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Trial record **1 of 1** for: CSPP100A2403

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Efficacy and Safety of Once Daily Dosing of Aliskiren (300 mg (qd) Once a Day) to Twice Daily Dosing of Aliskiren (150 mg (Bid) Twice a Day) in Treating Moderate Hypertension.

This study has been completed.

Sponsor:
Novartis

Information provided by:
Novartis

ClinicalTrials.gov Identifier:
NCT00654875

First received: April 3, 2008
Last updated: June 24, 2011
Last verified: June 2011
History of Changes

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Results First Received: December 13, 2010

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Investigator); Primary Purpose: Treatment
Condition:	Essential Hypertension
Interventions:	Drug: Aliskiren Drug: Placebo to Aliskiren

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
Aliskiren 300 mg (Once a Day)	Participants received Aliskiren 300 mg tablet + Placebo to Aliskiren matching 150 mg tablet daily in the morning and Placebo to Aliskiren matching 150 mg tablet daily in the evening for a total of 10 weeks.
Aliskiren 150 mg (Twice a Day)	Participants received Aliskiren 150 mg tablet + Placebo to Aliskiren matching 300 mg tablet daily in the morning and Aliskiren 150 mg tablet daily in the evening for the first 6 weeks then for the next 4 weeks received Aliskiren 300 mg tablet + Placebo to Aliskiren matching 150 mg tablet daily in the morning and Placebo to Aliskiren matching 150 mg tablet daily in the evening.

Participant Flow: Overall Study

	Aliskiren 300 mg (Once a Day)	Aliskiren 150 mg (Twice a Day)
STARTED	**164**	**164**
COMPLETED	**147**	**147**
NOT COMPLETED	**17**	**17**
Adverse Event	**5**	**5**
Withdrawal by Subject	**4**	**4**
Protocol Violation	**3**	**3**
Lack of Efficacy	**2**	**2**
Lost to Follow-up	**1**	**3**
Abnormal Test Procedure Result(s)	**1**	**0**
Administrative Problems	**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
Aliskiren 300 mg (Once a Day)	Participants received Aliskiren 300 mg tablet + Placebo to Aliskiren matching 150 mg tablet daily in the morning and Placebo to Aliskiren matching 150 mg tablet daily in the evening for a total of 10 weeks.
Aliskiren 150 mg (Twice a Day)	Participants received Aliskiren 150 mg tablet + Placebo to Aliskiren matching 300 mg tablet daily in the morning and Aliskiren 150 mg tablet daily in the evening for the first 6 weeks then for the next 4 weeks received Aliskiren 300 mg tablet + Placebo to Aliskiren matching 150 mg tablet daily in the morning and Placebo to Aliskiren matching 150 mg tablet daily in the evening.
Total	Total of all reporting groups

Baseline Measures

	Aliskiren 300 mg (Once a Day)	Aliskiren 150 mg (Twice a Day)	Total
Number of Participants [units: participants]	**164**	**164**	**328**
Age [units: years] Mean (Standard Deviation)	**55 (10.3)**	**54 (10.2)**	**54 (10.3)**
Gender [units: participants]			
Female	**63**	**77**	**140**
Male	**101**	**87**	**188**

Outcome Measures

Hide All Outcome Measures

1. Primary: Change From Baseline to Week 6 in the Mean 24-hour Ambulatory Diastolic Blood Pressure (MADBP) [Time Frame: Baseline,

Week 6]

Measure Type	Primary
Measure Title	Change From Baseline to Week 6 in the Mean 24-hour Ambulatory Diastolic Blood Pressure (MADBP)
Measure Description	An Ambulatory Blood Pressure Monitoring (ABPM) device was attached to the non-dominant arm of the participant. The mean of Blood Pressure readings during the 24 hour period were calculated. The difference of the 24 hour MADBP from baseline to the 24 hour MADBP at 6 weeks was calculated using an Analysis of covariance (ANCOVA) model with baseline mean 24 hour ambulatory diastolic blood pressure as a covariate.
Time Frame	Baseline, Week 6
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.
Participants from the Full analysis set (consisting of all randomized patients) for whom data was available at Baseline and Week 6.

Reporting Groups

	Description
Aliskiren 300 mg (Once a Day)	Participants received Aliskiren 300 mg tablet + Placebo to Aliskiren matching 150 mg tablet daily in the morning and Placebo to Aliskiren matching 150 mg tablet daily in the evening for a total of 10 weeks.
Aliskiren 150 mg (Twice a Day)	Participants received Aliskiren 150 mg tablet + Placebo to Aliskiren matching 300 mg tablet daily in the morning and Aliskiren 150 mg tablet daily in the evening for the first 6 weeks then for the next 4 weeks received Aliskiren 300 mg tablet + Placebo to Aliskiren matching 150 mg tablet daily in the morning and Placebo to Aliskiren matching 150 mg tablet daily in the evening.

Measured Values

	Aliskiren 300 mg (Once a Day)	**Aliskiren 150 mg (Twice a Day)**
Number of Participants Analyzed [units: participants]	**139**	**127**
Change From Baseline to Week 6 in the Mean 24-hour Ambulatory Diastolic Blood Pressure (MADBP) [units: mm Hg] Least Squares Mean (Standard Error)	**-4.10 (0.60)**	**-5.24 (0.64)**

No statistical analysis provided for Change From Baseline to Week 6 in the Mean 24-hour Ambulatory Diastolic Blood Pressure (MADBP)

2. Secondary: Change From Baseline to Week 6 in the Mean Ambulatory Diastolic Blood Pressure (MADBP) During the Last 3 Hours of the 24-hour Dosing Period [Time Frame: Baseline, Week 6]

Measure Type	Secondary
Measure Title	Change From Baseline to Week 6 in the Mean Ambulatory Diastolic Blood Pressure (MADBP) During the Last 3 Hours of the 24-hour Dosing Period
Measure Description	An Ambulatory Blood Pressure Monitoring (ABPM) device was attached to the non-dominant arm of the participant. The mean of Blood Pressure readings during the 22-24 hour period were calculated. The difference from the last 3 hours MADBP at baseline to the last 3 hour MADBP at Week 6 was calculated using an ANCOVA model with baseline mean 24 hour ambulatory diastolic blood pressure as a covariate.
Time Frame	Baseline, Week 6
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.
Participants from the Full analysis set (consisting of all randomized patients) for whom data was available at Baseline and Week 6.

Reporting Groups

	Description
Aliskiren 300 mg (Once a Day)	Participants received Aliskiren 300 mg tablet + Placebo to Aliskiren matching 150 mg tablet daily in the morning and Placebo to Aliskiren matching 150 mg tablet daily in the evening for a total of 10 weeks.
Aliskiren 150 mg (Twice a Day)	Participants received Aliskiren 150 mg tablet + Placebo to Aliskiren matching 300 mg tablet daily in the morning and Aliskiren 150 mg tablet daily in the evening for the first 6 weeks then for the next 4 weeks received Aliskiren 300 mg tablet + Placebo to Aliskiren matching 150 mg tablet daily in the morning and Placebo to Aliskiren matching 150 mg tablet daily in the evening.

Measured Values

	Aliskiren 300 mg (Once a Day)	**Aliskiren 150 mg (Twice a Day)**
Number of Participants Analyzed [units: participants]	**136**	**121**
Change From Baseline to Week 6 in the Mean Ambulatory Diastolic Blood Pressure (MADBP) During the Last 3 Hours of the 24-hour Dosing Period [units: mm Hg] Least Squares Mean (Standard Error)	**-5.03 (0.77)**	**-5.24 (0.81)**

No statistical analysis provided for Change From Baseline to Week 6 in the Mean Ambulatory Diastolic Blood Pressure (MADBP) During the Last 3 Hours of the 24-hour Dosing Period

3. Secondary: Change From Baseline to Week 6 in the Mean Ambulatory Systolic Blood Pressure (MASBP) During the Last Three Hours of the 24-hour Dosing Period [Time Frame: Baseline, Week 6]

Measure Type	Secondary
Measure Title	Change From Baseline to Week 6 in the Mean Ambulatory Systolic Blood Pressure (MASBP) During the Last Three Hours of the 24-hour Dosing Period
Measure Description	An Ambulatory Blood Pressure Monitoring (ABPM) device was attached to the non-dominant arm of the participant. The mean of Blood Pressure readings during the 22-24 hour period were calculated. The difference from the last 3 hours MASBP at baseline to the last 3 hour MASBP at Week 6 was calculated using an ANCOVA model with baseline mean 24 hour ambulatory systolic blood pressure as a covariate.
Time Frame	Baseline, Week 6
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.
Participants from the Full analysis set (consisting of all randomized patients) for whom data was available at Baseline and Week 6.

Reporting Groups

	Description
Aliskiren 300 mg (Once a Day)	Participants received Aliskiren 300 mg tablet + Placebo to Aliskiren matching 150 mg tablet daily in the morning and Placebo to Aliskiren matching 150 mg tablet daily in the evening for a total of 10 weeks.
Aliskiren 150 mg (Twice a Day)	Participants received Aliskiren 150 mg tablet + Placebo to Aliskiren matching 300 mg tablet daily in the morning and Aliskiren 150 mg tablet daily in the evening for the first 6 weeks then for the next 4 weeks received Aliskiren 300 mg tablet + Placebo to Aliskiren matching 150 mg tablet daily in the morning and

	Placebo to Aliskiren matching 150 mg tablet daily in the evening.

Measured Values

	Aliskiren 300 mg (Once a Day)	Aliskiren 150 mg (Twice a Day)
Number of Participants Analyzed [units: participants]	**136**	**121**
Change From Baseline to Week 6 in the Mean Ambulatory Systolic Blood Pressure (MASBP) During the Last Three Hours of the 24-hour Dosing Period [units: mm Hg] Least Squares Mean (Standard Error)	**-6.39 (1.04)**	**-7.12 (1.10)**

No statistical analysis provided for Change From Baseline to Week 6 in the Mean Ambulatory Systolic Blood Pressure (MASBP) During the Last Three Hours of the 24-hour Dosing Period

4. Secondary: Change From Baseline to Week 6 in the Mean 24-hour Ambulatory Systolic Blood Pressure (MASBP) [Time Frame: Baseline, Week 6]

Measure Type	Secondary
Measure Title	Change From Baseline to Week 6 in the Mean 24-hour Ambulatory Systolic Blood Pressure (MASBP)
Measure Description	An Ambulatory Blood Pressure Monitoring (ABPM) device was attached to the non-dominant arm of the participant. The mean of Blood Pressure readings during the 24 hour period were calculated. The difference of the 24 hour MASBP from baseline to the 24 hour MASBP at 6 weeks was calculated using an ANCOVA model with baseline mean 24 hour ambulatory systolic blood pressure as a covariate.
Time Frame	Baseline, Week 6
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.
Participants from the Full analysis set (consisting of all randomized patients) for whom data was available at Baseline and Week 6.

Reporting Groups

	Description
Aliskiren 300 mg (Once a Day)	Participants received Aliskiren 300 mg tablet + Placebo to Aliskiren matching 150 mg tablet daily in the morning and Placebo to Aliskiren matching 150 mg tablet daily in the evening for a total of 10 weeks.
Aliskiren 150 mg (Twice a Day)	Participants received Aliskiren 150 mg tablet + Placebo to Aliskiren matching 300 mg tablet daily in the morning and Aliskiren 150 mg tablet daily in the evening for the first 6 weeks then for the next 4 weeks received Aliskiren 300 mg tablet + Placebo to Aliskiren matching 150 mg tablet daily in the morning and Placebo to Aliskiren matching 150 mg tablet daily in the evening.

Measured Values

	Aliskiren 300 mg (Once a Day)	Aliskiren 150 mg (Twice a Day)
Number of Participants Analyzed [units: participants]	**139**	**127**
Change From Baseline to Week 6 in the Mean 24-hour Ambulatory Systolic Blood Pressure (MASBP) [units: mm Hg] Least Squares Mean (Standard Error)	**-5.74 (0.87)**	**-7.44 (0.92)**

No statistical analysis provided for Change From Baseline to Week 6 in the Mean 24-hour Ambulatory Systolic Blood Pressure (MASBP)

5. Secondary: Change From Baseline to Week 6 in the Mean Sitting Systolic and Mean Sitting Diastolic Blood Pressure [Time Frame: Baseline, Week 6]

Measure Type	Secondary
Measure Title	Change From Baseline to Week 6 in the Mean Sitting Systolic and Mean Sitting Diastolic Blood Pressure
Measure Description	After the patient had been sitting for 5 minutes, with the back supported and both feet placed on the floor, systolic and diastolic blood pressures were measured 3 times using a calibrated standard sphygmomanometer and appropriate size cuff. The repeat sitting measurements were made at 1-2 minute intervals and the mean of these 3 sitting blood pressure measurements was used as the average sitting blood pressure for that visit. A negative number indicates lowered blood pressure. The ANCOVA model used baseline as a covariate.
Time Frame	Baseline, Week 6
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.
Participants from the Full analysis set (consisting of all randomized patients) for whom data was available at Baseline and Week 6.

Reporting Groups

	Description
Aliskiren 300 mg (Once a Day)	Participants received Aliskiren 300 mg tablet + Placebo to Aliskiren matching 150 mg tablet daily in the morning and Placebo to Aliskiren matching 150 mg tablet daily in the evening for a total of 10 weeks.
Aliskiren 150 mg (Twice a Day)	Participants received Aliskiren 150 mg tablet + Placebo to Aliskiren matching 300 mg tablet daily in the morning and Aliskiren 150 mg tablet daily in the evening for the first 6 weeks then for the next 4 weeks received Aliskiren 300 mg tablet + Placebo to Aliskiren matching 150 mg tablet daily in the morning and Placebo to Aliskiren matching 150 mg tablet daily in the evening.

Measured Values

	Aliskiren 300 mg (Once a Day)	**Aliskiren 150 mg (Twice a Day)**
Number of Participants Analyzed [units: participants]	**158**	**156**
Change From Baseline to Week 6 in the Mean Sitting Systolic and Mean Sitting Diastolic Blood Pressure [units: mm Hg] Least Squares Mean (Standard Error)		
Diastolic Blood Pressure	**-10.30 (0.66)**	**-10.57 (0.67)**
Systolic Blood Pressure	**-11.72 (1.11)**	**-13.10 (1.11)**

No statistical analysis provided for Change From Baseline to Week 6 in the Mean Sitting Systolic and Mean Sitting Diastolic Blood Pressure

6. Secondary: Percentage of Participants Achieving Blood Pressure Control at Week 6 [Time Frame: Week 6]

Measure Type	Secondary
Measure Title	Percentage of Participants Achieving Blood Pressure Control at Week 6
Measure Description	After the patient had been sitting for 5 minutes, with the back supported and both feet placed on the floor, systolic and diastolic blood pressures were measured 3 times using a calibrated standard sphygmomanometer. The mean of these 3 sitting blood pressure measurements was used as the average sitting blood pressure at visit 3 (week 6).

	Blood pressure control was defined as having a mean sitting diastolic blood pressure (msDBP) <90 mm Hg and a mean sitting systolic blood pressure (msSBP) <140 mm Hg.
Time Frame	Week 6
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.
Participants from the Full analysis set (consisting of all randomized patients) for whom data was available at Week 6.

Reporting Groups

	Description
Aliskiren 300 mg (Once a Day)	Participants received Aliskiren 300 mg tablet + Placebo to Aliskiren matching 150 mg tablet daily in the morning and Placebo to Aliskiren matching 150 mg tablet daily in the evening for a total of 10 weeks.
Aliskiren 150 mg (Twice a Day)	Participants received Aliskiren 150 mg tablet + Placebo to Aliskiren matching 300 mg tablet daily in the morning and Aliskiren 150 mg tablet daily in the evening for the first 6 weeks then for the next 4 weeks received Aliskiren 300 mg tablet + Placebo to Aliskiren matching 150 mg tablet daily in the morning and Placebo to Aliskiren matching 150 mg tablet daily in the evening.

Measured Values

	Aliskiren 300 mg (Once a Day)	**Aliskiren 150 mg (Twice a Day)**
Number of Participants Analyzed [units: participants]	**158**	**156**
Percentage of Participants Achieving Blood Pressure Control at Week 6 [units: Percentage of participants]	**24.7**	**26.9**

No statistical analysis provided for Percentage of Participants Achieving Blood Pressure Control at Week 6

7. Secondary: Percentage of Participants Achieving Blood Pressure Control at the End of the Study (Week 10) [Time Frame: Week 10]

Measure Type	Secondary
Measure Title	Percentage of Participants Achieving Blood Pressure Control at the End of the Study (Week 10)
Measure Description	After the patient had been sitting for 5 minutes, with the back supported and both feet placed on the floor, systolic and diastolic blood pressures were measured 3 times using a calibrated standard sphygmomanometer. The mean of these 3 sitting blood pressure measurements was used as the average sitting blood pressure at visit 4 (week 10). Blood pressure control was defined as having a mean sitting diastolic blood pressure (msDBP) <90 mm Hg and a mean sitting systolic blood pressure (msSBP) <140 mm Hg.
Time Frame	Week 10
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.
Participants from the Full analysis set (consisting of all randomized patients) for whom data was available at Week 10.

Reporting Groups

	Description
Aliskiren 300 mg (Once a Day)	Participants received Aliskiren 300 mg tablet + Placebo to Aliskiren matching 150 mg tablet daily in the

	morning and Placebo to Aliskiren matching 150 mg tablet daily in the evening for a total of 10 weeks.
Aliskiren 150 mg (Twice a Day)	Participants received Aliskiren 150 mg tablet + Placebo to Aliskiren matching 300 mg tablet daily in the morning and Aliskiren 150 mg tablet daily in the evening for the first 6 weeks then for the next 4 weeks received Aliskiren 300 mg tablet + Placebo to Aliskiren matching 150 mg tablet daily in the morning and Placebo to Aliskiren matching 150 mg tablet daily in the evening.

Measured Values

	Aliskiren 300 mg (Once a Day)	Aliskiren 150 mg (Twice a Day)
Number of Participants Analyzed [units: participants]	**154**	**155**
Percentage of Participants Achieving Blood Pressure Control at the End of the Study (Week 10) [units: Percentage of participants]	**24.0**	**27.7**

No statistical analysis provided for Percentage of Participants Achieving Blood Pressure Control at the End of the Study (Week 10)

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	10 Weeks
Additional Description	No text entered.

Reporting Groups

	Description
Aliskiren 300 mg (Once a Day)	Participants received Aliskiren 300 mg tablet + Placebo to Aliskiren matching 150 mg tablet daily in the morning and Placebo to Aliskiren matching 150 mg tablet daily in the evening for a total of 10 weeks.
Aliskiren 150 mg (Twice a Day)	Participants received Aliskiren 150 mg tablet + Placebo to Aliskiren matching 300 mg tablet daily in the morning and Aliskiren 150 mg tablet daily in the evening for the first 6 weeks then for the next 4 weeks received Aliskiren 300 mg tablet + Placebo to Aliskiren matching 150 mg tablet daily in the morning and Placebo to Aliskiren matching 150 mg tablet daily in the evening.

Serious Adverse Events

	Aliskiren 300 mg (Once a Day)	Aliskiren 150 mg (Twice a Day)
Total, serious adverse events		
# participants affected / at risk	**2/164 (1.22%)**	**2/164 (1.22%)**
Infections and infestations		
Appendicitis † 1		
# participants affected / at risk	**1/164 (0.61%)**	**0/164 (0.00%)**
Injury, poisoning and procedural complications		
Contusion † 1		
# participants affected / at risk	**0/164 (0.00%)**	**1/164 (0.61%)**
Head injury † 1		
# participants affected / at risk	**0/164 (0.00%)**	**1/164 (0.61%)**
Investigations		
Blood creatine phosphokinase increased † 1		
# participants affected / at risk	**0/164 (0.00%)**	**1/164 (0.61%)**

Nervous system disorders		
Syncope † 1		
# participants affected / at risk	**1/164 (0.61%)**	**0/164 (0.00%)**

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

Other Adverse Events

Hide Other Adverse Events

Time Frame	10 Weeks
Additional Description	No text entered.

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
Aliskiren 300 mg (Once a Day)	Participants received Aliskiren 300 mg tablet + Placebo to Aliskiren matching 150 mg tablet daily in the morning and Placebo to Aliskiren matching 150 mg tablet daily in the evening for a total of 10 weeks.
Aliskiren 150 mg (Twice a Day)	Participants received Aliskiren 150 mg tablet + Placebo to Aliskiren matching 300 mg tablet daily in the morning and Aliskiren 150 mg tablet daily in the evening for the first 6 weeks then for the next 4 weeks received Aliskiren 300 mg tablet + Placebo to Aliskiren matching 150 mg tablet daily in the morning and Placebo to Aliskiren matching 150 mg tablet daily in the evening.

Other Adverse Events

	Aliskiren 300 mg (Once a Day)	**Aliskiren 150 mg (Twice a Day)**
Total, other (not including serious) adverse events		
# participants affected / at risk	**0/164 (0.00%)**	**0/164 (0.00%)**

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:	NCT00654875 History of Changes
Other Study ID Numbers:	**CSPP100A2403**
Study First Received:	April 3, 2008
Results First Received:	December 13, 2010
Last Updated:	June 24, 2011
Health Authority:	United States: Food and Drug Administration Germany: Federal Institute for Drugs and Medical Devices Spain: Spanish Agency of Medicines