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Trial record **1 of 1** for: CSPP100A2406

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Efficacy and Safety of Aliskiren in Patients With Mild to Moderate Hypertension During Exercise

This study has been completed.

Sponsor:
Novartis

Information provided by:
Novartis

ClinicalTrials.gov Identifier:
NCT00819767

First received: January 7, 2009
Last updated: June 2, 2011
Last verified: June 2011
History of Changes

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Results First Received: December 7, 2010

Study Type:	Interventional
Study Design:	Allocation: Randomized; Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Investigator); Primary Purpose: Treatment
Condition:	Hypertension
Interventions:	Drug: Aliskiren Drug: Valsartan Drug: Placebo to aliskiren Drug: Placebo to 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
All patients underwent a 2-week washout and a 1-2 week single blind placebo run in. Eligible patients then performed the treadmill exercise test for randomization according to the Bruce Protocol. Patients capable of reaching the defined peak exercise (85% of their predicted HR) were randomized into the study.

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	For the first week of the 8 week treatment period, patients received aliskiren 150 mg, placebo to aliskiren, and 2 capsules of placebo to valsartan. For the remaining 7 weeks of the study, patients received aliskiren 300 mg (two 150 mg tablets) and 2 capsules of placebo to valsartan. The tablets and capsules (2 of each) were taken orally once daily each morning. To evaluate a missed dose, the last dose of medication was administered at the clinic, and the patient was scheduled to return 2 days later for exercise testing (8 weeks + 2 days).
Valsartan	For the first week of the 8 week treatment period, patients received valsartan 160 mg, placebo to valsartan, and 2 tablets of placebo to aliskiren. For the remaining 7 weeks of the study, patients received valsartan 320 mg (two 160 mg capsules) and 2

	tablets of placebo to aliskiren. The tablets and capsules (2 of each) were taken orally once daily each morning. To evaluate a missed dose, the last dose of medication was administered at the clinic, and the patient was scheduled to return 2 days later for exercise testing (8 weeks + 2 days).

Participant Flow: Overall Study

	Aliskiren	Valsartan
STARTED	33	35
COMPLETED	32	33
NOT COMPLETED	1	2
Unsatisfactory therapeutic effect	1	2

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	For the first week of the 8 week treatment period, patients received aliskiren 150 mg, placebo to aliskiren, and 2 capsules of placebo to valsartan. For the remaining 7 weeks of the study, patients received aliskiren 300 mg (two 150 mg tablets) and 2 capsules of placebo to valsartan. The tablets and capsules (2 of each) were taken orally once daily each morning. To evaluate a missed dose, the last dose of medication was administered at the clinic, and the patient was scheduled to return 2 days later for exercise testing (8 weeks + 2 days).
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Total	Total of all reporting groups

Baseline Measures

	Aliskiren	Valsartan	Total
Number of Participants [units: participants]	33	35	68
Age [units: years] Mean (Standard Deviation)	58 (6.3)	60 (8.3)	59 (7.4)
Gender [units: participants]			
Female	14	8	22
Male	19	27	46

Outcome Measures

Hide All Outcome Measures

1. Primary: Change in Resting vs. Peak Heart Rate Systolic Blood Pressure (SBP) From Baseline to Week 8 After a Missed Dose [Time

Frame: Baseline and Week 8 + 2 days (48-hours after the last dose; 24 hours after a missed dose). Blood Pressure measurements were taken at rest and at peak heart rate at both timepoints.]

Measure Type	Primary
Measure Title	Change in Resting vs. Peak Heart Rate Systolic Blood Pressure (SBP) From Baseline to Week 8 After a Missed Dose
Measure Description	The difference in resting vs. peak (85% of maximal predicted) heart rate (HR) SBP was calculated by measuring SBP before and during exercise on a standardized treadmill test, conducted according to the Bruce Protocol. Treadmill speed and incline were increased every 3 minutes until the patient was exhausted or peak HR was reached. The SBP at rest vs peak HR was recorded at Baseline and at Week 8 + 2 days (24-hrs after a missed dose); the change in rest vs. peak SBP between these timepoints is reported. The analysis included the rest to peak increase in SBP at baseline as a covariate.
Time Frame	Baseline and Week 8 + 2 days (48-hours after the last dose; 24 hours after a missed dose). Blood Pressure measurements were taken at rest and at peak heart rate at both timepoints.
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.
The Full Analysis Set (FAS) consisted of all patients who were randomized and took at least one dose of study drug. The Exercise Evaluable Set (EES) included all patients included in the FAS for whom the treadmill test values for SBP at peak were available at baseline and after a missed dose.

Reporting Groups

	Description
Aliskiren	For the first week of the 8 week treatment period, patients received aliskiren 150 mg, placebo to aliskiren, and 2 capsules of placebo to valsartan. For the remaining 7 weeks of the study, patients received aliskiren 300 mg (two 150 mg tablets) and 2 capsules of placebo to valsartan. The tablets and capsules (2 of each) were taken orally once daily each morning. To evaluate a missed dose, the last dose of medication was administered at the clinic, and the patient was scheduled to return 2 days later for exercise testing (8 weeks + 2 days).
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Measured Values

	Aliskiren	**Valsartan**
Number of Participants Analyzed [units: participants]	**32**	**33**
Change in Resting vs. Peak Heart Rate Systolic Blood Pressure (SBP) From Baseline to Week 8 After a Missed Dose [units: mmHg] Least Squares Mean (Standard Error)	**2.58 (3.54)**	**8.26 (3.48)**

No statistical analysis provided for Change in Resting vs. Peak Heart Rate Systolic Blood Pressure (SBP) From Baseline to Week 8 After a Missed Dose

2. Secondary: Change in Resting vs. Peak Heart Rate Systolic Blood Pressure (SBP) From Baseline to Week 8 [Time Frame: Baseline and Week 8 (end of active treatment). Blood Pressure measurements were taken at rest and at peak heart rate at both timepoints.]

Measure Type	Secondary
Measure Title	Change in Resting vs. Peak Heart Rate Systolic Blood Pressure (SBP) From Baseline to Week 8

Measure Description	The difference in resting vs. peak (85% of the maximal predicted) heart rate (HR) SBP was calculated by measuring SBP before and during exercise on a standardized treadmill test, conducted according to the Bruce Protocol. Treadmill speed and incline were increased every 3 minutes until the patient was exhausted or peak HR was reached. The SBP at rest vs peak HR was recorded at Baseline and at Week 8 (end of active treatment); the change in SBP between these timepoints is reported. The analysis included the rest to peak increase in SBP at baseline as a covariate.
Time Frame	Baseline and Week 8 (end of active treatment). Blood Pressure measurements were taken at rest and at peak heart rate at both timepoints.
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.
The Full Analysis Set (FAS) consisted of all patients who were randomized and took at least one dose of study drug.

Reporting Groups

	Description
Aliskiren	For the first week of the 8 week treatment period, patients received aliskiren 150 mg, placebo to aliskiren, and 2 capsules of placebo to valsartan. For the remaining 7 weeks of the study, patients received aliskiren 300 mg (two 150 mg tablets) and 2 capsules of placebo to valsartan. The tablets and capsules (2 of each) were taken orally once daily each morning. To evaluate a missed dose, the last dose of medication was administered at the clinic, and the patient was scheduled to return 2 days later for exercise testing (8 weeks + 2 days).
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Measured Values

	Aliskiren	**Valsartan**
Number of Participants Analyzed [units: participants]	**32**	**33**
Change in Resting vs. Peak Heart Rate Systolic Blood Pressure (SBP) From Baseline to Week 8 [units: mmHg] Least Squares Mean (Standard Error)	**5.78 (3.22)**	**7.79 (3.18)**

No statistical analysis provided for Change in Resting vs. Peak Heart Rate Systolic Blood Pressure (SBP) From Baseline to Week 8

3. Secondary: Change in Resting vs. Peak Heart Rate Systolic Blood Pressure (SBP) From Week 8 (End of Active Treatment) to 24-hours After a Missed Dose [Time Frame: Week 8 (Last dose; end of active treatment) and Week 8 + 2 days (48-hours after the last dose; 24 hours after a missed dose). Blood Pressure measurements were taken at rest and at peak heart rate at both timepoints.]

