Clinical trial results:
Double Blind, Randomized, Placebo-Controlled, Parallel-Group, Multicenter/Multinational, Efficacy and Safety Study of Desloratadine 5 mg in the Treatment of Subjects With Allergic Rhinitis Who Meet the Criteria for Intermittent Allergic Rhinitis (IAR)

Summary

EudraCT number	2005-005449-20
Trial protocol	FI PT ES DE HU SE GR DK IT BE Outside EU/EEA
Global end of trial date	21 November 2007

Results information

Result version number	v1 (current)
This version publication date	10 February 2016
First version publication date	17 July 2015

Trial information

Trial identification

Sponsor protocol code	P04683

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT00406783
WHO universal trial number (UTN)	-
Other trial identifiers	Protocol number: MK-4117-174

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
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	Yes

1901/2006 apply to this trial?	

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	21 November 2007
Is this the analysis of the primary completion data?	Yes
Primary completion date	21 November 2007
Global end of trial reached?	Yes
Global end of trial date	21 November 2007
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

This study will investigate the effectiveness of desloratadine in treating subjects with allergic rhinitis (AR) who meet the criteria for intermittent allergic rhinitis.

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	28 August 2006
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	Netherlands: 2
Country: Number of subjects enrolled	Portugal: 2
Country: Number of subjects enrolled	Spain: 21
Country: Number of subjects enrolled	Sweden: 35
Country: Number of subjects enrolled	Denmark: 2
Country: Number of subjects enrolled	Finland: 9
Country: Number of subjects enrolled	France: 109
Country: Number of subjects enrolled	Germany: 55
Country: Number of subjects enrolled	Greece: 17
Country: Number of subjects enrolled	Hungary: 24
Country: Number of subjects enrolled	Italy: 68
Country: Number of subjects enrolled	Canada: 134
Country: Number of subjects enrolled	Russian Federation: 48
Country: Number of subjects enrolled	Turkey: 21
Worldwide total number of subjects	547
EEA total number of subjects	344

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)	20
Adults (18-64 years)	519
From 65 to 84 years	8
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Study sites were part of the Global Allergy and Asthma European Network (GA2LEN).

Pre-assignment

Screening details:

Approximately eight subjects were to be enrolled at each site, but up to approximately 30 subjects could be enrolled at each site with the sponsor’s approval.

Period 1

Period 1 title	Treatment (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:

Desloratadine 5 mg, oral, tablet, once daily for 15 days

Arm type	Experimental
Investigational medicinal product name	Desloratadine
Investigational medicinal product code	
Other name	SCH 34117, Aerius, MK-4117
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Desloratadine 5 mg, oral, tablet, once daily for 15 days

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

Dosage and administration details:

Placebo to Desloratadine, oral, tablet, once daily for 15 days

Arm title	Placebo

Arm description:

Placebo to Desloratadine, oral, tablet, once daily for 15 days

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 to desloratadine, oral, tablet once daily for 15 days

Number of subjects in period 1	Desloratadine 5 mg	Placebo
Started	276	271
Completed	262	256
Not completed	14	15
Did not meet protocol eligibility	-	1
Consent withdrawn by subject	1	4
Adverse event, non-fatal	4	4
Lost to follow-up	3	-
Lack of efficacy	2	3
Protocol deviation	4	3

Baseline characteristics

Reporting groups	
Reporting group title	Desloratadine 5 mg
Reporting group description:	
Desloratadine 5 mg, oral, tablet, once daily for 15 days	
Reporting group title	Placebo
Reporting group description:	
Placebo to Desloratadine, oral, tablet, once daily for 15 days	

Reporting group values	Desloratadine 5 mg	Placebo	Total
Number of subjects	276	271	547
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)	12	8	20
Adults (18-64 years)	262	257	519
From 65-84 years	2	6	8
85 years and over	0	0	0
Age continuous Units: years			
arithmetic mean	33.8	34.6	
standard deviation	± 12	± 12.8	-
Gender categorical Units: Subjects			
Female	154	164	318
Male	122	107	229

End points

End points reporting groups

Reporting group title	Desloratadine 5 mg
Reporting group description:	
Desloratadine 5 mg, oral, tablet, once daily for 15 days	
Reporting group title	Placebo
Reporting group description:	
Placebo to Desloratadine, oral, tablet, once daily for 15 days	

Primary: The Change From Baseline in the 12-hour AM/PM-PRIOR (Reflective) Total 5 Symptom Score (T5SS) From Subject Daily Diaries Averaged Over Treatment Days 1 to 15

End point title	The Change From Baseline in the 12-hour AM/PM-PRIOR (Reflective) Total 5 Symptom Score (T5SS) From Subject Daily Diaries Averaged Over Treatment Days 1 to 15
End point description:	
AM/PM is the average of separate morning (AM) and evening (PM) evaluations. T5SS = the sum of the individual scores for nasal congestion/stuffiness, sneezing, rhinorrhea/nasal discharge, nasal pruritis, and ocular pruritis. Each individual symptom/sign was scored from 0 (none) to 3 (severe).	
End point type	Primary
End point timeframe:	
Baseline and Days 1 to 15	

End point values	Desloratadine 5 mg	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	271[1]	265[2]		
Units: Scores on a scale				
least squares mean (standard error)	-3.01 (± 0.21)	-2.13 (± 0.2)		

Notes:

[1] - All randomized participants with a non-missing baseline and at least some post-baseline data.

[2] - All randomized participants with a non-missing baseline and at least some post-baseline data.

Statistical analyses

Statistical analysis title	Treatment Difference
Statistical analysis description:	
Difference in the least squares means between change from baseline in AM/PM PRIOR (reflective) T5SS for participants taking desloratadine over Day 1 to Day 15 of treatment vs. change from baseline in AM/PM PRIOR (reflective) T5SS for participants taking placebo over Day 1 to Day 15 of treatment. Negative differences are in favor of the desloratadine treatment group in the comparison.	
Comparison groups	Desloratadine 5 mg v Placebo

Number of subjects included in analysis	536
Analysis specification	Pre-specified
Analysis type	superiority[3]
P-value	< 0.001
Method	ANOVA
Parameter estimate	Mean difference (final values)
Point estimate	-0.88
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.31
upper limit	-0.46

Notes:

[3] - LS means, SEM, and 95% Confidence Intervals are obtained from an ANOVA model with treatment and site effects.

Secondary: Change From Baseline in the Rhinoconjunctivitis Quality of Life Questionnaire-Standardized Version (RQLQ-S) at the Final Visit

End point title	Change From Baseline in the Rhinoconjunctivitis Quality of Life Questionnaire-Standardized Version (RQLQ-S) at the Final Visit

End point description:

The RQLQ-S questionnaire consists of 28 questions grouped into 7 domains. Each question is scored on a scale of 0 (not troubled with symptoms) to 6 (extremely troubled with symptoms). The total RQLQ-S score is the average score of the 28 questions which consisted of a total of 7 domains.

End point type	Secondary

End point timeframe:

Baseline and 15 days

End point values	Desloratadine 5 mg	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	250[4]	248[5]		
Units: Scores on a scale				
least squares mean (standard error)	-1.1 (± 0.1)	-0.73 (± 0.1)		

Notes:

[4] - Participant >=18 years of age and where available in the local language.

[5] - Participants >=18 years of age and where available in the local language.

Statistical analyses

Statistical analysis title	Treatment Difference

Statistical analysis description:

Difference in the least squares means between change from baseline in RQLQ-S for participants taking desloratadine at Day 15 of treatment vs. change from baseline in RQLQ-S for participants taking placebo at Day 15 of treatment. Negative differences are in favor of the desloratadine treatment group in the comparison.

Comparison groups	Desloratadine 5 mg v Placebo

Number of subjects included in analysis	498
Analysis specification	Pre-specified
Analysis type	superiority[6]
P-value	< 0.001
Method	ANOVA
Parameter estimate	Mean difference (final values)
Point estimate	-0.37
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.58
upper limit	-0.17

Notes:

[6] - LS means, SEM, and 95% Confidence Intervals are obtained from an ANOVA model with treatment and site effects.

Other pre-specified: Total 5 Symptom Score (T5SS) - Average AM/PM PRIOR (Reflective) 12 Hours Diary: BASELINE

End point title	Total 5 Symptom Score (T5SS) - Average AM/PM PRIOR (Reflective) 12 Hours Diary: BASELINE

End point description:

AM/PM is the average of separate morning (AM) and evening (PM) evaluations. T5SS = the sum of the individual scores for nasal congestion/stuffiness, sneezing, rhinorrhea/nasal discharge, nasal pruritis, and ocular pruritis. Each individual symptom/sign was scored from 0 (none) to 3 (severe).

End point type	Other pre-specified

End point timeframe:

Baseline

End point values	Desloratadine 5 mg	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	271[7]	265[8]		
Units: Scores on a scale				
least squares mean (standard error)	8.5 (± 0.14)	8.33 (± 0.14)		

Notes:

[7] - All participants with a non-missing baseline and at least some post-baseline data.

[8] - All particants with a non-missing baseline and at least some post-baseline data.

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Rhinoconjunctivitis Quality of Life Questionnaire-Standardized Version (RQLQ-S: BASELINE)

End point title	Rhinoconjunctivitis Quality of Life Questionnaire-Standardized Version (RQLQ-S: BASELINE)

End point description:

The RQLQ-S questionnaire consists of 28 questions grouped into 7 domains. Each question is scored on a scale of 0 (not troubled with symptoms) to 6 (extremely troubled with symptoms). The total RQLQ-S score is the average score of the 28 questions which consisted of a total of 7 domains.

End point type	Other pre-specified

End point timeframe:
Baseline

End point values	Desloratadine 5 mg	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	250[9]	248[10]		
Units: Scores on a scale				
least squares mean (standard error)	2.96 (± 0.08)	2.8 (± 0.08)		

Notes:
[9] - All participants >=18 years of age and where available in the local language.
[10] - All participants >=18 years of age and where available in the local language.

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events: Up to Day 15	
Assessment type	Systematic
Dictionary used	
Dictionary name	MedDRA
Dictionary version	12.0
Reporting groups	
Reporting group title	Desloratadine 5 mg
Reporting group description: -	
Reporting group title	Placebo
Reporting group description: -	

Serious adverse events	Desloratadine 5 mg	Placebo	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 276 (0.00%)	0 / 271 (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	Desloratadine 5 mg	Placebo	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	18 / 276 (6.52%)	17 / 271 (6.27%)	
Nervous system disorders			
Headache			
subjects affected / exposed	18 / 276 (6.52%)	17 / 271 (6.27%)	
occurrences (all)	23	21	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
14 June 2006	This amendment provided an updated version of a study questionnaire.
05 June 2007	This amendment changed criteria for subject discontinuation from the study and changed the grading scale for a study assessment.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported