change from Baseline at Week 2	-3.17 (-3.56 to -2.77)	-3.21 (-3.6 to -2.81)	-1.91 (-2.31 to -1.5)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in the Rash Score Assessed by Investigator at Day 3, Week 1 and Week 2

End point title	Change From Baseline in the Rash Score Assessed by Investigator at Day 3, Week 1 and Week 2

End point description:

The Investigator assessed the severity of participant rash (erythema: 0=no symptom to 3=intensive redness, and wheal: 0=no symptom to 3=significant ridge). The sum score for erythema plus wheal could range from 0 to 6, with a higher score indicating greater severity. The changes from Baseline in the sum score for erythema plus wheal at the Day 3, Week 1 and Week 2 clinic visits were calculated. The population analyzed consisted of all randomized participants who took at least one dose of study drug, had a Baseline assessment and at least one post Baseline assessment for this outcome measure.

End point type	Secondary

End point timeframe:

Baseline Visit and Day 3 Visit, Week 1 Visit, Week 2 Visit

End point values	Desloratadine 5 mg	Desloratadine 10 mg	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	80	79	80	
Units: Score on a scale				
least squares mean (confidence interval 95%)				
Change from Baseline at Day 3	-2.31 (-2.63 to -2)	-2.61 (-2.93 to -2.29)	-0.99 (-1.31 to -0.67)	
Change from Baseline at Week 1	-2.65 (-2.97 to -2.33)	-2.98 (-3.3 to -2.66)	-1.44 (-1.76 to -1.12)	
Change from Baseline at Week 2	-2.94 (-3.28 to -2.61)	-2.91 (-3.25 to -2.57)	-1.98 (-2.33 to -1.64)	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants With a Moderate or Remarkable Improvement in the Global Improvement Rate of Both Pruritus/Itch and Rash (Erythema and Wheal) Assessed by the Investigator at Day 3, Week 1 and Week 2

End point title	Number of Participants With a Moderate or Remarkable Improvement in the Global Improvement Rate of Both Pruritus/Itch and Rash (Erythema and Wheal) Assessed by the Investigator at Day 3, Week 1 and Week 2

End point description:

The global improvement judgment criteria were used to assess overall improvement in pruritus/itch and rash. The Investigator assessed participant global improvement according to 5 grades (Grade 1=Remarkable improvement to Grade 5=Aggravated). The number of participants with moderate or remarkable improvements was calculated. Remarkable improvement (Grade 1) was defined as both pruritus/itch and rash (erythema and wheal) disappeared, or pruritus/itch disappeared and rash (erythema and wheal) was apparently improved. Moderate improvement (Grade 2) was defined as both pruritus/itch and rash (erythema and wheal) were greatly improved. The population analyzed consisted of all randomized participants who took at least one dose of study drug, had a Baseline assessment and at least one post Baseline assessment for this outcome measure.

End point type	Secondary

End point timeframe:

Baseline Visit and Day 3 Visit, Week 1 Visit, Week 2 Visit

End point values	Desloratadine 5 mg	Desloratadine 10 mg	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	80	79	80	
Units: Participants				
number (not applicable)				
Day 3	54	55	15	
Week 1	54	58	32	
Week 2	59	53	38	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in the Pruritus/Itch Score Reported in Participant Diaries at Day 3, Week 1 and Week 2

End point title	Change From Baseline in the Pruritus/Itch Score Reported in Participant Diaries at Day 3, Week 1 and Week 2

End point description:

Participants assessed the severity of their pruritus/itch during the daytime and nighttime (0=asymptomatic to 4=severe). The sum of the daytime and nighttime pruritus/itch scores could range from 0 to 8, with a higher score indicating greater severity. The changes from Baseline in the sum of the daytime and nighttime scores at the Day 3, Week 1 and Week 2 clinic visits were calculated. The population analyzed consisted of all randomized participants who took at least one dose of study drug, had a Baseline assessment and at least one post Baseline assessment for this outcome measure.

End point type	Secondary

End point timeframe:

Baseline Visit and Day 3 Visit, Week 1 Visit, Week 2 Visit

End point values	Desloratadine 5 mg	Desloratadine 10 mg	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	80	79	80	
Units: Score on a scale				
least squares mean (confidence interval 95%)				
Change from Baseline at Day 3	-2.37 (-2.74 to -2)	-2.73 (-3.1 to -2.36)	-0.5 (-0.87 to -0.13)	
Change from Baseline at Week 1	-2.53 (-2.91 to -2.15)	-2.85 (-3.24 to -2.47)	-1.27 (-1.65 to -0.88)	
Change from Baseline at Week 2	-2.85 (-3.3 to -2.41)	-2.97 (-3.42 to -2.51)	-1.75 (-2.23 to -1.27)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Pruritus/Itch on a Visual Analog Scale (VAS) Reported by Participants at Day 3, Week 1 and Week 2

End point title	Change From Baseline in Pruritus/Itch on a Visual Analog Scale (VAS) Reported by Participants at Day 3, Week 1 and Week 2

End point description:

Participants assessed the degree of their pruritus/itching using a 100mm visual analog scale (VAS) (0 mm=No itch to 100 mm=Worst imaginable itch), with a higher score indicating more severe itching. The changes from Baseline in participant assessed pruritus/itch at the Day 3, Week 1 and Week 2 clinic visits were calculated. The population analyzed consisted of all randomized participants who took at least one dose of study drug, had a Baseline assessment and at least one post Baseline assessment for this outcome measure.

End point type	Secondary

End point timeframe:

Baseline Visit and Day 3 Visit, Week 1 Visit, Week 2 Visit

End point values	Desloratadine 5 mg	Desloratadine 10 mg	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	80	79	80	
Units: Score on a scale				
least squares mean (confidence interval 95%)				
Change from Baseline at Day 3	-35.94 (-41.91 to -29.97)	-39.6 (-45.61 to -33.6)	-5.22 (-11.19 to 0.75)	
Change from Baseline at Week 1	-40.82 (-46.55 to -35.09)	-48.82 (-54.6 to -43.03)	-15.88 (-21.63 to -10.13)	
Change from Baseline at Week 2	-45.86 (-51.96 to -39.75)	-45.01 (-51.17 to 38.84)	-25.24 (-31.52 to -18.97)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in the Rash Score Reported in Participant Diaries at Day 3, Week 1 and Week 2

End point title	Change From Baseline in the Rash Score Reported in Participant Diaries at Day 3, Week 1 and Week 2

End point description:

Participants assessed the severity of their rash (erythema: 0=no symptom to 3=intensive redness, and wheal: 0=no symptom to 3=significant ridge). The sum score for erythema plus wheal could range from 0 to 6, with a higher score indicating greater severity. The changes from Baseline in the sum score for erythema plus wheal at the Day 3, Week 1 and Week 2 clinic visits were calculated. The population analyzed consisted of all randomized participants who took at least one dose of study drug, had a Baseline assessment and at least one post Baseline assessment for this outcome measure.

End point type	Secondary

End point timeframe:

Baseline Visit and Day 3 Visit, Week 1 Visit, Week 2 Visit

End point values	Desloratadine 5 mg	Desloratadine 10 mg	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	80	79	80	
Units: Score on a scale				
least squares mean (confidence interval 95%)				
Change from Baseline at Day 3	-2.21 (-2.57 to -1.85)	-2.31 (-2.67 to -1.94)	-0.77 (-1.13 to -0.4)	
Change from Baseline at Week 1	-2.15 (-2.5 to -1.81)	-2.43 (-2.77 to -2.08)	-1.17 (-1.52 to -0.83)	
Change from Baseline at Week 2	-2.51 (-2.88 to -2.13)	-2.45 (-2.83 to -2.06)	-1.7 (-2.11 to -1.29)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in the Dermatology Life Quality Index (DLQI) Total Score Reported by Participants at Week 1 and Week 2

End point title	Change From Baseline in the Dermatology Life Quality Index (DLQI) Total Score Reported by Participants at Week 1 and Week 2

End point description:

The DLQI is a 10 item questionnaire measuring how much participant skin problems have affected their life. Responses to questions ranged from 0=Not at all to 3=Very much. The DLQI consists of 6 subscales: Symptoms and feelings (range 0-6), Daily activities (range 0-6), Leisure (range 0-6), Work and school (range 0-3),Personal relationships (range 0-6), and Treatment (range 0-3). DLQI subscales were summed to yield the DLQI total score, which could range from 0 to 30. For DLQI subscales and DLQI total score, a higher score indicated a greater negative impact on life. Participants >=16 years of age completed the DLQI questionnaire over the previous week. The changes from Baseline in the DLQI total score at the Week 1 and Week 2 clinic visits were calculated. The population analyzed was all randomized participants who took at least one dose of study drug, had a Baseline assessment and at least one post Baseline assessment for DLQI.

End point type	Secondary

End point timeframe:

Baseline Visit and Week 1 Visit, Week 2 Visit

End point values	Desloratadine 5 mg	Desloratadine 10 mg	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	79	77	77	
Units: Score on a scale				
least squares mean (confidence interval 95%)				
Change from Baseline at Week 1	-3.82 (-4.52 to -3.12)	-4.08 (-4.78 to -3.37)	-1.6 (-2.31 to -0.89)	
Change from Baseline at Week 2	-4.1 (-4.83 to -3.38)	-4.01 (-4.74 to -3.28)	-2.53 (-3.28 to -1.78)	

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Up to 4 weeks (Up to 2 weeks after last dose of study drug)

Adverse event reporting additional description:

All participants who received at least one dose of study drug. One Placebo group participant took the wrong study drug. This participant was analyzed separately.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	16.1

Reporting groups

Reporting group title	Desloratadine 5 mg

Reporting group description:

Participants received desloratadine 5 mg, as one 5 mg tablet and one placebo tablet, orally, once daily in the evening for 2 weeks

Reporting group title	Desloratadine 10 mg

Reporting group description:

Participants received desloratadine 10 mg, as two 5 mg tablets, orally, once daily in the evening for 2 weeks

Reporting group title	Placebo

Reporting group description:

Participants received placebo, as two tablets, orally, once daily in the evening for 2 weeks

Reporting group title	Desloratadine 5 mgPlacebo

Reporting group description:

Participant received desloratadine 5 mg, as one 5 mg tablet and one placebo tablet, orally, once daily for 1 week and then received placebo, as two tablets, orally, once daily for 1 week

Serious adverse events	Desloratadine 5 mg	Desloratadine 10 mg	Placebo
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 80 (0.00%)	0 / 79 (0.00%)	0 / 79 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0

Serious adverse events	Desloratadine 5 mgPlacebo		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 1 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		

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

Non-serious adverse events	Desloratadine 5 mg	Desloratadine 10 mg	Placebo
Total subjects affected by non-serious adverse events			
subjects affected / exposed	10 / 80 (12.50%)	8 / 79 (10.13%)	5 / 79 (6.33%)
Nervous system disorders			
Somnolence			
subjects affected / exposed	3 / 80 (3.75%)	5 / 79 (6.33%)	3 / 79 (3.80%)
occurrences (all)	3	6	3
Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	8 / 80 (10.00%)	3 / 79 (3.80%)	2 / 79 (2.53%)
occurrences (all)	8	3	2

Non-serious adverse events	Desloratadine 5 mgPlacebo		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 1 (0.00%)		
Nervous system disorders			
Somnolence			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported