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Trial record **1 of 1** for: CVAH631BDE06

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Safety and Efficacy of Valsartan vs Atenolol and Hydrochlorothiazide Combination on Blood Flow in Hypertensive Patients

This study has been completed.

Sponsor:
Novartis

Information provided by:
Novartis

ClinicalTrials.gov Identifier:
NCT00396656

First received: November 6, 2006
Last updated: May 5, 2011
Last verified: May 2011
History of Changes

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Results First Received: January 7, 2011

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Crossover Assignment; Masking: Open Label; Primary Purpose: Treatment
Condition:	Hypertension
Interventions:	Drug: Atenolol Drug: Hydrochlorothiazide (HCTZ)) Drug: Valsartan

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
Valsartan Followed by Atenolol + Hydrochlorothiazide (HCTZ)	After a 2-week washout period, patients were treated with valsartan for 20 weeks followed by one week in which it was tapered off. Patients received valsartan 160 mg for 4 weeks, followed by valsartan 320 mg for 16 weeks. The valsartan dose was then tapered off to 80 mg for one week. Patients took valsartan film coated tablets orally once a day (od) in the morning. After a second 2-week washout period, patients were treated with atenolol plus HCTZ for 20 weeks. Patients received atenolol 100 mg for 20 weeks. Patients took atenolol tablets orally once a day (od) in the morning. Patients

	received HCTZ 12.5 mg for 4 weeks starting at the beginning of the 5th week and then received 25 mg for 12 weeks. Patients took HCTZ tablets orally once a day (od) in the morning.
Atenolol + Hydrochlorothiazide (HCTZ) Followed by Valsartan	After a 2-week washout period, patients were treated with atenolol plus HCTZ for 20 weeks followed by one week in which atenolol was tapered off and HCTZ was discontinued. Patients received atenolol 100 mg for 20 weeks. Patients took atenolol tablets orally once a day (od) in the morning. Patients received HCTZ 12.5 mg for 4 weeks starting at the beginning of the 5th week and then received 25 mg for 12 weeks. Patients took HCTZ tablets orally once a day (od) in the morning. After a second 2-week washout period, patients were treated with valsartan for 20 weeks. Patients received valsartan 160 mg for 4 weeks, followed by valsartan 320 mg for 16 weeks. Patients took valsartan film coated tablets orally once a day (od) in the morning

Participant Flow for 2 periods

Period 1: First Treatment Period

	Valsartan Followed by Atenolol + Hydrochlorothiazide (HCTZ)	Atenolol + Hydrochlorothiazide (HCTZ) Followed by Valsartan
STARTED	**15**	**15**
COMPLETED	**15**	**13**
NOT COMPLETED	**0**	**2**
Withdrawal by Subject	**0**	**2**

Period 2: Second Treatment Period

	Valsartan Followed by Atenolol + Hydrochlorothiazide (HCTZ)	Atenolol + Hydrochlorothiazide (HCTZ) Followed by Valsartan
STARTED	**15**	**13**
COMPLETED	**15**	**12**
NOT COMPLETED	**0**	**1**
Adverse Event	**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
Entire Study Population	Includes patients that received valsartan followed by atenolol + hydrochlorothiazide and patients that received atenolol + hydrochlorothiazide followed by valsartan.

Baseline Measures

	Entire Study Population

Number of Participants [units: participants]	**30**
Age [units: years] Mean (Standard Deviation)	**52.3 (7.2)**
Gender [units: participants]	
Female	**11**
Male	**19**

Outcome Measures

Hide All Outcome Measures

1. Primary: Difference in Mean Post-treatment Microcirculation at Acetylcholine (ACH) Injected Sites Compared to NaCl Injected Sites [Time Frame: At end of each treatment period (Week 21 and Week 43)]

Measure Type	Primary
Measure Title	Difference in Mean Post-treatment Microcirculation at Acetylcholine (ACH) Injected Sites Compared to NaCl Injected Sites
Measure Description	10 µl of acetylcholine (ACH) at 3 concentrations (10-7, 10-8, 10-9 M) was injected intra-dermally at 3 sites on the forearms. NaCl was injected at 2 sites on the forearms. Microcirculation was measured using laser doppler velocimetry before and 12 times in the 30 minutes following injection. The mean difference of the 12 post-injection measurements to the pre-injection measurement was calculated. Means for the 3 ACH and the 2 NaCl sites were calculated and compared. Microcirculation was measured in perfusion units which is an arbitrary measure specific to each laser doppler scanner.
Time Frame	At end of each treatment period (Week 21 and Week 43)
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 with at least one valid post-baseline primary efficacy measurement in both treatment periods.

Reporting Groups

	Description
Valsartan	Patients received valsartan 160 mg for 4 weeks, followed by valsartan 320 mg for 16 weeks. The valsartan dose was then tapered off to 80 mg for one week. Patients took valsartan film coated tablets orally once a day (od) in the morning.
Atenolol + Hydrochlorothiazide	Patients received atenolol 100 mg for 19 weeks. In the last week of this intervention, the atenolol dose was reduced to 50 mg. Patients took atenolol tablets orally once a day (od) in the morning. Patients received hydrochlorothiazide 100 mg for 15 weeks starting at the beginning of the 5th week of this intervention. In the last week of this intervention, the hydrochlorothiazide dose was increased to 25 mg. Patients took hydrochlorothiazide tablets orally once a day (od) in the morning.

Measured Values

	Valsartan	**Atenolol + Hydrochlorothiazide**
Number of Participants Analyzed [units: participants]	**27**	**27**
Difference in Mean Post-treatment Microcirculation at Acetylcholine (ACH) Injected Sites Compared		

to NaCl Injected Sites [units: Perfusion units] Mean (Standard Deviation)	**61.21 (38.11)**	**61.04 (49.16)**

No statistical analysis provided for Difference in Mean Post-treatment Microcirculation at Acetylcholine (ACH) Injected Sites Compared to NaCl Injected Sites

2. Secondary: Difference in Mean Post-treatment Microcirculation at Acetylcholine (ACH) Plus L-NMMA Injected Sites Compared to NaCl Injected Sites [Time Frame: At end of each treatment period (Week 21 and Week 43)]

Measure Type	Secondary
Measure Title	Difference in Mean Post-treatment Microcirculation at Acetylcholine (ACH) Plus L-NMMA Injected Sites Compared to NaCl Injected Sites
Measure Description	10 µl of acetylcholine (ACH) at 3 concentrations (10-7, 10-8, 10-9 M) plus 10 µl L-NMMA (10-6 M) was injected intra-dermally at 3 sites on the forearms. NaCl was injected at 2 sites. Microcirculation was measured using laser doppler velocimetry before and 12 times in the 30 minutes following injection. The mean difference of the 12 post-injection measurements to the pre-injection measurement was calculated. Means for the 3 ACH and the 2 NaCl sites were calculated and compared. Microcirculation was measured in perfusion units which is an arbitrary measure specific to each laser doppler scanner.
Time Frame	At end of each treatment period (Week 21 and Week 43)
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 with at least one valid post-baseline primary efficacy measurement in both treatment periods.

Reporting Groups

	Description
Valsartan	Patients received valsartan 160 mg for 4 weeks, followed by valsartan 320 mg for 16 weeks. The valsartan dose was then tapered off to 80 mg for one week. Patients took valsartan film coated tablets orally once a day (od) in the morning.
Atenolol + Hydrochlorothiazide	Patients received atenolol 100 mg for 19 weeks. In the last week of this intervention, the atenolol dose was reduced to 50 mg. Patients took atenolol tablets orally once a day (od) in the morning. Patients received hydrochlorothiazide 100 mg for 15 weeks starting at the beginning of the 5th week of this intervention. In the last week of this intervention, the hydrochlorothiazide dose was increased to 25 mg. Patients took hydrochlorothiazide tablets orally once a day (od) in the morning.

Measured Values

	Valsartan	**Atenolol + Hydrochlorothiazide**
Number of Participants Analyzed [units: participants]	**27**	**27**
Difference in Mean Post-treatment Microcirculation at Acetylcholine (ACH) Plus L-NMMA Injected Sites Compared to NaCl Injected Sites [units: Perfusion units] Mean (Standard Deviation)	**-9.11 (22.19)**	**-5.60 (40.47)**

No statistical analysis provided for Difference in Mean Post-treatment Microcirculation at Acetylcholine (ACH) Plus L-NMMA Injected Sites Compared to NaCl Injected Sites

3. Secondary: Difference in Mean Post-treatment Microcirculation at a Sodium Nitroprusside Injected Site Compared to NaCl Injected Sites [Time Frame: At end of each treatment period (Week 21 and Week 43)]

Measure Type	Secondary
Measure Title	Difference in Mean Post-treatment Microcirculation at a Sodium Nitroprusside Injected Site Compared to NaCl Injected Sites
Measure Description	10 µl of sodium nitroprusside at a concentration of 10-7 M was injected intra-dermally at 1 site on the forearms. NaCl was injected at 2 sites on the forearms. Microcirculation was measured using laser doppler velocimetry before and 12 times in the 30 minutes following injection. The mean difference of the 12 post-injection measurements to the pre-injection measurement was calculated. A mean for the 2 NaCl sites was calculated and compared to the sodium nitroprusside mean. Microcirculation was measured in perfusion units which is an arbitrary measure specific to each laser doppler scanner.
Time Frame	At end of each treatment period (Week 21 and Week 43)
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 with at least one valid post-baseline primary efficacy measurement in both treatment periods.

Reporting Groups

	Description
Valsartan	Patients received valsartan 160 mg for 4 weeks, followed by valsartan 320 mg for 16 weeks. The valsartan dose was then tapered off to 80 mg for one week. Patients took valsartan film coated tablets orally once a day (od) in the morning.
Atenolol + Hydrochlorothiazide	Patients received atenolol 100 mg for 19 weeks. In the last week of this intervention, the atenolol dose was reduced to 50 mg. Patients took atenolol tablets orally once a day (od) in the morning. Patients received hydrochlorothiazide 100 mg for 15 weeks starting at the beginning of the 5th week of this intervention. In the last week of this intervention, the hydrochlorothiazide dose was increased to 25 mg. Patients took hydrochlorothiazide tablets orally once a day (od) in the morning.

Measured Values

	Valsartan	**Atenolol + Hydrochlorothiazide**
Number of Participants Analyzed [units: participants]	**27**	**27**
Difference in Mean Post-treatment Microcirculation at a Sodium Nitroprusside Injected Site Compared to NaCl Injected Sites [units: Perfusion units] Mean (Standard Deviation)	**120.65 (74.52)**	**128.14 (63.79)**

No statistical analysis provided for Difference in Mean Post-treatment Microcirculation at a Sodium Nitroprusside Injected Site Compared to NaCl Injected Sites

4. Secondary: Mean Post-treatment Microcirculation at NaCl Injected Sites [Time Frame: At end of each treatment period (Week 21 and Week 43)]

Measure Type	Secondary
Measure Title	Mean Post-treatment Microcirculation at NaCl Injected Sites
Measure Description	10 µl of NaCl was injected intra-dermally at 2 sites on the forearms. Microcirculation was measured using laser

	doppler velocimetry before and 12 times in the 30 minutes following injection. The mean difference of the 12 post-injection measurements to the pre-injection measurement was calculated. A mean for the 2 NaCl sites was calculated. Microcirculation was measured in perfusion units which is an arbitrary measure specific to each laser doppler scanner.
Time Frame	At end of each treatment period (Week 21 and Week 43)
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 with at least one valid post-baseline primary efficacy measurement in both treatment periods.

Reporting Groups

	Description
Valsartan	Patients received valsartan 160 mg for 4 weeks, followed by valsartan 320 mg for 16 weeks. The valsartan dose was then tapered off to 80 mg for one week. Patients took valsartan film coated tablets orally once a day (od) in the morning.
Atenolol + Hydrochlorothiazide	Patients received atenolol 100 mg for 19 weeks. In the last week of this intervention, the atenolol dose was reduced to 50 mg. Patients took atenolol tablets orally once a day (od) in the morning. Patients received hydrochlorothiazide 100 mg for 15 weeks starting at the beginning of the 5th week of this intervention. In the last week of this intervention, the hydrochlorothiazide dose was increased to 25 mg. Patients took hydrochlorothiazide tablets orally once a day (od) in the morning.

Measured Values

	Valsartan	**Atenolol + Hydrochlorothiazide**
Number of Participants Analyzed [units: participants]	**27**	**27**
Mean Post-treatment Microcirculation at NaCl Injected Sites [units: Perfusion units] Mean (Standard Deviation)	**44.78 (47.53)**	**50.96 (67.88)**

No statistical analysis provided for Mean Post-treatment Microcirculation at NaCl Injected Sites

5. Secondary: Arterial Pressure Waveform Augmentation Index at the End of Treatment [Time Frame: At end of each treatment period (Week 21 and Week 43)]

Measure Type	Secondary
Measure Title	Arterial Pressure Waveform Augmentation Index at the End of Treatment
Measure Description	Using applanation tonometry, the arterial pulse form measured at the wrist was analyzed using computerized pulse wave analysis. The arterial pressure waveform has two components; the first is the forward traveling wave when the left ventricle contracts and the second is the reflected wave returning from the periphery. The augmentation index is the ratio of the first and second systolic peaks and is used as a surrogate measure of arterial stiffness.
Time Frame	At end of each treatment period (Week 21 and Week 43)
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 with at least one valid post-baseline primary efficacy measurement in both treatment periods.

Reporting Groups

	Description
Valsartan	Patients received valsartan 160 mg for 4 weeks, followed by valsartan 320 mg for 16 weeks. The valsartan dose was then tapered off to 80 mg for one week. Patients took valsartan film coated tablets orally once a day (od) in the morning.
Atenolol + Hydrochlorothiazide	Patients received atenolol 100 mg for 19 weeks. In the last week of this intervention, the atenolol dose was reduced to 50 mg. Patients took atenolol tablets orally once a day (od) in the morning. Patients received hydrochlorothiazide 100 mg for 15 weeks starting at the beginning of the 5th week of this intervention. In the last week of this intervention, the hydrochlorothiazide dose was increased to 25 mg. Patients took hydrochlorothiazide tablets orally once a day (od) in the morning.

Measured Values

	Valsartan	Atenolol + Hydrochlorothiazide
Number of Participants Analyzed [units: participants]	**27**	**27**
Arterial Pressure Waveform Augmentation Index at the End of Treatment [units: Ratio] Mean (Standard Deviation)	**139.05 (20.64)**	**144.51 (21.97)**

No statistical analysis provided for Arterial Pressure Waveform Augmentation Index at the End of Treatment

6. Secondary: Arterial Pressure Waveform Pulse Wave Velocity at the End of Treatment [Time Frame: At end of each treatment period (Week 21 and Week 43)]

Measure Type	Secondary
Measure Title	Arterial Pressure Waveform Pulse Wave Velocity at the End of Treatment
Measure Description	Using applanation tonometry, the arterial pulse form measured at the wrist was analyzed using computerized pulse wave analysis. The arterial pressure waveform has two components; the first is the forward traveling wave when the left ventricle contracts and the second is the reflected wave returning from the periphery. Pulse wave velocity is the speed of the forward traveling wave and can be used as a measure of arterial stiffness since the more rigid the wall of the artery, the faster the wave moves.
Time Frame	At end of each treatment period (Week 21 and Week 43)
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 with at least one valid post-baseline primary efficacy measurement in both treatment periods.

Reporting Groups

	Description
Valsartan	Patients received valsartan 160 mg for 4 weeks, followed by valsartan 320 mg for 16 weeks. The valsartan dose was then tapered off to 80 mg for one week. Patients took valsartan film coated tablets orally once a day (od) in the morning.
Atenolol + Hydrochlorothiazide	Patients received atenolol 100 mg for 19 weeks. In the last week of this intervention, the atenolol dose was reduced to 50 mg. Patients took atenolol tablets orally once a day (od) in the morning. Patients received hydrochlorothiazide 100 mg for 15 weeks starting at the beginning of the 5th week of this intervention. In the last week of this intervention, the hydrochlorothiazide dose was increased to 25 mg. Patients took hydrochlorothiazide tablets orally once a day (od) in the morning.

Measured Values

	Valsartan	Atenolol + Hydrochlorothiazide
Number of Participants Analyzed [units: participants]	**27**	**27**
Arterial Pressure Waveform Pulse Wave Velocity at the End of Treatment [units: Meters per second] Mean (Standard Deviation)	**8.07 (1.28)**	**7.60 (1.18)**

No statistical analysis provided for Arterial Pressure Waveform Pulse Wave Velocity at the End of Treatment

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	No text entered.
Additional Description	Two patients in the treatment sequence atenolol + hydrochlorothiazide followed by valsartan did not receive treatment during the second treatment period and were excluded from the valsartan safety population analysis set.

Reporting Groups

	Description
Valsartan	Patients received valsartan 160 mg for 4 weeks, followed by valsartan 320 mg for 16 weeks. The valsartan dose was then tapered off to 80 mg for one week. Patients took valsartan film coated tablets orally once a day (od) in the morning.
Atenolol + Hydrochlorothiazide	Patients received atenolol 100 mg for 19 weeks. In the last week of this intervention, the atenolol dose was reduced to 50 mg. Patients took atenolol tablets orally once a day (od) in the morning. Patients received hydrochlorothiazide 100 mg for 15 weeks starting at the beginning of the 5th week of this intervention. In the last week of this intervention, the hydrochlorothiazide dose was increased to 25 mg. Patients took hydrochlorothiazide tablets orally once a day (od) in the morning.

Serious Adverse Events

	Valsartan	Atenolol + Hydrochlorothiazide
Total, serious adverse events		
# participants affected / at risk	**0/28 (0.00%)**	**1/30 (3.33%)**
Infections and infestations		
Diverticulitis † 1		
# participants affected / at risk	**0/28 (0.00%)**	**1/30 (3.33%)**

† 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	Two patients in the treatment sequence atenolol + hydrochlorothiazide followed by valsartan did not receive treatment during the second treatment period and were excluded from the valsartan safety population analysis set.

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
Valsartan	Patients received valsartan 160 mg for 4 weeks, followed by valsartan 320 mg for 16 weeks. The valsartan dose was then tapered off to 80 mg for one week. Patients took valsartan film coated tablets orally once a day (od) in the morning.
Atenolol + Hydrochlorothiazide	Patients received atenolol 100 mg for 19 weeks. In the last week of this intervention, the atenolol dose was reduced to 50 mg. Patients took atenolol tablets orally once a day (od) in the morning. Patients received hydrochlorothiazide 100 mg for 15 weeks starting at the beginning of the 5th week of this intervention. In the last week of this intervention, the hydrochlorothiazide dose was increased to 25 mg. Patients took hydrochlorothiazide tablets orally once a day (od) in the morning.

Other Adverse Events

	Valsartan	Atenolol + Hydrochlorothiazide
Total, other (not including serious) adverse events		
# participants affected / at risk	**16/28 (57.14%)**	**12/30 (40.00%)**
Ear and labyrinth disorders		
Vertigo † 1		
# participants affected / at risk	**3/28 (10.71%)**	**2/30 (6.67%)**
Gastrointestinal disorders		
Diarrhoea † 1		
# participants affected / at risk	**1/28 (3.57%)**	**2/30 (6.67%)**
General disorders		
Chest pain † 1		
# participants affected / at risk	**0/28 (0.00%)**	**2/30 (6.67%)**
Infections and infestations		
Bronchitis † 1		
# participants affected / at risk	**2/28 (7.14%)**	**1/30 (3.33%)**
Cystitis † 1		
# participants affected / at risk	**2/28 (7.14%)**	**1/30 (3.33%)**
Otitis externa † 1		
# participants affected / at risk	**0/28 (0.00%)**	**2/30 (6.67%)**
Sinusitis † 1		
# participants affected / at risk	**2/28 (7.14%)**	**1/30 (3.33%)**
Upper respiratory tract infection † 1		
# participants affected / at risk	**2/28 (7.14%)**	**1/30 (3.33%)**
Musculoskeletal and connective tissue disorders		
Back pain † 1		
# participants affected / at risk	**1/28 (3.57%)**	**2/30 (6.67%)**
Musculoskeletal pain † 1		
# participants affected / at risk	**2/28 (7.14%)**	**0/30 (0.00%)**
Pain in extremity † 1		
# participants affected / at risk	**1/28 (3.57%)**	**2/30 (6.67%)**
Nervous system disorders		
Headache † 1		
# participants affected / at risk	**3/28 (10.71%)**	**6/30 (20.00%)**
Vascular disorders		

Hypotension † 1		
# participants affected / at risk	**2/28 (7.14%)**	**0/30 (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 (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:	Anna Mitchell, MD, University Hospital Essen, Essen, Germany et al.
ClinicalTrials.gov Identifier:	NCT00396656 History of Changes
Other Study ID Numbers:	**CVAH631BDE06**
Study First Received:	November 6, 2006
Results First Received:	January 7, 2011
Last Updated:	May 5, 2011
Health Authority:	Germany: Federal Institute for Drugs and Medical Devices