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Trial record **1 of 1** for: CSPP100A2353

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Efficacy and Safety of the Combination Aliskiren (300 mg) and Hydrochlorothiazide (25mg) to Aliskiren (300mg) Monotherapy in Patients With Staged II Hypertension (ACQUIRE)

This study has been completed.

Sponsor:
Novartis

Information provided by:
Novartis

ClinicalTrials.gov Identifier:
NCT00705575

First received: June 23, 2008
Last updated: May 24, 2011
Last verified: May 2011
History of Changes

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Results First Received: December 22, 2010

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:	Hypertension
Interventions:	Drug: Aliskiren/hydrochlorothiazide (HCTZ) (300/25 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
Aliskiren/Hydrochlorothiazide (HCTZ) (300/25 mg)	During the titration period, patients received aliskiren/hydrochlorothiazide (HCTZ) 150/12.5 mg for 1 week. Subsequently, patients were up-titrated and received aliskiren/HCTZ 300/25 mg.
Aliskiren (300 mg)	During the titration period, patients received aliskiren 150 mg for one week. Subsequently, patients were up-titrated and received aliskiren 300 mg.

Participant Flow: Overall Study

	Aliskiren/Hydrochlorothiazide (HCTZ) (300/25 mg)	Aliskiren (300 mg)

STARTED	**349**	**339**
COMPLETED	**326**	**293**
NOT COMPLETED	**23**	**46**
Abnormal laboratory value(s)	**0**	**3**
Abnormal test procedure result(s)	**2**	**12**
Adverse Event	**11**	**15**
Lost to Follow-up	**3**	**4**
Protocol Violation	**2**	**2**
Withdrawal by Subject	**5**	**10**

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/Hydrochlorothiazide (HCTZ) (300/25 mg)	During the titration period, patients received aliskiren/hydrochlorothiazide (HCTZ) 150/12.5 mg for 1 week. Subsequently, patients were up-titrated and received aliskiren/HCTZ 300/25 mg.
Aliskiren (300 mg)	During the titration period, patients received aliskiren 150 mg for one week. Subsequently, patients were up-titrated and received aliskiren 300 mg.
Total	Total of all reporting groups

Baseline Measures

	Aliskiren/Hydrochlorothiazide (HCTZ) (300/25 mg)	**Aliskiren (300 mg)**	**Total**
Number of Participants [units: participants]	**349**	**339**	**688**
Age [units: years] Mean (Standard Deviation)	**57.4 (10.33)**	**56.4 (10.73)**	**56.9 (10.53)**
Gender [units: participants]			
Female	**169**	**172**	**341**
Male	**180**	**167**	**347**

Outcome Measures

Hide All Outcome Measures

1. Primary: Change in Mean Sitting Systolic Blood Pressure (msSBP) From Baseline to End of Study (Week 12) [Time Frame: Baseline to end of study (Week 12)]

Measure Type	Primary

Measure Title	Change in Mean Sitting Systolic Blood Pressure (msSBP) From Baseline to End of Study (Week 12)
Measure Description	At the first visit, blood pressure (BP) was measured in both arms and the arm having the higher BP reading was the arm used for all subsequent readings throughout the study. Patients were required to sit for five minutes with feet flat on the floor, with arm resting so that the bottom of the cuff was at the same level as the heart. BP was measured three times at 1 to 2-minute intervals at each visit using the correct cuff size. The mean BP was calculated from the 3 readings.
Time Frame	Baseline to end of study (Week 12)
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. For each patient, the last post-baseline measurement during the double-blind period was carried forward. n = number of patients with non-missing Week 12 measurement or last observation carried forward (LOCF) value.

Reporting Groups

	Description
Aliskiren/Hydrochlorothiazide (HCTZ) (300/25 mg)	During the titration period, patients received aliskiren/hydrochlorothiazide (HCTZ) 150/12.5 mg for 1 week. Subsequently, patients were up-titrated and received aliskiren/HCTZ 300/25 mg.
Aliskiren (300 mg)	During the titration period, patients received aliskiren 150 mg for one week. Subsequently, patients were up-titrated and received aliskiren 300 mg.

Measured Values

	Aliskiren/Hydrochlorothiazide (HCTZ) (300/25 mg)	**Aliskiren (300 mg)**
Number of Participants Analyzed [units: participants]	**346**	**335**
Change in Mean Sitting Systolic Blood Pressure (msSBP) From Baseline to End of Study (Week 12) [units: mm Hg] Least Squares Mean (Standard Error)	**-30.01 (1.053)**	**-20.29 (1.067)**

No statistical analysis provided for Change in Mean Sitting Systolic Blood Pressure (msSBP) From Baseline to End of Study (Week 12)

2. Secondary: Change in Mean Sitting Systolic Blood Pressure (msSBP) From Baseline to Week 8 [Time Frame: Baseline to Week 8]

Measure Type	Secondary
Measure Title	Change in Mean Sitting Systolic Blood Pressure (msSBP) From Baseline to Week 8
Measure Description	At the first visit, blood pressure (BP) was measured in both arms and the arm having the higher BP reading was the arm used for all subsequent readings throughout the study. Patients were required to sit for five minutes with feet flat on the floor, with arm resting so that the bottom of the cuff was at the same level as the heart. BP was measured three times at 1 to 2-minute intervals at each visit using the correct cuff size. The mean BP was calculated from the 3 readings.
Time Frame	Baseline to 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. For each patient, the last post-baseline measurement during the double-blind period was

carried forward. n = number of patients with non-missing Week 8 measurement or last observation carried forward (LOCF) value.

Reporting Groups

	Description
Aliskiren/Hydrochlorothiazide (HCTZ) (300/25 mg)	During the titration period, patients received aliskiren/hydrochlorothiazide (HCTZ) 150/12.5 mg for 1 week. Subsequently, patients were up-titrated and received aliskiren/HCTZ 300/25 mg.
Aliskiren (300 mg)	During the titration period, patients received aliskiren 150 mg for one week. Subsequently, patients were up-titrated and received aliskiren 300 mg.

Measured Values

	Aliskiren/Hydrochlorothiazide (HCTZ) (300/25 mg)	Aliskiren (300 mg)
Number of Participants Analyzed [units: participants]	**346**	**335**
Change in Mean Sitting Systolic Blood Pressure (msSBP) From Baseline to Week 8 [units: mm Hg] Least Squares Mean (Standard Error)	**-30.09 (1.079)**	**-20.75 (1.094)**

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

3. Secondary: Change in Mean Sitting Diastolic Blood Pressure (msDBP) From Baseline to Week 8 and to Week 12 [Time Frame: Baseline to Week 12]

Measure Type	Secondary
Measure Title	Change in Mean Sitting Diastolic Blood Pressure (msDBP) From Baseline to Week 8 and to Week 12
Measure Description	At the first visit, blood pressure (BP) was measured in both arms and the arm having the higher BP reading was the arm used for all subsequent readings throughout the study. Patients were required to sit for five minutes with feet flat on the floor, with arm resting so that the bottom of the cuff was at the same level as the heart. BP was measured three times at 1 to 2-minute intervals at each visit using the correct cuff size. The mean BP was calculated from the 3 readings.
Time Frame	Baseline to Week 12
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. For each patient, the last post-baseline measurement during the double-blind period was carried forward. n = number of patients with non-missing Week 8 or Week 12 measurement or last observation carried forward (LOCF) value.

Reporting Groups

	Description
Aliskiren/Hydrochlorothiazide (HCTZ) (300/25 mg)	During the titration period, patients received aliskiren/hydrochlorothiazide (HCTZ) 150/12.5 mg for 1 week. Subsequently, patients were up-titrated and received aliskiren/HCTZ 300/25 mg.
Aliskiren (300 mg)	During the titration period, patients received aliskiren 150 mg for one week. Subsequently, patients were up-titrated and received aliskiren 300 mg.

Measured Values

	Aliskiren/Hydrochlorothiazide (HCTZ)	Aliskiren (300

	(300/25 mg)	mg)
Number of Participants Analyzed [units: participants]	**346**	**335**
Change in Mean Sitting Diastolic Blood Pressure (msDBP) From Baseline to Week 8 and to Week 12 [units: mm Hg] Least Squares Mean (Standard Error)		
Baseline to Week 8	**-13.69 (0.599)**	**-7.99 (0.607)**
Baseline to Week 12	**-12.64 (0.590)**	**-8.18 (0.598)**

No statistical analysis provided for Change in Mean Sitting Diastolic Blood Pressure (msDBP) From Baseline to Week 8 and to Week 12

4. Secondary: Percentage of Patients Achieving the Target Blood Pressure (msSBP < 140 mm Hg and msDBP < 90 mm Hg, and msSBP < 130 mm Hg and msDBP < 80 mm Hg for Diabetics) at Week 8 and Week 12 [Time Frame: Baseline to Week 12]

Measure Type	Secondary
Measure Title	Percentage of Patients Achieving the Target Blood Pressure (msSBP < 140 mm Hg and msDBP < 90 mm Hg, and msSBP < 130 mm Hg and msDBP < 80 mm Hg for Diabetics) at Week 8 and Week 12
Measure Description	At the first visit, blood pressure (BP) was measured in both arms and the arm having the higher BP reading was the arm used for all subsequent readings throughout the study. Patients were required to sit for five minutes with feet flat on the floor, with arm resting so that the bottom of the cuff was at the same level as the heart. BP was measured three times at 1 to 2-minute intervals at each visit using the correct cuff size. The mean BP was calculated from the 3 readings.
Time Frame	Baseline to Week 12
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. For each patient, the last post-baseline measurement during the double-blind period was carried forward. n = number of patients with non-missing Week 8 or Week 12 measurement or last observation carried forward (LOCF) value.

Reporting Groups

	Description
Aliskiren/Hydrochlorothiazide (HCTZ) (300/25 mg)	During the titration period, patients received aliskiren/hydrochlorothiazide (HCTZ) 150/12.5 mg for 1 week. Subsequently, patients were up-titrated and received aliskiren/HCTZ 300/25 mg.
Aliskiren (300 mg)	During the titration period, patients received aliskiren 150 mg for one week. Subsequently, patients were up-titrated and received aliskiren 300 mg.

Measured Values

	Aliskiren/Hydrochlorothiazide (HCTZ) (300/25 mg)	**Aliskiren (300 mg)**
Number of Participants Analyzed [units: participants]	**346**	**335**
Percentage of Patients Achieving the Target Blood Pressure (msSBP < 140 mm Hg and msDBP < 90 mm Hg, and msSBP < 130 mm Hg and msDBP < 80 mm Hg for Diabetics) at Week 8 and Week 12 [units: Percentage]		

Baseline to Week 8	**53.5**	**30.4**
Baseline to Week 12	**54.6**	**32.2**

No statistical analysis provided for Percentage of Patients Achieving the Target Blood Pressure (msSBP < 140 mm Hg and msDBP < 90 mm Hg, and msSBP < 130 mm Hg and msDBP < 80 mm Hg for Diabetics) at Week 8 and Week 12

Serious Adverse Events

Hide Serious Adverse Events

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

Reporting Groups

	Description
Aliskiren/Hydrochlorothiazide (HCTZ) (300/25 mg)	During the titration period, patients received aliskiren/hydrochlorothiazide (HCTZ) 150/12.5 mg for 1 week. Subsequently, patients were up-titrated and received aliskiren/HCTZ 300/25 mg.
Aliskiren (300 mg)	During the titration period, patients received aliskiren 150 mg for one week. Subsequently, patients were up-titrated and received aliskiren 300 mg.

Serious Adverse Events

	Aliskiren/Hydrochlorothiazide (HCTZ) (300/25 mg)	Aliskiren (300 mg)
Total, serious adverse events		
# participants affected / at risk	**2/349 (0.57%)**	**4/339 (1.18%)**
Ear and labyrinth disorders		
Vertigo † 1		
# participants affected / at risk	**0/349 (0.00%)**	**1/339 (0.29%)**
Gastrointestinal disorders		
Haemorrhoids † 1		
# participants affected / at risk	**1/349 (0.29%)**	**0/339 (0.00%)**
Injury, poisoning and procedural complications		
Fracture displacement † 1		
# participants affected / at risk	**0/349 (0.00%)**	**1/339 (0.29%)**
Radius fracture † 1		
# participants affected / at risk	**0/349 (0.00%)**	**1/339 (0.29%)**
Tendon rupture † 1		
# participants affected / at risk	**1/349 (0.29%)**	**0/339 (0.00%)**
Renal and urinary disorders		
Nephrolithiasis † 1		
# participants affected / at risk	**0/349 (0.00%)**	**2/339 (0.59%)**

† 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/Hydrochlorothiazide (HCTZ) (300/25 mg)	During the titration period, patients received aliskiren/hydrochlorothiazide (HCTZ) 150/12.5 mg for 1 week. Subsequently, patients were up-titrated and received aliskiren/HCTZ 300/25 mg.
Aliskiren (300 mg)	During the titration period, patients received aliskiren 150 mg for one week. Subsequently, patients were up-titrated and received aliskiren 300 mg.

Other Adverse Events

	Aliskiren/Hydrochlorothiazide (HCTZ) (300/25 mg)	**Aliskiren (300 mg)**
Total, other (not including serious) adverse events		
# participants affected / at risk	**27/349 (7.74%)**	**34/339 (10.03%)**
Nervous system disorders		
Dizziness † 1		
# participants affected / at risk	**19/349 (5.44%)**	**10/339 (2.95%)**
Headache † 1		
# participants affected / at risk	**14/349 (4.01%)**	**29/339 (8.55%)**

† 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
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Other Study ID Numbers:	**CSPP100A2353**
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Results First Received:	December 22, 2010
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Health Authority:	United States: Food and Drug Administration Germany: Federal Institute for Drugs and Medical Devices Italy: The Italian Medicines Agency Switzerland: Swissmedic Turkey: General Directorate of Pharmaceuticals and Pharmacy (IEGM - Ilaç ve Eczacilik Genel Müdürlügü) Argentina: Administracion Nacional de Medicamentos, Alimentos y Tecnologia Medica Guatemala: MSPAS (Departamento de Regulación de Productos Farmacéuticos y Afines, Ministerio de Salud Pública y Asistencia Social) Ecuador: M&P Instituto Nacional de Higiene y Medicina Tropical (INH)