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Trial record **1 of 1** for: CSPA100A2306

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Efficacy and Safety of the Combination of Aliskiren (300 mg) and Amlodipine (10 mg) Compared to Amlodipine (10 mg) Monotherapy in Patients With Moderate to Severe Hypertension

This study has been completed.

Sponsor:
Novartis

Information provided by:
Novartis

ClinicalTrials.gov Identifier:
NCT00841672

First received: February 10, 2009
Last updated: July 5, 2011
Last verified: July 2011
History of Changes

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Results First Received: January 5, 2011

Study Type:	Interventional
Study Design:	Allocation: Randomized; Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Caregiver, Investigator); Primary Purpose: Treatment
Condition:	Moderate to Severe Hypertension
Interventions:	Drug: Aliskiren/amlodipine 300/10 mg tablet Drug: Amlodipine 10 mg capsule

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/Amlodipine 300/10 mg Tablet	Aliskiren/amlodipine treatment regimen: At randomization, patients were treated with aliskiren/amlodipine 150/5 mg for one week. For the remaining 7 weeks of the study, patients were force-titrated to receive aliskiren/amlodipine 300/10 mg.
Amlodipine 10 mg Capsule	Amlodipine treatment regimen: At randomization, patients were treated with amlodipine 5 mg for one week. For the remaining 7 weeks of the study, patients were force-titrated to receive amlodipine 10 mg.

Participant Flow: Overall Study

	Aliskiren/Amlodipine 300/10 mg Tablet	Amlodipine 10 mg Capsule

STARTED	**244** [1]	**241**
COMPLETED	**224**	**209**
NOT COMPLETED	**20**	**32**
Adverse Event	**7**	**16**
Abnormal test procedure result(s)	**0**	**1**
Subject withdrew consent	**2**	**4**
Lost to Follow-up	**1**	**1**
Administrative problems	**9**	**9**
Misrandomized	**1**	**0**
Protocol Deviation	**0**	**1**

[1] One patient was mis-randomized and was not treated in the double-blind treatment period.

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/Amlodipine 300/10 mg Tablet	Aliskiren/amlodipine treatment regimen: At randomization, patients were treated with aliskiren/amlodipine 150/5 mg for one week. For the remaining 7 weeks of the study, patients were force-titrated to receive aliskiren/amlodipine 300/10 mg.
Amlodipine 10 mg Capsule	Amlodipine treatment regimen: At randomization, patients were treated with amlodipine 5 mg for one week. For the remaining 7 weeks of the study, patients were force-titrated to receive amlodipine 10 mg.
Total	Total of all reporting groups

Baseline Measures

	Aliskiren/Amlodipine 300/10 mg Tablet	Amlodipine 10 mg Capsule	Total
Number of Participants [units: participants]	**244**	**241**	**485**
Age [units: years] Mean (Standard Deviation)	**59 (10.38)**	**59 (10.82)**	**59 (10.60)**
Gender [units: participants]			
Female	**136**	**139**	**275**
Male	**108**	**102**	**210**

Outcome Measures

Hide All Outcome Measures

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

Measure Type	Primary
Measure Title	Mean Sitting Systolic Blood Pressure (msSBP)
Measure Description	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)
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 - analysis set was the FAS excluding patients from one center due to Good Clinical Practices (GCP) issues

Reporting Groups

	Description
Aliskiren/Amlodipine 300/10 mg Tablet	Aliskiren/amlodipine treatment regimen: At randomization, patients were treated with aliskiren/amlodipine 150/5 mg for one week. For the remaining 7 weeks of the study, patients were force-titrated to receive aliskiren/amlodipine 300/10 mg.
Amlodipine 10 mg Capsule	Amlodipine treatment regimen: At randomization, patients were treated with amlodipine 5 mg for one week. For the remaining 7 weeks of the study, patients were force-titrated to receive amlodipine 10 mg.

