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Trial record **1 of 1** for: CIGE025ADE05

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Efficacy and Safety of Omalizumab in Adults (18-70 Years) With Moderate to Severe Chronic Urticaria

This study has been completed.

Sponsor:
Novartis

Information provided by (Responsible Party):
Novartis

ClinicalTrials.gov Identifier:
NCT00481676

First received: June 1, 2007
Last updated: September 14, 2011
Last verified: September 2011
History of Changes

Full Text View | Tabular View | **Study Results** | Disclaimer | How to Read a Study Record

Results First Received: December 17, 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 Urticaria
Interventions:	Drug: Omalizumab 75-375 mg Drug: Placebo to omalizumab Drug: Loratadine

	Drug: Clemastine

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
Omalizumab 75-375 mg	Omalizumab was dosed at 75 to 375 mg according to baseline IgE and body weight as described in dosing tables in the study protocol. Dosing occurred subcutaneously every 2 or 4 weeks depending on dose.
Placebo to Omalizumab	Placebo to omalizumab was dosed at 75 to 375 mg according to baseline IgE and body weight as described in dosing tables in the study protocol. Dosing occurred subcutaneously every 2 or 4 weeks depending on dose.

Participant Flow: Overall Study

	Omalizumab 75-375 mg	Placebo to Omalizumab
STARTED	**27**	**22**
COMPLETED	**25**	**17**
NOT COMPLETED	**2**	**5**
Adverse Event	**0**	**1**
Unsatisfactory therapeutic effect	**1**	**4**

Administrative problem	**1**	**0**

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
Omalizumab 75-375 mg	Omalizumab was dosed at 75 to 375 mg according to baseline IgE and body weight as described in dosing tables in the study protocol. Dosing occurred subcutaneously every 2 or 4 weeks depending on dose.
Placebo to Omalizumab	Placebo to omalizumab was dosed at 75 to 375 mg according to baseline IgE and body weight as described in dosing tables in the study protocol. Dosing occurred subcutaneously every 2 or 4 weeks depending on dose.
Total	Total of all reporting groups

Baseline Measures

	Omalizumab 75-375 mg	Placebo to Omalizumab	Total
Number of Participants [units: participants]	**27**	**22**	**49**
Age [units: years] Mean (Standard Deviation)	**39.1 (9.0)**	**42.3 (15.0)**	**40.5 (12.0)**
Gender [units: participants]			

Female	**19**	**19**	**38**
Male	**8**	**3**	**11**

Outcome Measures

Hide All Outcome Measures

1. Primary: Change in the Weekly Urticaria Activity Score (UAS7) From Baseline to the End of the Study (Week 24) [Time Frame: Baseline to end of the study (Week 24)]

Measure Type	Primary
Measure Title	Change in the Weekly Urticaria Activity Score (UAS7) From Baseline to the End of the Study (Week 24)
Measure Description	The UAS is a composite diary-recorded score with numeric severity ratings (0=none to 3=intense) for the number of wheals per 24 hours and the intensity of the pruritus. The total daily score (sum of the wheal and pruritus scores) ranges from 0 to 6. Because of variations in chronic urticaria disease intensity, assessment of disease activity was based on a weekly (7 days) UAS score called UAS7, that is, the sum of the daily UASs, ranging from 0 to 42 per week. A higher score indicates worse disease. A negative change score (Week 24 score minus Baseline score) indicates improvement.
Time Frame	Baseline to end of the study (Week 24)
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 (ITT) population: All randomized patients who received at least 1 dose of study drug and had at least 1 post-baseline assessment of the primary efficacy variable.

Reporting Groups

	Description

Omalizumab 75-375 mg	Omalizumab was dosed at 75 to 375 mg according to baseline IgE and body weight as described in dosing tables in the study protocol. Dosing occurred subcutaneously every 2 or 4 weeks depending on dose.
Placebo to Omalizumab	Placebo to omalizumab was dosed at 75 to 375 mg according to baseline IgE and body weight as described in dosing tables in the study protocol. Dosing occurred subcutaneously every 2 or 4 weeks depending on dose.

Measured Values

	Omalizumab 75-375 mg	**Placebo to Omalizumab**
Number of Participants Analyzed [units: participants]	**27**	**22**
Change in the Weekly Urticaria Activity Score (UAS7) From Baseline to the End of the Study (Week 24) [units: Units on a scale] Mean (Standard Deviation)	**-17.8 (10.52)**	**-5.8 (11.52)**

No statistical analysis provided for Change in the Weekly Urticaria Activity Score (UAS7) From Baseline to the End of the Study (Week 24)

2. Secondary: Number of Patients With Wheals, Erythemas, Pruritus, and Angioedemas at the End of the Study [Time Frame: At the end of the study (Week 24)]

Measure Type	Secondary
Measure Title	Number of Patients With Wheals, Erythemas, Pruritus, and Angioedemas at the End of the Study
Measure Description	Patients kept a daily diary of the number of wheals and erythema and the severity of pruritus and angioedemas during the study.
Time Frame	At the end of the study (Week 24)
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 (ITT) population: All randomized patients who received at least 1 dose of study drug and had at least 1 post-baseline assessment of the primary efficacy variable.

Reporting Groups

	Description
Omalizumab 75-375 mg	Omalizumab was dosed at 75 to 375 mg according to baseline IgE and body weight as described in dosing tables in the study protocol. Dosing occurred subcutaneously every 2 or 4 weeks depending on dose.
Placebo to Omalizumab	Placebo to omalizumab was dosed at 75 to 375 mg according to baseline IgE and body weight as described in dosing tables in the study protocol. Dosing occurred subcutaneously every 2 or 4 weeks depending on dose.

Measured Values

	Omalizumab 75-375 mg	**Placebo to Omalizumab**
Number of Participants Analyzed [units: participants]	**27**	**22**
Number of Patients With Wheals, Erythemas, Pruritus, and Angioedemas at the End of the Study [units: Participants]		
Wheals - None	**19**	**1**
Wheals - < 10	**3**	**11**
Wheals - 10-50	**1**	**3**
Wheals - > 50	**1**	**1**
Erythemas - None	**18**	**4**
Erythemas - < 10	**4**	**7**
Erythemas - 10-50	**1**	**4**

Erythemas - > 50	**1**	**1**
Pruritus - None	**16**	**2**
Pruritus - Mild	**4**	**8**
Pruritus - Moderate	**3**	**3**
Pruritus - Severe	**1**	**3**
Angioedema - None	**21**	**8**
Angioedema - Mild	**1**	**6**
Angioedema - Moderate	**0**	**1**
Angioedema - Severe	**2**	**1**

No statistical analysis provided for Number of Patients With Wheals, Erythemas, Pruritus, and Angioedemas at the End of the Study

3. Secondary: Standardized (With Respect to Length of Time) Area Under the Curve (AUC) for the Urticaria Activity Score (UAS) From Baseline to the End of the Study (Week 24) [Time Frame: Baseline to the end of the study (Week 24)]

Measure Type	Secondary
Measure Title	Standardized (With Respect to Length of Time) Area Under the Curve (AUC) for the Urticaria Activity Score (UAS) From Baseline to the End of the Study (Week 24)
Measure Description	The UAS is a composite diary-recorded score with numeric severity ratings (0=none to 3=intense) for the number of wheals per 24 hours and the intensity of the pruritus. The total daily score (sum of the wheal and pruritus scores) ranges from 0 to 6. A higher score indicates worse disease. AUC was calculated from daily UASs where no urticaria medication was taken using the trapezoidal rule. The standardized AUC UAS was calculated as the sum of trapezoids divided by the length of time.
Time Frame	Baseline to the end of the study (Week 24)
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 (ITT) population: All randomized patients who received at least 1 dose of study drug and had at least 1 post-baseline assessment of the primary efficacy variable.

Reporting Groups

	Description
Omalizumab 75-375 mg	Omalizumab was dosed at 75 to 375 mg according to baseline IgE and body weight as described in dosing tables in the study protocol. Dosing occurred subcutaneously every 2 or 4 weeks depending on dose.
Placebo to Omalizumab	Placebo to omalizumab was dosed at 75 to 375 mg according to baseline IgE and body weight as described in dosing tables in the study protocol. Dosing occurred subcutaneously every 2 or 4 weeks depending on dose.

