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Trial record **1 of 1** for: CSPP100A2405

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Efficacy and Safety of Aliskiren 75 mg, 150 mg, and 300 mg in Elderly Patients With Essential Hypertension When Given With a Light Meal in a 8 Week Placebo-controlled Study

This study has been completed.

Sponsor:
Novartis

Information provided by:
Novartis

ClinicalTrials.gov Identifier:
NCT00706134

First received: June 25, 2008
Last updated: June 24, 2011
Last verified: June 2011
History of Changes

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Results First Received: January 10, 2011

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:	Hypertension
Interventions:	Drug: Placebo Drug: Aliskiren 75 mg Drug: Aliskiren 150 mg Drug: Aliskiren 300 mg

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
Placebo	Placebo tablet taken once daily in the morning with a light meal.
Aliskiren 75 mg	Aliskiren 75 mg tablet taken once daily in the morning with a light meal.
Aliskiren 150 mg	Aliskiren 150 mg tablet taken once daily in the morning with a light meal.
Aliskiren 300 mg	Aliskiren 300 mg tablet taken once daily in the morning with a light meal.

Participant Flow: Overall Study

	Placebo	Aliskiren 75 mg	Aliskiren 150 mg	Aliskiren 300 mg
STARTED	189	192	189	186
Entered Double-blind Period	187	192	189	186
COMPLETED	169	173	183	175
NOT COMPLETED	20	19	6	11
Adverse Event	8	7	2	3
Lost to Follow-up	0	1	0	0
Protocol Violation	0	6	0	3
Withdrawal by Subject	1	2	1	0
Unsatisfactory therapeutic effect	9	3	3	5
Did not meet study criteria	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
Placebo	Placebo tablet taken once daily in the morning with a light meal.
Aliskiren 75 mg	Aliskiren 75 mg tablet taken once daily in the morning with a light meal.
Aliskiren 150 mg	Aliskiren 150 mg tablet taken once daily in the morning with a light meal.
Aliskiren 300 mg	Aliskiren 300 mg tablet taken once daily in the morning with a light meal.
Total	Total of all reporting groups

Baseline Measures

	Placebo	Aliskiren 75 mg	Aliskiren 150 mg	Aliskiren 300 mg	Total
Number of Participants [units: participants]	189	192	189	186	756
Age, Customized [units: Participants]					
≥ 65 and < 75 years of age	128	131	129	129	517
≥ 75 years of age	61	61	60	57	239
Gender [units: Participants]					
Female	100	109	106	102	417
Male	89	83	83	84	339

Outcome Measures

Hide All Outcome Measures

1. Primary: Change in Mean Sitting Systolic Blood Pressure (msSBP)From Baseline to End of Study (Week 8) [Time Frame: Baseline to end of study (Week 8)]

Measure Type	Primary
Measure Title	Change in Mean Sitting Systolic Blood Pressure (msSBP)From Baseline to End of Study (Week 8)
Measure Description	No text entered.
Time Frame	Baseline to end of study (Week 8)
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.
Full analysis set (FAS) - All randomized patients. Two randomized patients who did not meet study criteria were excluded from the FAS.

Reporting Groups

	Description
Placebo	Placebo tablet taken once daily in the morning with a light meal.
Aliskiren 75 mg	Aliskiren 75 mg tablet taken once daily in the morning with a light meal.
Aliskiren 150 mg	Aliskiren 150 mg tablet taken once daily in the morning with a light meal.
Aliskiren 300 mg	Aliskiren 300 mg tablet taken once daily in the morning with a light meal.

Measured Values

	Placebo	**Aliskiren 75 mg**	**Aliskiren 150 mg**	**Aliskiren 300 mg**
Number of Participants Analyzed [units: participants]	**184**	**192**	**188**	**186**
Change in Mean Sitting Systolic Blood Pressure (msSBP)From Baseline to End of Study (Week 8) [units: mmHg] Least Squares Mean (Standard Error)	**-7.97 (1.043)**	**-12.51 (1.024)**	**-15.28 (1.035)**	**-14.14 (1.042)**

No statistical analysis provided for Change in Mean Sitting Systolic Blood Pressure (msSBP)From Baseline to End of Study (Week 8)

2. Secondary: Change in Mean Sitting Diastolic Blood Pressure (msDBP) From Baseline to End of Study (Week 8) [Time Frame: Baseline to end of study (Week 8)]

Measure Type	Secondary
Measure Title	Change in Mean Sitting Diastolic Blood Pressure (msDBP) From Baseline to End of Study (Week 8)
Measure Description	No text entered.
Time Frame	Baseline to end of study (Week 8)
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.

Full analysis set (FAS) - All randomized patients. Two randomized patients who did not meet study criteria were excluded from the FAS.

Reporting Groups

	Description
Placebo	Placebo tablet taken once daily in the morning with a light meal.
Aliskiren 75 mg	Aliskiren 75 mg tablet taken once daily in the morning with a light meal.
Aliskiren 150 mg	Aliskiren 150 mg tablet taken once daily in the morning with a light meal.
Aliskiren 300 mg	Aliskiren 300 mg tablet taken once daily in the morning with a light meal.

Measured Values

	Placebo	Aliskiren 75 mg	Aliskiren 150 mg	Aliskiren 300 mg
Number of Participants Analyzed [units: participants]	**184**	**192**	**188**	**186**
Change in Mean Sitting Diastolic Blood Pressure (msDBP) From Baseline to End of Study (Week 8) [units: mmHg] Least Squares Mean (Standard Error)	**-3.50 (0.579)**	**-5.33 (0.568)**	**-6.42 (0.575)**	**-6.66 (0.579)**

No statistical analysis provided for Change in Mean Sitting Diastolic Blood Pressure (msDBP) From Baseline to End of Study (Week 8)

3. Secondary: Percentage of Patients Achieving Systolic Blood Pressure Response [Time Frame: Baseline to end of study (Week 8)]

Measure Type	Secondary
Measure Title	Percentage of Patients Achieving Systolic Blood Pressure Response
Measure Description	Patients achieving a systolic blood pressure response had to have a msSBP < 140 mmHg at the end of the study and/or a ≥ 20 mmHg reduction in msSBP from baseline to the end of the study.
Time Frame	Baseline to end of study (Week 8)
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.
Full analysis set (FAS) - All randomized patients. Two randomized patients who did not meet study criteria were excluded from the FAS.

Reporting Groups

	Description
Placebo	Placebo tablet taken once daily in the morning with a light meal.
Aliskiren 75 mg	Aliskiren 75 mg tablet taken once daily in the morning with a light meal.
Aliskiren 150 mg	Aliskiren 150 mg tablet taken once daily in the morning with a light meal.
Aliskiren 300 mg	Aliskiren 300 mg tablet taken once daily in the morning with a light meal.

Measured Values

	Placebo	Aliskiren 75 mg	Aliskiren 150 mg	Aliskiren 300 mg
Number of Participants Analyzed [units: participants]	**184**	**192**	**188**	**186**

Percentage of Patients Achieving Systolic Blood Pressure Response [units: Percentage of participants]	**28.8**	**42.4**	**44.1**	**47.3**

No statistical analysis provided for Percentage of Patients Achieving Systolic Blood Pressure Response

4. Secondary: Change in Mean 24 Hour Ambulatory Systolic and Diastolic Blood Pressure From Baseline to End of Study [Time Frame: Baseline to end of study (Week 8)]

Measure Type	Secondary
Measure Title	Change in Mean 24 Hour Ambulatory Systolic and Diastolic Blood Pressure From Baseline to End of Study
Measure Description	Two 24-hour ambulatory blood pressure monitoring (ABPM) evaluations were performed, one at baseline and one at the end of the study. For each evaluation, the ABPM device was attached to the non-dominant arm of the patient.
Time Frame	Baseline to end of study (Week 8)
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.
Ambulatory blood pressure monitoring completers population: All patients that completed both ambulatory blood pressure monitoring assessments successfully.

Reporting Groups

	Description
Placebo	Placebo tablet taken once daily in the morning with a light meal.
Aliskiren 75 mg	Aliskiren 75 mg tablet taken once daily in the morning with a light meal.
Aliskiren 150 mg	Aliskiren 150 mg tablet taken once daily in the morning with a light meal.
Aliskiren 300 mg	Aliskiren 300 mg tablet taken once daily in the morning with a light meal.

Measured Values

	Placebo	**Aliskiren 75 mg**	**Aliskiren 150 mg**	**Aliskiren 300 mg**
Number of Participants Analyzed [units: participants]	**50**	**64**	**70**	**58**
Change in Mean 24 Hour Ambulatory Systolic and Diastolic Blood Pressure From Baseline to End of Study [units: mmHg] Mean (Standard Error)				
Ambulatory Systolic Blood Pressure	**-1.15 (1.280)**	**-3.33 (1.155)**	**-5.76 (1.128)**	**-5.83 (1.520)**
Ambulatory Diastolic Blood Pressure	**0.31 (0.990)**	**-1.78 (0.877)**	**-3.26 (0.693)**	**-2.45 (0.823)**

No statistical analysis provided for Change in Mean 24 Hour Ambulatory Systolic and Diastolic Blood Pressure From Baseline to End of Study

5. Secondary: Change in the Smoothness Index (SI) of the Ambulatory Systolic Blood Pressure From Baseline to End of Study (Week 8) [Time Frame: Baseline to end of study (Week 8)]

Measure Type	Secondary

Measure Title	Change in the Smoothness Index (SI) of the Ambulatory Systolic Blood Pressure From Baseline to End of Study (Week 8)
Measure Description	Smoothness index (SI) is a measure of consistency of the BP reduction over 24 hours. The SI was obtained by first calculating the mean blood pressure value at each hour of the 24-hour ambulatory blood pressure monitoring period, both before and during treatment. Similarly, the change from baseline in blood pressure was calculated at each hour. The average hourly change from baseline (δh) and standard deviation (std δh) of the hourly changes were computed, and the SI was derived: SI = δh/std δh. A negative change score indicates improvement.
Time Frame	Baseline to end of study (Week 8)
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.
Ambulatory blood pressure monitoring completers population: All patients that completed both ambulatory blood pressure monitoring assessments successfully.

Reporting Groups

	Description
Placebo	Placebo tablet taken once daily in the morning with a light meal.
Aliskiren 75 mg	Aliskiren 75 mg tablet taken once daily in the morning with a light meal.
Aliskiren 150 mg	Aliskiren 150 mg tablet taken once daily in the morning with a light meal.
Aliskiren 300 mg	Aliskiren 300 mg tablet taken once daily in the morning with a light meal.

Measured Values

	Placebo	**Aliskiren 75 mg**	**Aliskiren 150 mg**	**Aliskiren 300 mg**
Number of Participants Analyzed [units: participants]	**50**	**64**	**70**	**58**
Change in the Smoothness Index (SI) of the Ambulatory Systolic Blood Pressure From Baseline to End of Study (Week 8) [units: Ratio] Least Squares Mean (Standard Error)	**-0.11 (0.102)**	**-0.38 (0.092)**	**-0.50 (0.089)**	**-0.51 (0.096)**

No statistical analysis provided for Change in the Smoothness Index (SI) of the Ambulatory Systolic Blood Pressure From Baseline to End of Study (Week 8)

6. Secondary: Change in Morning Surge of Ambulatory Systolic Blood Pressure From Baseline to End of Study (Week 8) [Time Frame: Baseline to end of study (week 8)]

Measure Type	Secondary
Measure Title	Change in Morning Surge of Ambulatory Systolic Blood Pressure From Baseline to End of Study (Week 8)
Measure Description	The morning surge was defined as the average of the hourly means in the last three hours (hours 22, 23, 24) of the 24 hour ambulatory blood pressure monitoring assessment period.
Time Frame	Baseline to end of study (week 8)
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.

Ambulatory blood pressure monitoring completers population: All patients that completed both ambulatory blood pressure monitoring assessments successfully.

Reporting Groups

	Description
Placebo	Placebo tablet taken once daily in the morning with a light meal.
Aliskiren 75 mg	Aliskiren 75 mg tablet taken once daily in the morning with a light meal.
Aliskiren 150 mg	Aliskiren 150 mg tablet taken once daily in the morning with a light meal.
Aliskiren 300 mg	Aliskiren 300 mg tablet taken once daily in the morning with a light meal.

Measured Values

	Placebo	Aliskiren 75 mg	Aliskiren 150 mg	Aliskiren 300 mg
Number of Participants Analyzed [units: participants]	**50**	**64**	**70**	**58**
Change in Morning Surge of Ambulatory Systolic Blood Pressure From Baseline to End of Study (Week 8) [units: mmHg] Least Squares Mean (Standard Error)	**0.46 (1.782)**	**-3.04 (1.596)**	**-7.03 (1.539)**	**-3.96 (1.660)**

No statistical analysis provided for Change in Morning Surge of Ambulatory Systolic Blood Pressure From Baseline to End of Study (Week 8)

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	End of study (week 8)
Additional Description	Population description of safety set.

Reporting Groups

	Description
Placebo	Placebo tablet taken once daily in the morning with a light meal.
Aliskiren 75 mg	Aliskiren 75 mg tablet taken once daily in the morning with a light meal.
Aliskiren 150 mg	Aliskiren 150 mg tablet taken once daily in the morning with a light meal.
Aliskiren 300 mg	Aliskiren 300 mg tablet taken once daily in the morning with a light meal.

Serious Adverse Events

	Placebo	Aliskiren 75 mg	Aliskiren 150 mg	Aliskiren 300 mg
Total, serious adverse events				
# participants affected / at risk	**1/186 (0.54%)**	**2/191 (1.05%)**	**3/189 (1.59%)**	**0/188 (0.00%)**
Ear and labyrinth disorders				
Vertigo † 1				
# participants affected / at risk	**1/186 (0.54%)**	**0/191 (0.00%)**	**0/189 (0.00%)**	**0/188 (0.00%)**
Eye disorders				
Glaucoma † 1				
# participants affected / at risk	**0/186 (0.00%)**	**0/191 (0.00%)**	**1/189 (0.53%)**	**0/188 (0.00%)**
Gastrointestinal disorders				

Haemorrhoidal haemorrhage † 1				
# participants affected / at risk	**0/186 (0.00%)**	**0/191 (0.00%)**	**1/189 (0.53%)**	**0/188 (0.00%)**
Infections and infestations				
Erysipelas † 1				
# participants affected / at risk	**0/186 (0.00%)**	**1/191 (0.52%)**	**0/189 (0.00%)**	**0/188 (0.00%)**
Injury, poisoning and procedural complications				
Concussion † 1				
# participants affected / at risk	**1/186 (0.54%)**	**0/191 (0.00%)**	**0/189 (0.00%)**	**0/188 (0.00%)**
Contusion † 1				
# participants affected / at risk	**1/186 (0.54%)**	**0/191 (0.00%)**	**0/189 (0.00%)**	**0/188 (0.00%)**
Wrist fracture † 1				
# participants affected / at risk	**1/186 (0.54%)**	**0/191 (0.00%)**	**0/189 (0.00%)**	**0/188 (0.00%)**
Musculoskeletal and connective tissue disorders				
Osteoarthritis † 1				
# participants affected / at risk	**0/186 (0.00%)**	**1/191 (0.52%)**	**0/189 (0.00%)**	**0/188 (0.00%)**
Nervous system disorders				
Haemorrhagic stroke † 1				
# participants affected / at risk	**0/186 (0.00%)**	**0/191 (0.00%)**	**1/189 (0.53%)**	**0/188 (0.00%)**

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

Other Adverse Events

Hide Other Adverse Events

Time Frame	End of study (week 8)
Additional Description	Population description of safety set.

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
Placebo	Placebo tablet taken once daily in the morning with a light meal.
Aliskiren 75 mg	Aliskiren 75 mg tablet taken once daily in the morning with a light meal.
Aliskiren 150 mg	Aliskiren 150 mg tablet taken once daily in the morning with a light meal.
Aliskiren 300 mg	Aliskiren 300 mg tablet taken once daily in the morning with a light meal.

Other Adverse Events

	Placebo	**Aliskiren 75 mg**	**Aliskiren 150 mg**	**Aliskiren 300 mg**
Total, other (not including serious) adverse events				
# participants affected / at risk	**0/186 (0.00%)**	**0/191 (0.00%)**	**0/189 (0.00%)**	**0/188 (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:	NCT00706134 History of Changes
Other Study ID Numbers:	**CSPP100A2405**
Study First Received:	June 25, 2008
Results First Received:	January 10, 2011
Last Updated:	June 24, 2011
Health Authority:	Czech Republic: State Institute for Drug Control France: Afssaps - Agence française de sécurité sanitaire des produits de santé (Saint-Denis) Germany: Federal Institute for Drugs and Medical Devices Italy: National Institute of Health Netherlands: Medicines Evaluation Board (MEB) Poland: Office for Registration of Medicinal Products, Medical Devices and Biocidal Products Slovakia: State Institute for Drug Control