Measured Values

	Aliskiren/Amlodipine 300/10 mg Tablet	**Amlodipine 10 mg Capsule**
Number of Participants Analyzed [units: participants]	**233**	**230**
Mean Sitting Systolic Blood Pressure (msSBP) [units: mm Hg] Least Squares Mean (Standard Error)	**-37.72 (0.937)**	**-30.63 (0.941)**

No statistical analysis provided for Mean Sitting Systolic Blood Pressure (msSBP)

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

Measure Type	Secondary
Measure Title	Mean Sitting Diastolic Blood Pressure (msDBP)
Measure Description	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)
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 - analysis set was the FAS excluding patients from one center due to Good Clinical Practices (GCP) issues

Reporting Groups

	Description
Aliskiren/Amlodipine 300/10 mg Tablet	Aliskiren/amlodipine treatment regimen: At randomization, patients were treated with aliskiren/amlodipine 150/5 mg for one week. For the remaining 7 weeks of the study, patients were

	force-titrated to receive aliskiren/amlodipine 300/10 mg.
Amlodipine 10 mg Capsule	Amlodipine treatment regimen: At randomization, patients were treated with amlodipine 5 mg for one week. For the remaining 7 weeks of the study, patients were force-titrated to receive amlodipine 10 mg.

Measured Values

	Aliskiren/Amlodipine 300/10 mg Tablet	**Amlodipine 10 mg Capsule**
Number of Participants Analyzed [units: participants]	**233**	**230**
Mean Sitting Diastolic Blood Pressure (msDBP) [units: mm Hg] Least Squares Mean (Standard Error)	**-16.10 (0.557)**	**-12.27 (0.559)**

No statistical analysis provided for Mean Sitting Diastolic Blood Pressure (msDBP)

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

Measure Type	Secondary
Measure Title	Systolic Blood Pressure Response
Measure Description	Percentage of patients achieving a mean sitting systolic blood pressure response (msSBP < 140 mmHg or a reduction => 20 mmHg from the baseline) from baseline to end of study (Week 8)
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 - analysis set was the FAS excluding patients from one center due to GCP issues

Reporting Groups

	Description
Aliskiren/Amlodipine 300/10 mg Tablet	Aliskiren/amlodipine treatment regimen: At randomization, patients were treated with aliskiren/amlodipine 150/5 mg for one week. For the remaining 7 weeks of the study, patients were force-titrated to receive aliskiren/amlodipine 300/10 mg.
Amlodipine 10 mg Capsule	Amlodipine treatment regimen: At randomization, patients were treated with amlodipine 5 mg for one week. For the remaining 7 weeks of the study, patients were force-titrated to receive amlodipine 10 mg.

Measured Values

	Aliskiren/Amlodipine 300/10 mg Tablet	**Amlodipine 10 mg Capsule**
Number of Participants Analyzed [units: participants]	**233**	**230**
Systolic Blood Pressure Response [units: Percentage of participants]	**88.8**	**79.1**

No statistical analysis provided for Systolic Blood Pressure Response

4. Secondary: Diastolic Blood Pressure Response [Time Frame: Baseline to end of study (Week 8)]

Measure Type	Secondary
Measure Title	Diastolic Blood Pressure Response
Measure Description	Percentage of patients achieving a mean sitting diastolic blood pressure response (msDBP < 90 mmHg or a reduction ≥ 10 mmHg from the baseline) from baseline to end of study (Week 8)
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 - analysis set was the FAS excluding patients from one center due to Good Clinical Practices (GCP) issues All randomized patients who received the study medication. The measurement at Week 8 was used unless it was not available, in which case, the last observation carried forward was used.

Reporting Groups

	Description
Aliskiren/Amlodipine 300/10 mg Tablet	Aliskiren/amlodipine treatment regimen: At randomization, patients were treated with aliskiren/amlodipine 150/5 mg for one week. For the remaining 7 weeks of the study, patients were force-titrated to receive aliskiren/amlodipine 300/10 mg.
Amlodipine 10 mg Capsule	Amlodipine treatment regimen: At randomization, patients were treated with amlodipine 5 mg for one week. For the remaining 7 weeks of the study, patients were force-titrated to receive amlodipine 10 mg.

Measured Values

	Aliskiren/Amlodipine 300/10 mg Tablet	**Amlodipine 10 mg Capsule**
Number of Participants Analyzed [units: participants]	**233**	**230**
Diastolic Blood Pressure Response [units: Percentage of participants]	**92.7**	**86.5**

No statistical analysis provided for Diastolic Blood Pressure Response

5. Secondary: Blood Pressure Control [Time Frame: End of study (Week 8)]

Measure Type	Secondary
Measure Title	Blood Pressure Control
Measure Description	Percentage of patients achieving blood pressure control (msSBP < 140 mm Hg and msDBP < 90 mm Hg) at end of study
Time Frame	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 - analysis set was the FAS excluding patients from one center due to Good Clinical Practices (GCP) issues