Measured Values

	Omalizumab 75-375 mg	**Placebo to Omalizumab**
Number of Participants Analyzed [units: participants]	**27**	**21**
Standardized (With Respect to Length of Time) Area Under the Curve (AUC) for the Urticaria Activity Score (UAS) From Baseline to the End of the Study (Week 24) [units: Units on a scale] Mean (Standard Deviation)	**1.0 (1.28)**	**2.5 (1.23)**

No statistical analysis provided for Standardized (With Respect to Length of Time) Area Under the Curve (AUC) for the Urticaria Activity Score (UAS) From Baseline to the End of the Study (Week 24)

4. Secondary: Use of Concomitant and Rescue Medications [Time Frame: At Weeks 4, 8, 12, 16, 20, and 24]

Measure Type	Secondary

Measure Title	Use of Concomitant and Rescue Medications
Measure Description	Data was collected from the patients' diaries about the number of clemastine and loratadine pills taken during the last 7 days of each month of the study.
Time Frame	At Weeks 4, 8, 12, 16, 20, and 24
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 (ITT) population: All randomized patients who received at least 1 dose of study drug and had at least 1 post-baseline assessment of the primary efficacy variable.

Reporting Groups

	Description
Omalizumab 75-375 mg	Omalizumab was dosed at 75 to 375 mg according to baseline IgE and body weight as described in dosing tables in the study protocol. Dosing occurred subcutaneously every 2 or 4 weeks depending on dose.
Placebo to Omalizumab	Placebo to omalizumab was dosed at 75 to 375 mg according to baseline IgE and body weight as described in dosing tables in the study protocol. Dosing occurred subcutaneously every 2 or 4 weeks depending on dose.

Measured Values

	Omalizumab 75-375 mg	**Placebo to Omalizumab**
Number of Participants Analyzed [units: participants]	**27**	**22**
Use of Concomitant and Rescue Medications [units: Pills] Mean (Standard Deviation)		
Week 4 - clemastine (N=27,21)	**0.7 (3.10)**	**3.7 (5.30)**
Week 4 - loratadine (N=27,22)	**1.3 (2.51)**	**4.2 (2.61)**

Week 8 - clemastine (N=26,20)	**1.3 (4.05)**	**2.4 (3.69)**
Week 8 - loratadine (N=26,21)	**1.2 (2.45)**	**4.2 (2.62)**
Week 12 - clemastine (N=25,17)	**1.1 (3.81)**	**1.8 (3.80)**
Week 12 - loratadine (N=25,19)	**1.2 (2.33)**	**3.3 (2.64)**
Week 16 - clemastine (N=24,16)	**0.2 (0.72)**	**1.4 (2.13)**
Week 16 - loratadine (N=24,17)	**0.6 (1.56)**	**3.6 (3.00)**
Week 20 - clemastine (N=24,16)	**0.9 (3.88)**	**2.2 (2.88)**
Week 20 - loratadine (N=24,17)	**0.5 (1.47)**	**4.6 (3.48)**
Week 24 - clemastine (N=23,14)	**0.7 (2.72)**	**1.4 (2.13)**
Week 24 - clemastine (N=23,16)	**0.3 (1.11)**	**3.3 (2.50)**

No statistical analysis provided for Use of Concomitant and Rescue Medications

5. Secondary: Change in the Dermatology Life Quality Index (DLQI) Score From Baseline to the End of the Study (Week 24) [Time Frame: Baseline to the end of the study (Week 24)]

Measure Type	Secondary
Measure Title	Change in the Dermatology Life Quality Index (DLQI) Score From Baseline to the End of the Study (Week 24)
Measure Description	The DLQI is a dermatology-specific quality of life (QoL) questionnaire designed for use in patients over 16 years of age. Patients are asked to respond to each of 10 questions on a 4-point Likert scale in regard to how much their skin problem has affected their life over the last week (0=not at all, 1=a little, 2=a lot, 3=very much). The overall (total) DLQI score (range=0 to 30) is calculated by summing the scores of all 10 questions. The higher the score, the more QoL is impaired. A negative change score (Week 24 score minus Baseline score) indicates improvement.
Time Frame	Baseline to the end of the study (Week 24)
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 (ITT) population: All randomized patients who received at least 1 dose of study drug and had at least 1 post-baseline assessment of the primary efficacy variable.

Reporting Groups

	Description
Omalizumab 75-375 mg	Omalizumab was dosed at 75 to 375 mg according to baseline IgE and body weight as described in dosing tables in the study protocol. Dosing occurred subcutaneously every 2 or 4 weeks depending on dose.
Placebo to Omalizumab	Placebo to omalizumab was dosed at 75 to 375 mg according to baseline IgE and body weight as described in dosing tables in the study protocol. Dosing occurred subcutaneously every 2 or 4 weeks depending on dose.

Measured Values

	Omalizumab 75-375 mg	**Placebo to Omalizumab**
Number of Participants Analyzed [units: participants]	**27**	**22**
Change in the Dermatology Life Quality Index (DLQI) Score From Baseline to the End of the Study (Week 24) [units: Units on a scale] Mean (Standard Deviation)		
Baseline (N=27, 22)	**10.1 (6.04)**	**9.8 (5.29)**
Week 24 (N=27,21)	**3.7 (7.12)**	**8.1 (6.11)**
Week 24 minus Baseline (N=27,21)	**-6.3 (8.36)**	**-1.5 (5.83)**

No statistical analysis provided for Change in the Dermatology Life Quality Index (DLQI) Score From Baseline to the End of the Study (Week 24)

6. Secondary: Change in the Skindex Score From Baseline to the End of the Study (Week 24) [Time Frame: Baseline to the end of the study (Week 24)]

Measure Type	Secondary
Measure Title	Change in the Skindex Score From Baseline to the End of the Study (Week 24)
Measure Description	Skindex is a 30-item questionnaire with 3 scores (functioning, emotions,symptoms) and a composite score (average scale score) that assesses the effects of skin disease on patients' quality of life (QoL). Item responses are standardized on a scale from 0 to 100. The mean of all 61 items was calculated. A higher score indicates a lower QoL. A negative change score (Week 24 score minus Baseline score) indicates improvement.
Time Frame	Baseline to the end of the study (Week 24)
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 (ITT) population: All randomized patients who received at least 1 dose of study drug and had at least 1 post-baseline assessment of the primary efficacy variable.

Reporting Groups

	Description
Omalizumab 75-375 mg	Omalizumab was dosed at 75 to 375 mg according to baseline IgE and body weight as described in dosing tables in the study protocol. Dosing occurred subcutaneously every 2 or 4 weeks depending on dose.
Placebo to Omalizumab	Placebo to omalizumab was dosed at 75 to 375 mg according to baseline IgE and body weight as described in dosing tables in the study protocol. Dosing occurred subcutaneously every 2 or 4 weeks depending on dose.

Measured Values

	Omalizumab 75-375 mg	**Placebo to Omalizumab**
Number of Participants Analyzed		

[units: participants]	**27**	**22**
Change in the Skindex Score From Baseline to the End of the Study (Week 24) [units: Units on a scale] Mean (Standard Deviation)		
Baseline (N=27,22)	**1.8 (0.69)**	**1.6 (0.53)**
Week 24 (N=27,21)	**0.9 (1.00)**	**1.5 (0.79)**
Week 24 minus Baseline (N=27,21)	**-0.9 (0.89)**	**-0.1 (0.61)**

No statistical analysis provided for Change in the Skindex Score From Baseline to the End of the Study (Week 24)

7. Secondary: Change in Chronic Urticaria Quality of Life (CU-Q2oL) Scores From Baseline to the End of the Study (Week 24) [Time Frame: Baseline to the end of the study (Week 24)]

Measure Type	Secondary
Measure Title	Change in Chronic Urticaria Quality of Life (CU-Q2oL) Scores From Baseline to the End of the Study (Week 24)
Measure Description	The CU-Q2oL (German version) is a questionnaire that measures the relative burden of chronic urticaria on subjective well-being. It has 23 questions in 3 domains (symptoms, general impairment, difficulties and problems due to urticaria). Patients are asked to respond how much they are troubled by each problem on a 5-point Likert scale (1=not at all to 5=very much). Each domain and the overall (total) scores are normalized to a scale of 1 to 100. A higher score indicates lower QoL. A negative change score (Week 24 score minus Baseline score) indicates improvement.
Time Frame	Baseline to the end of the study (Week 24)
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 (ITT) population: All randomized patients who received at least 1 dose of study drug and had at least 1 post-baseline

assessment of the primary efficacy variable.