Measure Type	Secondary
Measure Title	Change in Resting vs. Peak Heart Rate Systolic Blood Pressure (SBP) From Week 8 (End of Active Treatment) to 24-hours After a Missed Dose
Measure Description	The difference in resting vs. peak (85% of maximal predicted) heart rate (HR) SBP was calculated by measuring SBP before and during exercise on a standardized treadmill test, conducted according to the Bruce Protocol. The SBP at rest vs peak HR was recorded at Week 8 (end of active treatment) and Week 8 + 2 days (48-hrs after last dose; 24-hrs after missed dose); the change in rest vs. peak SBP between these timepoints is reported. The analysis included the rest to peak increase in SBP at baseline as a covariate.
Time Frame	Week 8 (Last dose; end of active treatment) and Week 8 + 2 days (48-hours after the last dose; 24 hours after a missed dose). Blood Pressure measurements were taken at rest and at peak heart rate at both timepoints.
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.
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Measured Values

	Aliskiren	**Valsartan**
Number of Participants Analyzed [units: participants]	**32**	**33**
Change in Resting vs. Peak Heart Rate Systolic Blood Pressure (SBP) From Week 8 (End of Active Treatment) to 24-hours After a Missed Dose [units: mmHg] Least Squares Mean (Standard Error)	**-4.16 (3.28)**	**1.37 (3.16)**

No statistical analysis provided for Change in Resting vs. Peak Heart Rate Systolic Blood Pressure (SBP) From Week 8 (End of Active Treatment) to 24-hours After a Missed Dose

Serious Adverse Events

Hide Serious Adverse Events

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

Reporting Groups

	Description
Aliskiren	For the first week of the 8 week treatment period, patients received aliskiren 150 mg, placebo to aliskiren, and 2 capsules of placebo to valsartan. For the remaining 7 weeks of the study, patients received aliskiren 300 mg (two 150 mg tablets) and 2 capsules of placebo to valsartan. The tablets and capsules (2 of each) were taken orally once daily each morning. To evaluate a missed dose, the last dose of medication was administered at the clinic, and the patient was scheduled to return 2 days later for exercise testing (8 weeks + 2 days).
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Serious Adverse Events

	Aliskiren	**Valsartan**

Total, serious adverse events		
# participants affected / at risk	**0/33 (0.00%)**	**0/35 (0.00%)**

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	For the first week of the 8 week treatment period, patients received aliskiren 150 mg, placebo to aliskiren, and 2 capsules of placebo to valsartan. For the remaining 7 weeks of the study, patients received aliskiren 300 mg (two 150 mg tablets) and 2 capsules of placebo to valsartan. The tablets and capsules (2 of each) were taken orally once daily each morning. To evaluate a missed dose, the last dose of medication was administered at the clinic, and the patient was scheduled to return 2 days later for exercise testing (8 weeks + 2 days).
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Other Adverse Events

	Aliskiren	Valsartan
Total, other (not including serious) adverse events		
# participants affected / at risk	**3/33 (9.09%)**	**4/35 (11.43%)**
Infections and infestations		
Bronchitis † 1		
# participants affected / at risk	**0/33 (0.00%)**	**2/35 (5.71%)**
Nervous system disorders		
Headache † 1		
# participants affected / at risk	**2/33 (6.06%)**	**0/35 (0.00%)**
Vascular disorders		
Hypertension † 1		
# participants affected / at risk	**1/33 (3.03%)**	**2/35 (5.71%)**

† 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:	External Affairs, Novartis Pharmaceuticals
ClinicalTrials.gov Identifier:	NCT00819767 History of Changes
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Study First Received:	January 7, 2009
Results First Received:	December 7, 2010
Last Updated:	June 2, 2011
Health Authority:	United Kingdom: Medicines and Healthcare Products Regulatory Agency Czech Republic: State Institute for Drug Control Hungary: National Institute of Pharmacy Singapore: Health Sciences Authority