Study for the Treatment of Chronic Idiopathic Urticaria With High Doses of AERIUS (Desloratadine) (Study P04849)

This study has been completed.

Sponsor:
Merck Sharp & Dohme Corp.

Information provided by (Responsible Party):
Merck Sharp & Dohme Corp.

ClinicalTrials.gov Identifier:
NCT00536380

First received: September 26, 2007
Last updated: October 15, 2015
Last verified: October 2015
History of Changes

Purpose

This study will investigate the effectiveness of desloratadine at doses higher (10 mg and 20 mg) than currently approved (5 mg) for the treatment of chronic idiopathic urticaria. Subjects with chronic urticaria who are currently taking a second generation antihistamine will be treated with desloratadine (5, 10, or 20 mg) for 28 days.

Condition	Intervention	Phase
Chronic Idiopathic Urticaria	Drug: 5-mg Desloratadine Drug: 10-mg Desloratadine Drug: 20-mg Desloratadine	Phase 4

Study Type: Interventional
Study Design: Allocation: Randomized
Endpoint Classification: Safety/Efficacy Study
Intervention Model: Parallel Assignment
Masking: Double Blind (Subject, Caregiver, Investigator, Outcomes Assessor)
Primary Purpose: Treatment

Official Title: A Study of the Efficacy, Safety, and Quality of Life (QOL) in Patients With Chronic Idiopathic Urticaria Dosed With AERIUS Tablets (Desloratadine 5 mg, 10 mg, or 20 mg Once Daily)

Resource links provided by NLM:

MedlinePlus related topics: Hives

Drug Information available for: Desloratadine

U.S. FDA Resources

Further study details as provided by Merck Sharp & Dohme Corp.:

Primary Outcome Measures:

- Change in the Urticaria Activity Score (UAS) From Baseline to the Final Week for Desloratadine 5 mg Versus Desloratadine 20 mg
  [Time Frame: Baseline and 4 treatment weeks] [Designated as safety issue: No]

  The UAS is a composite diary-recorded score. The diary recorded scores included wheal score and pruritus score with numeric severity intensity ratings of 0 = none to 3 = intense. The scoring was to be done twice daily within one hour of arising and in the evening, approximately 12 hours later. Scoring was "reflective", covering the 12-hour period since the previous recording. The daily UAS is the average of the morning and evening scores. The final week by definition was the terminal week. It was the last week participants stayed for the treatment period.

Enrollment:	314
Study Start Date:	September 2007
Study Completion Date:	April 2009
Primary Completion Date:	April 2009 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: 5-mg Desloratadine 5-mg Desloratadine once daily	Drug: 5-mg Desloratadine 5-mg desloratadine tablets, once daily for four weeks. Other Name: SCH 34117, Clarinex, Aerius
Experimental: 10-mg Desloratadine 10-mg Desloratadine once daily	Drug: 10-mg Desloratadine 10-mg desloratadine tablets, once daily for four weeks. Other Name: SCH 34117, Clarinex, Aerius
Experimental: 20-mg Desloratadine 20-mg Desloratadine once daily	Drug: 20-mg Desloratadine 20-mg desloratadine tablets, once daily for four weeks. Other Name: SCH 34117, Clarinex, Aerius

Eligibility

Ages Eligible for Study:	18 Years to 75 Years
Genders Eligible for Study:	Both
Accepts Healthy Volunteers:	No

Criteria

Inclusion Criteria:

- Subjects must satisfy the following criteria before being enrolled/randomized into the study.
- Subject must demonstrate willingness to participate in the study.
- Subject must be 18 to 75 years of age, of either gender, and any race.
- Subject must have had this episode of chronic idiopathic urticaria for at least 6 weeks or more, and has been dosing with a "2nd generation antihistamine (AH)" for 2 weeks or longer, and
- Subject's current episode of urticaria is sufficiently symptomatic at the Screening Visit to qualify for this study, in the opinion of the investigator.
- Subject has a Baseline Week (entry period) UAS between 10 and 30 inclusive.
- Patient must understand and be willing to assess and record symptom scores.
- Has voluntarily signed a written informed consent.
- Subjects must confirm that all prior medication washout times have been observed.
- Subject must confirm that he/she is practicing adequate contraception:

Female volunteers of childbearing potential (including women who are less than 1 year postmenopausal and women who will be sexually active during the study) must agree to use a medically accepted method of contraception or be surgically sterilized prior to screening, while receiving protocol-specified medication, and for 30 days after stopping the medication. Women who are postmenopausal for >1 year (i.e., women who have experienced 12 consecutive months of amenorrhea) will be exempted from the use of contraception during the study. Nonsterile or premenopausal female subjects must be using a medically accepted method of birth control, ie, double-barrier method (eg, male or female condom and spermicide), oral contraceptive, Depo-Provera, NuvaRing, contraceptive transdermal patch, etc, for female subjects of childbearing potential prior to screening and during the study. Women of childbearing potential should be counseled in the appropriate use of birth control while in the study. Vasectomy or tubal ligation is considered a single barrier. Women who are not currently sexually active must agree and consent to use one of the

above-mentioned methods if they become sexually active while participating in the study.

- If subject is a female volunteer of childbearing potential, she must have a negative urine pregnancy test at Screening/Visit 1.
- Subjects must be free of any clinically relevant disease other than chronic idiopathic urticaria (CIU) that would, in the principal investigator's and/or sponsor's opinion, interfere with the conduct of the study or study evaluations.
- Subjects must be able to adhere to the dosing and visit schedules and agree to record symptom severity scores, medication times, concomitant medications, and adverse events (AEs) accurately and consistently in a daily diary.

Exclusion Criteria:

- Is a female who is pregnant, or intends to become pregnant during the study.
- Is nursing, or intends to be nursing during the study or within 90 days after study completion.
- Has not observed the designated washout periods for any of the prohibited medications.
- Has used any investigational product within 30 days prior to enrollment.
- Have any of the following clinical conditions:
  - Symptomatic seasonal or perennial allergic rhinitis.
  - Asthma not controlled by short-acting beta-2 agonists used as necessary.
  - The presence of permanent severe diseases, especially those affecting the immune system, except urticaria.
  - The presence of a permanent gastrointestinal condition which may influence the oral therapy (chronic diarrhea diseases, congenital malformations or surgical mutilations of gastrointestinal tract).
  - History of/or presence of epilepsy, significant neurological disorders, cerebrovascular attacks or ischemia.
  - History of/or presence of myocardial infarction or cardiac arrhythmia which requires drug therapy.
  - Evidence of/or a history of significant renal disease.
  - Evidence of/or a history of significant hepatic disease.
  - Presence of cancer which requires chemotherapy or radiation therapy.
  - Presence of glaucoma.
  - Presence of urinary bladder neck obstruction with emptying difficulties.
  - Presence of acute urticaria .
  - Body mass index (BMI) > 35
- Has any clinically significant deviation from the appropriate reference range in the physical examination, or other clinical evaluation that, in the investigator's judgment, may interfere with the study evaluation or affect subject safety.
- Is in a situation or condition that, in the opinion of the investigator, may interfere with optimal participation in the study.
- Is participating in any other clinical study(ies).
- Is on the staff, affiliated with, or a family member of the staff personnel directly involved with this study.
- Is allergic to or has a history of hypersensitivity to the study drug (desloratadine), to any of its excipients, or to loratadine.
- Has the rare hereditary problem of galactose intolerance, the Lapp lactase deficiency, or glucose-galactose malabsorption.

Contacts and Locations

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the Contacts provided below. For general information, see Learn About Clinical Studies.