Reporting Groups

	Description
Omalizumab 75-375 mg	Omalizumab was dosed at 75 to 375 mg according to baseline IgE and body weight as described in dosing tables in the study protocol. Dosing occurred subcutaneously every 2 or 4 weeks depending on dose.
Placebo to Omalizumab	Placebo to omalizumab was dosed at 75 to 375 mg according to baseline IgE and body weight as described in dosing tables in the study protocol. Dosing occurred subcutaneously every 2 or 4 weeks depending on dose.

Measured Values

	Omalizumab 75-375 mg	Placebo to Omalizumab
Number of Participants Analyzed [units: participants]	**27**	**22**
Change in Chronic Urticaria Quality of Life (CU-Q2oL) Scores From Baseline to the End of the Study (Week 24) [units: Units on a scale] Mean (Standard Deviation)		
Baseline : Limits Looks (N=27,21)	**31.5 (23.86)**	**34.5 (24.97)**
Baseline : Swelling/eating (N=27,22)	**21.8 (20.17)**	**26.7 (19.97)**
Baseline : Sleep (N=27,22)	**45.8 (24.02)**	**46.6 (23.91)**
Baseline : Mental status (N=27,22)	**42.6 (21.72)**	**42.4 (18.71)**
Baseline : Functioning (N=27,22)	**36.0 (22.47)**	**30.7 (15.88)**
Baseline : Itching/embarrassment (N=27,22)	**58.1 (18.97)**	**56.8 (14.80)**
Baseline : Total score (N=27,22)	**39.5 (16.34)**	**38.9 (8.87)**
Week 24 : Limits looks (N=27,21)	**17.1 (20.26)**	**23.2 (20.27)**
Week 24 : Swelling/eating (N=27,21)	**10.4 (23.58)**	**27.4 (23.92)**

Week 24 : Sleep (N=27,21)	**27.3 (29.73)**	**47.3 (27.36)**
Week 24 : Mental status (N=27,21)	**25.9 (27.77)**	**40.1 (25.22)**
Week 24 : Functioning (N=27,21)	**11.9 (22.43)**	**27.0 (20.73)**
Week 24 : Itching/embarrassment (N=27,21)	**22.9 (29.42)**	**57.4 (22.41)**
Week 24 : Total score (N=27,21)	**18.5 (22.66)**	**37.3 (16.22)**
Week 24 - Baseline: Limits looks (N=27,20)	**-14.4 (24.69)**	**-9.4 (18.08)**
Week 24 - Baseline: Swelling/eating (N=27,21)	**-11.3 (22.40)**	**-0.6 (18.74)**
Week 24 - Baseline: Sleep (N=27,21)	**-18.5 (27.05)**	**-0.6 (23.13)**
Week 24 - Baseline: Mental status (N=27,21)	**-16.7 (27.35)**	**-2.4 (19.57)**
Week 24 - Baseline: Functioning (N=27,21)	**-24.1 (23.94)**	**-3.8 (21.08)**
Week 24 - Baseline: itching/embarrassmen (N=27,21)	**-35.2 (32.71)**	**-0.9 (20.76)**
Week 24 - Baseline: Total score (N=27,21)	**-21.0 (21.97)**	**-2.3 (14.14)**

No statistical analysis provided for Change in Chronic Urticaria Quality of Life (CU-Q2oL) Scores From Baseline to the End of the Study (Week 24)

8. Secondary: Patient’s Global Assessment of Their Chronic Urticaria Symptoms [Time Frame: At Baseline and at the end of the study (Week 24)]

Measure Type	Secondary
Measure Title	Patient’s Global Assessment of Their Chronic Urticaria Symptoms
Measure Description	Patients made a global assessment of their chronic urticaria symptoms on a 4-point Likert scale (none, mild moderate, severe) at Baseline and again at the end of the study. The number of patients in each category is reported.
Time Frame	At Baseline and at the end of the study (Week 24)
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 (ITT) population: All randomized patients who received at least 1 dose of study drug and had at least 1 post-baseline assessment of the primary efficacy variable.

Reporting Groups

	Description
Omalizumab 75-375 mg	Omalizumab was dosed at 75 to 375 mg according to baseline IgE and body weight as described in dosing tables in the study protocol. Dosing occurred subcutaneously every 2 or 4 weeks depending on dose.
Placebo to Omalizumab	Placebo to omalizumab was dosed at 75 to 375 mg according to baseline IgE and body weight as described in dosing tables in the study protocol. Dosing occurred subcutaneously every 2 or 4 weeks depending on dose.

Measured Values

	Omalizumab 75-375 mg	**Placebo to Omalizumab**
Number of Participants Analyzed [units: participants]	**27**	**22**
Patient's Global Assessment of Their Chronic Urticaria Symptoms [units: Participants]		
Baseline: Missing	**0**	**0**
Baseline: No complaints	**3**	**0**
Baseline: Moderate complaints	**13**	**13**
Baseline: Severe complaints	**11**	**8**
Baseline: Maximum complaints	**0**	**1**
Week 24: Missing	**1**	**1**
Week 24: No complaints	**16**	**3**
Week 24: Moderate complaints	**6**	**7**

Week 24: Severe complaints	**3**	**9**
Week 24: Maximum complaints	**1**	**2**

No statistical analysis provided for Patient's Global Assessment of Their Chronic Urticaria Symptoms

9. Secondary: Investigator's Global Assessment of the Patient's Chronic Urticaria Symptoms [Time Frame: At Baseline and at the end of the study (Week 24)]

Measure Type	Secondary
Measure Title	Investigator's Global Assessment of the Patient's Chronic Urticaria Symptoms
Measure Description	The investigator made a global assessment of the patient's chronic urticaria symptoms on a 4-point Likert scale (none, mild, moderate, severe) at Baseline and again at the end of the study. The number of patients in each category is reported.
Time Frame	At Baseline and at the end of the study (Week 24)
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 (ITT) population: All randomized patients who received at least 1 dose of study drug and had at least 1 post-baseline assessment of the primary efficacy variable.

Reporting Groups

	Description
Omalizumab 75-375 mg	Omalizumab was dosed at 75 to 375 mg according to baseline IgE and body weight as described in dosing tables in the study protocol. Dosing occurred subcutaneously every 2 or 4 weeks depending on dose.
Placebo to Omalizumab	Placebo to omalizumab was dosed at 75 to 375 mg according to baseline IgE and body weight as described in

	dosing tables in the study protocol. Dosing occurred subcutaneously every 2 or 4 weeks depending on dose.

Measured Values

	Omalizumab 75-375 mg	Placebo to Omalizumab
Number of Participants Analyzed [units: participants]	**27**	**22**
Investigator's Global Assessment of the Patient's Chronic Urticaria Symptoms [units: Participants]		
Baseline: Missing	**1**	**0**
Baseline: None	**1**	**0**
Baseline: Mild	**7**	**9**
Baseline: Moderate	**13**	**6**
Baseline: Severe	**5**	**7**
Week 24: Missing	**0**	**1**
Week 24: None	**18**	**1**
Week 24: Mild	**6**	**9**
Week 24: Moderate	**1**	**4**
Week 24: Severe	**2**	**7**

No statistical analysis provided for Investigator's Global Assessment of the Patient's Chronic Urticaria Symptoms

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	No text entered.

Additional Description	No text entered.

Reporting Groups

	Description
Omalizumab 75-375 mg	Omalizumab was dosed at 75 to 375 mg according to baseline IgE and body weight as described in dosing tables in the study protocol. Dosing occurred subcutaneously every 2 or 4 weeks depending on dose.
Placebo to Omalizumab	Placebo to omalizumab was dosed at 75 to 375 mg according to baseline IgE and body weight as described in dosing tables in the study protocol. Dosing occurred subcutaneously every 2 or 4 weeks depending on dose.