Reporting Groups

	Description

Aliskiren/Amlodipine 300/10 mg Tablet	Aliskiren/amlodipine treatment regimen: At randomization, patients were treated with aliskiren/amlodipine 150/5 mg for one week. For the remaining 7 weeks of the study, patients were force-titrated to receive aliskiren/amlodipine 300/10 mg.
Amlodipine 10 mg Capsule	Amlodipine treatment regimen: At randomization, patients were treated with amlodipine 5 mg for one week. For the remaining 7 weeks of the study, patients were force-titrated to receive amlodipine 10 mg.

Measured Values

	Aliskiren/Amlodipine 300/10 mg Tablet	Amlodipine 10 mg Capsule
Number of Participants Analyzed [units: participants]	**233**	**230**
Blood Pressure Control [units: Percentage of participants]	**67.0**	**49.1**

No statistical analysis provided for Blood Pressure Control

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	No text entered.
Additional Description	No text entered.

Reporting Groups

	Description
Aliskiren/Amlodipine 300/10 mg Tablet	Aliskiren/amlodipine treatment regimen: At randomization, patients were treated with aliskiren/amlodipine 150/5 mg for one week. For the remaining 7 weeks of the study, patients were force-titrated to receive aliskiren/amlodipine 300/10 mg.
Amlodipine 10 mg Capsule	Amlodipine treatment regimen: At randomization, patients were treated with amlodipine 5 mg for one week. For the remaining 7 weeks of the study, patients were force-titrated to receive amlodipine 10 mg.

Serious Adverse Events

	Aliskiren/Amlodipine 300/10 mg Tablet	Amlodipine 10 mg Capsule
Total, serious adverse events		
# participants affected / at risk	**0/243 (0.00%)**	**3/241 (1.24%)**
Blood and lymphatic system disorders		
Anaemia † 1		
# participants affected / at risk	**0/243 (0.00%)**	**1/241 (0.41%)**
Cardiac disorders		
Myocardial infarction † 1		
# participants affected / at risk	**0/243 (0.00%)**	**1/241 (0.41%)**
Nervous system disorders		
Cerebral infarction † 1		
# participants affected / at risk	**0/243 (0.00%)**	**1/241 (0.41%)**
Reproductive system and breast disorders		
Adenomyosis † 1		
# participants affected / at risk	**0/243 (0.00%)**	**1/241 (0.41%)**

Dysfunctional uterine bleeding † 1		
# participants affected / at risk	**0/243 (0.00%)**	**1/241 (0.41%)**

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

Other Adverse Events

Hide Other Adverse Events

Time Frame	No text entered.
Additional Description	No text entered.

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
Aliskiren/Amlodipine 300/10 mg Tablet	Aliskiren/amlodipine treatment regimen: At randomization, patients were treated with aliskiren/amlodipine 150/5 mg for one week. For the remaining 7 weeks of the study, patients were force-titrated to receive aliskiren/amlodipine 300/10 mg.
Amlodipine 10 mg Capsule	Amlodipine treatment regimen: At randomization, patients were treated with amlodipine 5 mg for one week. For the remaining 7 weeks of the study, patients were force-titrated to receive amlodipine 10 mg.

Other Adverse Events

	Aliskiren/Amlodipine 300/10 mg Tablet	**Amlodipine 10 mg Capsule**
Total, other (not including serious) adverse events		
# participants affected / at risk	**41/243 (16.87%)**	**56/241 (23.24%)**
General disorders		
Oedema peripheral † 1		
# participants affected / at risk	**35/243 (14.40%)**	**44/241 (18.26%)**
Nervous system disorders		
Headache † 1		
# participants affected / at risk	**8/243 (3.29%)**	**13/241 (5.39%)**

† 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:** No text entered.

Results Point of Contact:

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

No publications provided

Responsible Party:	External Affairs, Novartis
ClinicalTrials.gov Identifier:	NCT00841672 History of Changes
Other Study ID Numbers:	**CSPA100A2306**
Study First Received:	February 10, 2009
Results First Received:	January 5, 2011
Last Updated:	July 5, 2011
Health Authority:	Germany: Federal Institute for Drugs and Medical Devices Philippines: Bureau of Food and Drugs Spain: Spanish Agency of Medicines Romania: National Medicines Agency