No Contacts or Locations Provided

More Information

No publications provided

Responsible Party:	Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier:	NCT00536380 History of Changes
Other Study ID Numbers:	P04849
Study First Received:	September 26, 2007
Results First Received:	February 24, 2010
Last Updated:	October 15, 2015
Health Authority:	Germany: German Health Authority

Additional relevant MeSH terms:

Urticaria
Hypersensitivity
Hypersensitivity, Immediate
Immune System Diseases
Skin Diseases
Skin Diseases, Vascular
Desloratadine
Cholinergic Agents
Cholinergic Antagonists
Histamine Agents
Histamine Antagonists
Histamine H1 Antagonists
Histamine H1 Antagonists, Non-Sedating
Molecular Mechanisms of Pharmacological Action
Neurotransmitter Agents
Pharmacologic Actions
Physiological Effects of Drugs

ClinicalTrials.gov processed this record on April 10, 2016

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Results First Received: February 24, 2010

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Caregiver, Investigator, Outcomes Assessor); Primary Purpose: Treatment
Condition:	Chronic Idiopathic Urticaria
Interventions:	Drug: 5-mg Desloratadine Drug: 10-mg Desloratadine Drug: 20-mg Desloratadine

Participant Flow

Hide Participant Flow

Recruitment Details

Key information relevant to the recruitment process for the overall study, such as dates of the recruitment period and locations
No text entered.

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment
No text entered.

Reporting Groups

	Description
5-mg Desloratadine	5-mg Desloratadine once daily
10-mg Desloratadine	10-mg Desloratadine once daily
20-mg Desloratadine	20-mg Desloratadine once daily

Participant Flow: Overall Study

	5-mg Desloratadine	10-mg Desloratadine	20-mg Desloratadine
STARTED	**106**	**104**	**104**
COMPLETED	**94**	**95**	**94**
NOT COMPLETED	**12**	**9**	**10**
Adverse Event	**0**	**2**	**2**
Lost to Follow-up	**0**	**0**	**1**
Withdrawal unrelated to study drug	**2**	**0**	**1**
Withdrawal related to study drug	**7**	**5**	**2**
Noncompliance with protocol	**3**	**2**	**2**
Did not meet protocol eligibility	**0**	**0**	**1**
Administrative	**0**	**0**	**1**

Baseline Characteristics

Hide Baseline Characteristics

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
No text entered.

Reporting Groups

	Description
5-mg Desloratadine	5-mg Desloratadine once daily
10-mg Desloratadine	10-mg Desloratadine once daily
20-mg Desloratadine	20-mg Desloratadine once daily
Total	Total of all reporting groups

Baseline Measures

	5-mg Desloratadine	10-mg Desloratadine	20-mg Desloratadine	Total

Number of Participants [units: participants]	**106**	**104**	**104**	**314**
Age [units: years] Mean (Standard Deviation)	**41.4 (12.8)**	**40.4 (13.3)**	**40.1 (14.2)**	**40.6 (13.4)**
Gender [units: participants]				
Female	**70**	**69**	**70**	**209**
Male	**36**	**35**	**34**	**105**

Outcome Measures

1. Primary: Change in the Urticaria Activity Score (UAS) From Baseline to the Final Week for Desloratadine 5 mg Versus Desloratadine 20 mg [Time Frame: Baseline and 4 treatment weeks]

Hide Outcome Measure 1

Measure Type	Primary
Measure Title	Change in the Urticaria Activity Score (UAS) From Baseline to the Final Week for Desloratadine 5 mg Versus Desloratadine 20 mg
Measure Description	The UAS is a composite diary-recorded score. The diary recorded scores included wheal score and pruritus score with numeric severity intensity ratings of 0 = none to 3 = intense. The scoring was to be done twice daily within one hour of arising and in the evening, approximately 12 hours later. Scoring was “reflective”, covering the 12-hour period since the previous recording. The daily UAS is the average of the morning and evening scores. The final week by definition was the terminal week. It was the last week participants stayed for the treatment period.
Time Frame	Baseline and 4 treatment weeks
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Intent to treat population

Reporting Groups

	Description
5-mg Desloratadine	5-mg Desloratadine once daily
20-mg Desloratadine	20-mg Desloratadine once daily
10-mg Desloratadine	10-mg Desloratadine once daily

Measured Values

	5-mg Desloratadine	**20-mg Desloratadine**	**10-mg Desloratadine**
Number of Participants Analyzed [units: participants]	**104**	**100**	**104**
Change in the Urticaria Activity Score (UAS) From Baseline to the Final Week for			