Serious Adverse Events

	Omalizumab 75-375 mg	Placebo to Omalizumab
Total, serious adverse events		
# participants affected / at risk	**0/27 (0.00%)**	**2/22 (9.09%)**
Infections and infestations		
Eye Infection † 1		
# participants affected / at risk	**0/27 (0.00%)**	**1/22 (4.55%)**
Nervous system disorders		
Syncope † 1		
# participants affected / at risk	**0/27 (0.00%)**	**1/22 (4.55%)**
Skin and subcutaneous tissue disorders		
Angioedema † 1		
# participants affected / at risk	**0/27 (0.00%)**	**1/22 (4.55%)**

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

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
Omalizumab 75-375 mg	Omalizumab was dosed at 75 to 375 mg according to baseline IgE and body weight as described in dosing tables in the study protocol. Dosing occurred subcutaneously every 2 or 4 weeks depending on dose.
Placebo to Omalizumab	Placebo to omalizumab was dosed at 75 to 375 mg according to baseline IgE and body weight as described in dosing tables in the study protocol. Dosing occurred subcutaneously every 2 or 4 weeks depending on dose.

Other Adverse Events

	Omalizumab 75-375 mg	Placebo to Omalizumab
Total, other (not including serious) adverse events		
# participants affected / at risk	**19/27 (70.37%)**	**12/22 (54.55%)**
Gastrointestinal disorders		
Abdominal Pain † [1]		
# participants affected / at risk	**0/27 (0.00%)**	**2/22 (9.09%)**
Diarrhoea † [1]		
# participants affected / at risk	**4/27 (14.81%)**	**2/22 (9.09%)**
General disorders		

Injection Site Pain † 1		
# participants affected / at risk	**0/27 (0.00%)**	**1/22 (4.55%)**
Infections and infestations		
Gastroenteritis † 1		
# participants affected / at risk	**2/27 (7.41%)**	**0/22 (0.00%)**
Gastrointestinal Infection † 1		
# participants affected / at risk	**3/27 (11.11%)**	**2/22 (9.09%)**
Nasopharyngitis † 1		
# participants affected / at risk	**9/27 (33.33%)**	**11/22 (50.00%)**
Sinusitis † 1		
# participants affected / at risk	**3/27 (11.11%)**	**0/22 (0.00%)**
Musculoskeletal and connective tissue disorders		
Arthralgia † 1		
# participants affected / at risk	**3/27 (11.11%)**	**1/22 (4.55%)**
Back Pain † 1		
# participants affected / at risk	**1/27 (3.70%)**	**2/22 (9.09%)**
Nervous system disorders		
Headache † 1		
# participants affected / at risk	**10/27 (37.04%)**	**6/22 (27.27%)**
Psychiatric disorders		
Insomnia † 1		
# participants affected / at risk	**2/27 (7.41%)**	**0/22 (0.00%)**
Respiratory, thoracic and mediastinal disorders		
Cough † 1		
# participants affected / at risk	**2/27 (7.41%)**	**0/22 (0.00%)**

Skin and subcutaneous tissue disorders		
Angioedema † 1		
# participants affected / at risk	**0/27 (0.00%)**	**3/22 (13.64%)**
Eczema † 1		
# participants affected / at risk	**2/27 (7.41%)**	**2/22 (9.09%)**

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

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
No text entered.

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:** The terms and conditions of Novartis' agreements with its investigators may vary. However, Novartis does not prohibit any investigator from publishing. any publications from a single-site are postponed until the publication of the pooled date (ie, data from all sites) in the clinical trial.

Results Point of Contact:

Name/Title: Study Director
Organization: Novartis Pharmaceuticals
phone: 862 778-8300

No publications provided

Responsible Party:	Novartis
ClinicalTrials.gov Identifier:	NCT00481676 History of Changes
Other Study ID Numbers:	**CIGE025ADE05**
Study First Received:	June 1, 2007
Results First Received:	December 17, 2010
Last Updated:	September 14, 2011
Health Authority:	Germany: Federal Institute for Drugs and Medical Devices