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Trial record **1 of 1** for: CIGE025A2210

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A Study of Efficacy of New Doses of Xolair to Protect From Allergen Challenge in Groups of Asthma Patients Defined by IgE Levels

This study has been completed.

Sponsor:
Novartis

Collaborators:
Genentech, Inc.
Tanox

Information provided by:
Novartis

ClinicalTrials.gov Identifier:
NCT00624832

First received: February 18, 2008
Last updated: April 12, 2011
Last verified: April 2011
History of Changes

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Results First Received: January 21, 2011

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

Interventions:	Drug: Xolair Drug: Placebo

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
Xolair (Immunoglobulin E (IgE) = 30-300 IU/mL)	Patients with screening Immunoglobulin E (IgE) levels = 30-300 IU/mL. Participants received subcutaneous injections of Xolair (Omalizumab) every 2 weeks or every 4 weeks; dosage dependent on IgE level and body weight.
Xolair (Immunoglobulin E (IgE) = 700- 2000 IU/mL)	Patients with screening Immunoglobulin E (IgE) levels = 700- 2000 IU/mL. Participants received subcutaneous injections of Xolair (Omalizumab) every 2 weeks; dosage dependent on IgE level and body weight.
Xolair (Immunoglobulin E (IgE) = 301- 699 IU/mL)	Patients with screening Immunoglobulin E (IgE) levels = 301- 699 IU/mL. Participants received subcutaneous injections of Xolair (Omalizumab) every 2 weeks; dosage dependent on IgE level and body weight.
Placebo Comparator	By subcutaneous injection of a solution with a concentration of 125 mg/mL placebo in a supine position: Patients in Xolair (Immunoglobulin E (IgE) = 30-300 IU/mL) group received doses of 150 mg to 375 mg of placebo every 2 or 4 weeks for 12 or 14 weeks. Patients in Xolair (Immunoglobulin E (IgE) = 700- 2000 IU/mL) group received doses of

	450 mg, 525 mg, or 600 mg of placebo every 2 weeks for 14 weeks. Patients in Xolair (Immunoglobulin E (IgE) = 301- 699 IU/mL) group received doses of 225 mg to 375 mg of placebo every 2 weeks for 6 weeks.

Participant Flow: Overall Study

	Xolair (Immunoglobulin E (IgE) = 30-300 IU/mL)	Xolair (Immunoglobulin E (IgE) = 700- 2000 IU/mL)	Xolair (Immunoglobulin E (IgE) = 301- 699 IU/mL)	Placebo Comparator
STARTED	18	16	10	16
COMPLETED	16	15	10	15
NOT COMPLETED	2	1	0	1
Adverse Event	0	1	0	1
Abnormal Laboratory Value	2	0	0	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
Xolair (Immunoglobulin E (IgE) = 30-300 IU/mL)	Patients with screening Immunoglobulin E (IgE) levels = 30-300 IU/mL. Participants received subcutaneous injections of Xolair (Omalizumab) every 2 weeks or every 4 weeks; dosage dependent on IgE level and body weight.

Xolair (Immunoglobulin E (IgE) = 700- 2000 IU/mL)	Patients with screening Immunoglobulin E (IgE) levels = 700- 2000 IU/mL. Participants received subcutaneous injections of Xolair (Omalizumab) every 2 weeks; dosage dependent on IgE level and body weight.
Xolair (Immunoglobulin E (IgE) = 301- 699 IU/mL)	Patients with screening Immunoglobulin E (IgE) levels = 301- 699 IU/mL. Participants received subcutaneous injections of Xolair (Omalizumab) every 2 weeks; dosage dependent on IgE level and body weight.
Placebo Comparator	By subcutaneous injection of a solution with a concentration of 125 mg/mL placebo in a supine position: Patients in Xolair (Immunoglobulin E (IgE) = 30-300 IU/mL) group received doses of 150 mg to 375 mg of placebo every 2 or 4 weeks for 12 or 14 weeks. Patients in Xolair (Immunoglobulin E (IgE) = 700- 2000 IU/mL) group received doses of 450 mg, 525 mg, or 600 mg of placebo every 2 weeks for 14 weeks. Patients in Xolair (Immunoglobulin E (IgE) = 301- 699 IU/mL) group received doses of 225 mg to 375 mg of placebo every 2 weeks for 6 weeks.
Total	Total of all reporting groups

Baseline Measures

	Xolair (Immunoglobulin E (IgE) = 30-300 IU/mL)	Xolair (Immunoglobulin E (IgE) = 700- 2000 IU/mL)	Xolair (Immunoglobulin E (IgE) = 301- 699 IU/mL)	Placebo Comparator	Total
Number of Participants [units: participants]	**18**	**16**	**10**	**16**	**60**
Age [units: years] Mean (Standard Deviation)	**36 (11.9)**	**29 (11.0)**	**26 (6.0)**	**34 (10.4)**	**32 (10.9)**
Gender [units: participants]					
Female	**5**	**10**	**4**	**7**	**26**
Male	**13**	**6**	**6**	**9**	**34**

Outcome Measures

Hide All Outcome Measures

1. Primary: Early Phase Allergic Response After Treatment With Study Drug in Active and Placebo Patients [Time Frame: Week 8, Week 16]

Measure Type	Primary
Measure Title	Early Phase Allergic Response After Treatment With Study Drug in Active and Placebo Patients
Measure Description	The EAR was defined as the maximum percent drop in forced expiratory volume in one second (FEV1) in the first 30 minutes after the challenge: EAR = 100* [FEV1 (0) - Minimum FEV1 (10, 15, 30 min)] / FEV1 (0). For FEV1 (0), the ”best post saline (Control) FEV1” was used. The EAR was analyzed using a linear (ANCOVA) model with a fixed effect for treatment groups and the EAR from the baseline challenge was used as a covariate.
Time Frame	Week 8, Week 16
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.
Safety and Pharmacodynamic (PD) population. Although all patients had baseline EAR not all of them had a value determined for week 8 and 16 reducing the number evaluable for analysis particularly at week 8. Patients of first 2 Xolair groups received placebo treatment were pooled in one placebo group for analysis. No analysis on third Xolair groups.

Reporting Groups

	Description
Xolair (Immunoglobulin E (IgE) = 30-300 IU/mL)	Patients with screening Immunoglobulin E (IgE) levels = 30-300 IU/mL. Participants received subcutaneous injections of Xolair (Omalizumab) every 2 weeks or every 4 weeks; dosage dependent on IgE level and body weight.

Xolair (Immunoglobulin E (IgE) = 700- 2000 IU/mL)	Patients with screening Immunoglobulin E (IgE) levels = 700- 2000 IU/mL. Participants received subcutaneous injections of Xolair (Omalizumab) every 2 weeks; dosage dependent on IgE level and body weight.
Placebo Comparator	By subcutaneous injection of a solution with a concentration of 125 mg/mL placebo in a supine position: Patients in Xolair (Immunoglobulin E (IgE) = 30-300 IU/mL) group received doses of 150 mg to 375 mg of placebo every 2 or 4 weeks for 12 or 14 weeks. Patients in Xolair (Immunoglobulin E (IgE) = 700- 2000 IU/mL) group received doses of 450 mg, 525 mg, or 600 mg of placebo every 2 weeks for 14 weeks. Patients in Xolair (Immunoglobulin E (IgE) = 301- 699 IU/mL) group received doses of 225 mg to 375 mg of placebo every 2 weeks for 6 weeks.

Measured Values

	Xolair (Immunoglobulin E (IgE) = 30-300 IU/mL)	**Xolair (Immunoglobulin E (IgE) = 700- 2000 IU/mL)**	**Placebo Comparator**
Number of Participants Analyzed [units: participants]	**18**	**16**	**16**
Early Phase Allergic Response After Treatment With Study Drug in Active and Placebo Patients [units: Percentage of EAR] Least Squares Mean (Standard Error)			
Week 8 (n=12, 12, 13)	**9.3 (3.97)**	**5.6 (2.07)**	**23.1 (3.57)**
Week 16 (n=14, 15, 15)	**11.8 (3.81)**	**5.1 (2.02)**	**20.0 (2.43)**

No statistical analysis provided for Early Phase Allergic Response After Treatment With Study Drug in Active and Placebo Patients

2. Secondary: Late Phase Allergic Response After Treatment With Study Drug in Active and Placebo Patients [Time Frame: Week 0, Week 8 and Week 16]

Measure Type	Secondary

Measure Title	Late Phase Allergic Response After Treatment With Study Drug in Active and Placebo Patients
Measure Description	Late-phase allergic response (LAR) was only determined for those patients who had an LAR >= 15% at baseline allergen bronchoprovocation testing. For Forced Expiratory Volume, FEV1 (0), the "best post saline (Control) FEV1" was used. LAR (%) = 100*[FEV1 (0) - Minimum FEV1 (3-8h)]/FEV1 (0).
Time Frame	Week 0, Week 8 and Week 16
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.
Safety and Pharmacodynamic (PD) population. Although all patients had baseline EAR not all of them had a value determined for week 8 and 16 reducing the number evaluable for analysis particularly at week 8. Patients of first 2 Xolair groups received placebo treatment were pooled in one placebo group for analysis. No analysis on third Xolair groups.

Reporting Groups

	Description
Xolair (Immunoglobulin E (IgE) = 30-300 IU/mL)	Patients with screening Immunoglobulin E (IgE) levels = 30-300 IU/mL. Participants received subcutaneous injections of Xolair (Omalizumab) every 2 weeks or every 4 weeks; dosage dependent on IgE level and body weight.
Xolair (Immunoglobulin E (IgE) = 700- 2000 IU/mL)	Patients with screening Immunoglobulin E (IgE) levels = 700- 2000 IU/mL. Participants received subcutaneous injections of Xolair (Omalizumab) every 2 weeks; dosage dependent on IgE level and body weight.
Placebo Comparator	By subcutaneous injection of a solution with a concentration of 125 mg/mL placebo in a supine position: Patients in Xolair (Immunoglobulin E (IgE) = 30-300 IU/mL) group received doses of 150 mg to 375 mg of placebo every 2 or 4 weeks for 12 or 14 weeks. Patients in Xolair (Immunoglobulin E (IgE) = 700- 2000 IU/mL) group received doses of 450 mg, 525 mg, or 600 mg of placebo every 2 weeks for 14 weeks. Patients in Xolair (Immunoglobulin E (IgE) = 301- 699 IU/mL) group received doses of 225 mg to 375 mg of placebo every 2 weeks for 6 weeks.

Measured Values

	Xolair (Immunoglobulin E (IgE) = 30-300 IU/mL)	Xolair (Immunoglobulin E (IgE) = 700- 2000 IU/mL)	Placebo Comparator
Number of Participants Analyzed [units: participants]	**18**	**16**	**16**
Late Phase Allergic Response After Treatment With Study Drug in Active and Placebo Patients [units: Percentage of LAR] Mean (Standard Deviation)			
Week 0 (n=8, 3, 5)	**22.5 (6.12)**	**25.7 (12.62)**	**27.4 (7.27)**
Week 8 (n=6, 1, 3)	**5.3 (12.13)**	**-3.5 (0.0)**	**19.1 (13.42)**
Week 16 (n=7, 2, 4)	**0.23 (7.109)**	**1.5 (1.53)**	**12.3 (7.09)**

No statistical analysis provided for Late Phase Allergic Response After Treatment With Study Drug in Active and Placebo Patients

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	18- 26 weeks. Patients were dosed for 6 - 14 weeks depending on treatment group and adverse event data was collected until final study completion evaluation 12 weeks following last dose.
Additional Description	No text entered.

Reporting Groups

	Description
Xolair (IgE= 30- 300 IU/mL)	Patients with screening IgE levels= 30-300 IU/mL. Participants received subcutaneous injections of Xolair(Omalizumab) every 2 weeks or every 4 weeks; dosage dependent on IgE level and body weight.
Xolair (IgE= 700- 2000 IU/mL)	Patients with screening IgE levels= 700- 2000 IU/mL. Participants received subcutaneous injections of

	Xolair(Omalizumab) every 2 weeks; dosage dependent on IgE level and body weight.
Xolair (IgE= 301- 699 IU/mL)	Patients with screening IgE levels= 301- 699 IU/mL. Participants received subcutaneous injections of Xolair(Omalizumab) every 2 weeks; dosage dependent on IgE level and body weight.
Placebo Comparator	Placebo comparator

Serious Adverse Events

	Xolair (IgE= 30-300 IU/mL)	Xolair (IgE= 700-2000 IU/mL)	Xolair (IgE= 301-699 IU/mL)	Placebo Comparator
Total, serious adverse events				
# participants affected / at risk	**1/18 (5.56%)**	**1/16 (6.25%)**	**0/10 (0.00%)**	**0/16 (0.00%)**
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
Malignant melanoma † 1				
# participants affected / at risk	**0/18 (0.00%)**	**1/16 (6.25%)**	**0/10 (0.00%)**	**0/16 (0.00%)**
Papilloma † 1				
# participants affected / at risk	**1/18 (5.56%)**	**0/16 (0.00%)**	**0/10 (0.00%)**	**0/16 (0.00%)**

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

Other Adverse Events

Hide Other Adverse Events

Time Frame	18- 26 weeks. Patients were dosed for 6 - 14 weeks depending on treatment group and adverse event data was collected until final study completion evaluation 12 weeks following last dose.
Additional Description	No text entered.

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
Xolair (IgE= 30- 300 IU/mL)	Patients with screening IgE levels= 30-300 IU/mL. Participants received subcutaneous injections of Xolair(Omalizumab) every 2 weeks or every 4 weeks; dosage dependent on IgE level and body weight.
Xolair (IgE= 700- 2000 IU/mL)	Patients with screening IgE levels= 700- 2000 IU/mL. Participants received subcutaneous injections of Xolair(Omalizumab) every 2 weeks; dosage dependent on IgE level and body weight.
Xolair (IgE= 301- 699 IU/mL)	Patients with screening IgE levels= 301- 699 IU/mL. Participants received subcutaneous injections of Xolair(Omalizumab) every 2 weeks; dosage dependent on IgE level and body weight.
Placebo Comparator	Placebo comparator

Other Adverse Events

	Xolair (IgE= 30- 300 IU/mL)	Xolair (IgE= 700- 2000 IU/mL)	Xolair (IgE= 301- 699 IU/mL)	Placebo Comparator
Total, other (not including serious) adverse events				
# participants affected / at risk	**9/18 (50.00%)**	**15/16 (93.75%)**	**6/10 (60.00%)**	**12/16 (75.00%)**
Blood and lymphatic system disorders				
Lymphadenopathy † [1]				
# participants affected / at risk	**0/18 (0.00%)**	**1/16 (6.25%)**	**0/10 (0.00%)**	**0/16 (0.00%)**
Cardiac disorders				
Tachycardia † [1]				
# participants affected / at risk	**0/18 (0.00%)**	**0/16 (0.00%)**	**0/10 (0.00%)**	**1/16 (6.25%)**
Ear and labyrinth disorders				
Ear pain † [1]				

# participants affected / at risk	**0/18 (0.00%)**	**1/16 (6.25%)**	**0/10 (0.00%)**	**0/16 (0.00%)**
Vertigo † [1]				
# participants affected / at risk	**2/18 (11.11%)**	**0/16 (0.00%)**	**0/10 (0.00%)**	**1/16 (6.25%)**
Eye disorders				
Conjunctivitis † [1]				
# participants affected / at risk	**1/18 (5.56%)**	**0/16 (0.00%)**	**1/10 (10.00%)**	**2/16 (12.50%)**
Conjunctivitis allergic † [1]				
# participants affected / at risk	**0/18 (0.00%)**	**0/16 (0.00%)**	**2/10 (20.00%)**	**0/16 (0.00%)**
Eye irritation † [1]				
# participants affected / at risk	**1/18 (5.56%)**	**0/16 (0.00%)**	**0/10 (0.00%)**	**0/16 (0.00%)**
Eye pruritus † [1]				
# participants affected / at risk	**1/18 (5.56%)**	**0/16 (0.00%)**	**0/10 (0.00%)**	**0/16 (0.00%)**
Gastrointestinal disorders				
Abdominal pain † [1]				
# participants affected / at risk	**0/18 (0.00%)**	**1/16 (6.25%)**	**0/10 (0.00%)**	**0/16 (0.00%)**
Diarrhoea † [1]				
# participants affected / at risk	**0/18 (0.00%)**	**1/16 (6.25%)**	**0/10 (0.00%)**	**1/16 (6.25%)**
Dry mouth † [1]				
# participants affected / at risk	**0/18 (0.00%)**	**1/16 (6.25%)**	**0/10 (0.00%)**	**0/16 (0.00%)**
Dyspepsia † [1]				
# participants affected / at risk	**0/18 (0.00%)**	**0/16 (0.00%)**	**0/10 (0.00%)**	**1/16 (6.25%)**
Gastrointestinal disorder † [1]				
# participants affected / at risk	**0/18 (0.00%)**	**0/16 (0.00%)**	**0/10 (0.00%)**	**1/16 (6.25%)**
Nausea † [1]				
# participants affected / at risk	**0/18 (0.00%)**	**1/16 (6.25%)**	**0/10 (0.00%)**	**1/16 (6.25%)**

Toothache † [1]				
# participants affected / at risk	**1/18 (5.56%)**	**0/16 (0.00%)**	**0/10 (0.00%)**	**0/16 (0.00%)**
Vomiting † [1]				
# participants affected / at risk	**0/18 (0.00%)**	**1/16 (6.25%)**	**0/10 (0.00%)**	**0/16 (0.00%)**
General disorders				
Fatigue † [1]				
# participants affected / at risk	**0/18 (0.00%)**	**1/16 (6.25%)**	**0/10 (0.00%)**	**2/16 (12.50%)**
Infusion site erythema † [1]				
# participants affected / at risk	**1/18 (5.56%)**	**2/16 (12.50%)**	**0/10 (0.00%)**	**0/16 (0.00%)**
Infusion site haematoma † [1]				
# participants affected / at risk	**0/18 (0.00%)**	**1/16 (6.25%)**	**0/10 (0.00%)**	**0/16 (0.00%)**
Infusion site induration † [1]				
# participants affected / at risk	**0/18 (0.00%)**	**1/16 (6.25%)**	**0/10 (0.00%)**	**0/16 (0.00%)**
Infusion site irritation † [1]				
# participants affected / at risk	**0/18 (0.00%)**	**0/16 (0.00%)**	**1/10 (10.00%)**	**0/16 (0.00%)**
Infusion site swelling † [1]				
# participants affected / at risk	**0/18 (0.00%)**	**1/16 (6.25%)**	**0/10 (0.00%)**	**0/16 (0.00%)**
Infusion site warmth † [1]				
# participants affected / at risk	**0/18 (0.00%)**	**1/16 (6.25%)**	**0/10 (0.00%)**	**0/16 (0.00%)**
Injection site pain † [1]				
# participants affected / at risk	**0/18 (0.00%)**	**1/16 (6.25%)**	**0/10 (0.00%)**	**1/16 (6.25%)**
Injection site swelling † [1]				
# participants affected / at risk	**1/18 (5.56%)**	**0/16 (0.00%)**	**0/10 (0.00%)**	**2/16 (12.50%)**
Pyrexia † [1]				
# participants affected / at risk	**0/18 (0.00%)**	**0/16 (0.00%)**	**0/10 (0.00%)**	**1/16 (6.25%)**

Immune system disorders				
Seasonal allergy † 1				
# participants affected / at risk	**0/18 (0.00%)**	**0/16 (0.00%)**	**2/10 (20.00%)**	**0/16 (0.00%)**
Infections and infestations				
Bronchitis † 1				
# participants affected / at risk	**0/18 (0.00%)**	**0/16 (0.00%)**	**0/10 (0.00%)**	**1/16 (6.25%)**
Eczema infected † 1				
# participants affected / at risk	**0/18 (0.00%)**	**1/16 (6.25%)**	**0/10 (0.00%)**	**0/16 (0.00%)**
Herpes virus infection † 1				
# participants affected / at risk	**1/18 (5.56%)**	**1/16 (6.25%)**	**0/10 (0.00%)**	**0/16 (0.00%)**
Infectious mononucleosis † 1				
# participants affected / at risk	**0/18 (0.00%)**	**1/16 (6.25%)**	**0/10 (0.00%)**	**0/16 (0.00%)**
Laryngitis † 1				
# participants affected / at risk	**0/18 (0.00%)**	**1/16 (6.25%)**	**0/10 (0.00%)**	**0/16 (0.00%)**
Nasopharyngitis † 1				
# participants affected / at risk	**3/18 (16.67%)**	**5/16 (31.25%)**	**1/10 (10.00%)**	**4/16 (25.00%)**
Oral herpes † 1				
# participants affected / at risk	**0/18 (0.00%)**	**2/16 (12.50%)**	**0/10 (0.00%)**	**1/16 (6.25%)**
Oral infection † 1				
# participants affected / at risk	**0/18 (0.00%)**	**0/16 (0.00%)**	**0/10 (0.00%)**	**1/16 (6.25%)**
Pharyngitis † 1				
# participants affected / at risk	**0/18 (0.00%)**	**0/16 (0.00%)**	**1/10 (10.00%)**	**0/16 (0.00%)**
Pilonidal cyst † 1				
# participants affected / at risk	**0/18 (0.00%)**	**1/16 (6.25%)**	**0/10 (0.00%)**	**0/16 (0.00%)**
Rhinitis † 1				

# participants affected / at risk	0/18 (0.00%)	1/16 (6.25%)	0/10 (0.00%)	1/16 (6.25%)
Sinusitis † 1				
# participants affected / at risk	0/18 (0.00%)	0/16 (0.00%)	0/10 (0.00%)	2/16 (12.50%)
Tinea pedis † 1				
# participants affected / at risk	0/18 (0.00%)	1/16 (6.25%)	0/10 (0.00%)	0/16 (0.00%)
Tonsillitis † 1				
# participants affected / at risk	0/18 (0.00%)	0/16 (0.00%)	0/10 (0.00%)	1/16 (6.25%)
Upper respiratory tract infection † 1				
# participants affected / at risk	0/18 (0.00%)	0/16 (0.00%)	1/10 (10.00%)	2/16 (12.50%)
Urinary tract infection † 1				
# participants affected / at risk	0/18 (0.00%)	1/16 (6.25%)	0/10 (0.00%)	1/16 (6.25%)
Viral infection † 1				
# participants affected / at risk	1/18 (5.56%)	0/16 (0.00%)	0/10 (0.00%)	0/16 (0.00%)
Injury, poisoning and procedural complications				
Excoriation † 1				
# participants affected / at risk	0/18 (0.00%)	0/16 (0.00%)	0/10 (0.00%)	1/16 (6.25%)
Road traffic accident † 1				
# participants affected / at risk	0/18 (0.00%)	0/16 (0.00%)	0/10 (0.00%)	1/16 (6.25%)
Sunburn † 1				
# participants affected / at risk	0/18 (0.00%)	0/16 (0.00%)	0/10 (0.00%)	1/16 (6.25%)
Tooth injury † 1				
# participants affected / at risk	0/18 (0.00%)	0/16 (0.00%)	0/10 (0.00%)	1/16 (6.25%)
Wound complication † 1				
# participants affected / at risk	1/18 (5.56%)	0/16 (0.00%)	0/10 (0.00%)	0/16 (0.00%)
Investigations				

Blood pressure diastolic increased † 1				
# participants affected / at risk	**0/18 (0.00%)**	**0/16 (0.00%)**	**0/10 (0.00%)**	**1/16 (6.25%)**
Blood pressure systolic increased † 1				
# participants affected / at risk	**0/18 (0.00%)**	**0/16 (0.00%)**	**0/10 (0.00%)**	**1/16 (6.25%)**
Musculoskeletal and connective tissue disorders				
Back pain † 1				
# participants affected / at risk	**0/18 (0.00%)**	**1/16 (6.25%)**	**0/10 (0.00%)**	**0/16 (0.00%)**
Myosclerosis † 1				
# participants affected / at risk	**0/18 (0.00%)**	**0/16 (0.00%)**	**0/10 (0.00%)**	**1/16 (6.25%)**
Pain in extremity † 1				
# participants affected / at risk	**0/18 (0.00%)**	**0/16 (0.00%)**	**0/10 (0.00%)**	**1/16 (6.25%)**
Nervous system disorders				
Dizziness † 1				
# participants affected / at risk	**0/18 (0.00%)**	**1/16 (6.25%)**	**0/10 (0.00%)**	**0/16 (0.00%)**
Dysgeusia † 1				
# participants affected / at risk	**0/18 (0.00%)**	**1/16 (6.25%)**	**0/10 (0.00%)**	**0/16 (0.00%)**
Headache † 1				
# participants affected / at risk	**4/18 (22.22%)**	**5/16 (31.25%)**	**1/10 (10.00%)**	**3/16 (18.75%)**
Psychiatric disorders				
Sleep disorder † 1				
# participants affected / at risk	**0/18 (0.00%)**	**0/16 (0.00%)**	**0/10 (0.00%)**	**1/16 (6.25%)**
Reproductive system and breast disorders				
Dysmenorrhoea † 1				

# participants affected / at risk	**0/18 (0.00%)**	**1/16 (6.25%)**	**0/10 (0.00%)**	**1/16 (6.25%)**
Respiratory, thoracic and mediastinal disorders				
Asthma † [1]				
# participants affected / at risk	**0/18 (0.00%)**	**0/16 (0.00%)**	**0/10 (0.00%)**	**2/16 (12.50%)**
Bronchial obstruction † [1]				
# participants affected / at risk	**0/18 (0.00%)**	**1/16 (6.25%)**	**0/10 (0.00%)**	**0/16 (0.00%)**
Bronchospasm † [1]				
# participants affected / at risk	**0/18 (0.00%)**	**0/16 (0.00%)**	**0/10 (0.00%)**	**1/16 (6.25%)**
Cough † [1]				
# participants affected / at risk	**1/18 (5.56%)**	**0/16 (0.00%)**	**1/10 (10.00%)**	**2/16 (12.50%)**
Dyspnoea † [1]				
# participants affected / at risk	**1/18 (5.56%)**	**0/16 (0.00%)**	**1/10 (10.00%)**	**1/16 (6.25%)**
Epistaxis † [1]				
# participants affected / at risk	**0/18 (0.00%)**	**0/16 (0.00%)**	**0/10 (0.00%)**	**1/16 (6.25%)**
Oropharyngeal pain † [1]				
# participants affected / at risk	**0/18 (0.00%)**	**1/16 (6.25%)**	**0/10 (0.00%)**	**2/16 (12.50%)**
Productive cough † [1]				
# participants affected / at risk	**0/18 (0.00%)**	**0/16 (0.00%)**	**0/10 (0.00%)**	**1/16 (6.25%)**
Rhinitis allergic † [1]				
# participants affected / at risk	**0/18 (0.00%)**	**0/16 (0.00%)**	**0/10 (0.00%)**	**2/16 (12.50%)**
Skin and subcutaneous tissue disorders				
Dermatitis † [1]				
# participants affected / at risk	**0/18 (0.00%)**	**1/16 (6.25%)**	**0/10 (0.00%)**	**0/16 (0.00%)**
Dermographism † [1]				

# participants affected / at risk	**0/18 (0.00%)**	**0/16 (0.00%)**	**0/10 (0.00%)**	**1/16 (6.25%)**
Neurodermatitis † 1				
# participants affected / at risk	**0/18 (0.00%)**	**1/16 (6.25%)**	**0/10 (0.00%)**	**0/16 (0.00%)**
Photosensitivity reaction † 1				
# participants affected / at risk	**0/18 (0.00%)**	**0/16 (0.00%)**	**0/10 (0.00%)**	**1/16 (6.25%)**
Pruritus † 1				
# participants affected / at risk	**0/18 (0.00%)**	**1/16 (6.25%)**	**0/10 (0.00%)**	**1/16 (6.25%)**
Vascular disorders				
Hypertension † 1				
# participants affected / at risk	**1/18 (5.56%)**	**0/16 (0.00%)**	**0/10 (0.00%)**	**0/16 (0.00%)**

† 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 data (i.e., 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:	NCT00624832 History of Changes
Other Study ID Numbers:	**CIGE025A2210**
Study First Received:	February 18, 2008
Results First Received:	January 21, 2011
Last Updated:	April 12, 2011
Health Authority:	Germany: Paul-Ehrlich-Institut