Desloratadine 5 mg Versus Desloratadine 20 mg [units: Units on a scale] Least Squares Mean (Standard Error)			
Change from Baseline in UAS	-1.0 (0.12)	-1.0 (0.12)	-1.1 (0.12)
Baseline UAS (mean +/- standard deviation)	2.9 (0.82)	2.8 (0.74)	2.9 (0.77)

Statistical Analysis 1 for Change in the Urticaria Activity Score (UAS) From Baseline to the Final Week for Desloratadine 5 mg Versus Desloratadine 20 mg

Groups [1]	5-mg Desloratadine vs. 20-mg Desloratadine
Method [2]	ANCOVA
P Value [3]	0.721

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	No text entered.
Additional Description	No text entered.

Reporting Groups

	Description
5-mg Desloratadine	5-mg Desloratadine once daily
10-mg Desloratadine	10-mg Desloratadine once daily
20-mg Desloratadine	20-mg Desloratadine once daily

Serious Adverse Events

	5-mg Desloratadine	10-mg Desloratadine	20-mg Desloratadine
Total, serious adverse events			
# participants affected / at risk	0/106 (0.00%)	1/104 (0.96%)	1/104 (0.96%)

Infections and infestations			
Pneumonia † 1			
# participants affected / at risk	**0/106 (0.00%)**	**1/104 (0.96%)**	**0/104 (0.00%)**
# events	**0**	**1**	**0**
Skin and subcutaneous tissue disorders			
Urticaria † 1			
# participants affected / at risk	**0/106 (0.00%)**	**0/104 (0.00%)**	**1/104 (0.96%)**
# events	**0**	**0**	**1**

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA (11.1)

Other Adverse Events

Hide Other Adverse Events

Time Frame	No text entered.
Additional Description	No text entered.

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
5-mg Desloratadine	5-mg Desloratadine once daily
10-mg Desloratadine	10-mg Desloratadine once daily
20-mg Desloratadine	20-mg Desloratadine once daily

Other Adverse Events

	5-mg Desloratadine	**10-mg Desloratadine**	**20-mg Desloratadine**
Total, other (not including serious) adverse events			
# participants affected / at risk	**5/106 (4.72%)**	**4/104 (3.85%)**	**6/104 (5.77%)**
Nervous system disorders			
Headache † 1			
# participants affected / at risk	**5/106 (4.72%)**	**4/104 (3.85%)**	**6/104 (5.77%)**
# events	**6**	**5**	**9**

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA (11.1)

Limitations and Caveats

Hide Limitations and Caveats

Limitations of the study, such as early termination leading to small numbers of participants analyzed and technical problems with measurement leading to unreliable or uninterpretable data

Due to poor enrollment (even after extending the enrollment period), only 314 participants (not 600 participants) were randomized to the study and hence the study was inconclusive due to the lacking of statistical power and robustness.

More Information

Hide More Information

Certain Agreements:

Principal Investigators are **NOT** employed by the organization sponsoring the study.

There **IS** an agreement between Principal Investigators and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.

The agreement is:

☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **less than or equal to 60 days**. The sponsor cannot require changes to the communication and cannot extend the embargo.

☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **more than 60 days but less than or equal to 180 days**. The sponsor cannot require changes to the communication and cannot extend the embargo.

Other disclosure agreement that restricts the right of the PI to discuss or publish trial results after the trial is completed.

☑ **Restriction Description:** PI agrees not to publish or publicly present any interim results of Study without prior written consent of sponsor. PI further agrees to provide 45 days written notice to sponsor prior to submission for publication or presentation to permit sponsor to review copies of abstracts or manuscripts for publication (including, without limitation, slides and text of oral or other public presentations and text of any transmission through any electronic media) which report any results of Study.

Results Point of Contact:

Name/Title: Senior Vice President, Global Clinical Development
Organization: Merck, Sharp & Dohme Corp.
e-mail: ClinicalTrialsDisclosure@merck.com

No publications provided

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