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Trial record **1 of 1** for: CSPP100A2360

Previous Study | Return to List | Next Study

Efficacy and Tolerability of an Aliskiren-based Treatment Algorithm in Patients With Mild to Moderate Hypertension

This study has been completed.

Sponsor:
Novartis

Information provided by:
Novartis

ClinicalTrials.gov Identifier:
NCT00765947

First received: October 2, 2008
Last updated: March 8, 2011
Last verified: March 2011
History of Changes

Full Text View | Tabular View | Study Results | Disclaimer | How to Read a Study Record

Results First Received: December 13, 2010

Study Type:	Interventional
Study Design:	Allocation: Non-Randomized; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Single Group Assignment; Masking: Open Label; Primary Purpose: Treatment
Condition:	Essential Hypertension (Mild to Moderate)
Interventions:	Drug: Aliskiren Drug: Hydrochlorothiazide Drug: Amlodipine

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-based Regimen	Patients initiated treatment with aliskiren 150 mg (up-titrated to aliskiren 300 mg), followed by the addition of HCTZ 12.5 mg (up-titrated to 25 mg) and amlodipine 5 mg (up-titrated to 10 mg), as necessary to achieve the Blood Pressure goal.

Participant Flow: Overall Study

	Aliskiren-based Regimen
STARTED	**256**

COMPLETED	**232**
NOT COMPLETED	**24**

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-based Regimen	Patients initiated treatment with aliskiren 150 mg (up-titrated to aliskiren 300 mg), followed by the addition of HCTZ 12.5 mg (up-titrated to 25 mg) and amlodipine 5 mg (up-titrated to 10 mg), as necessary to achieve the Blood Pressure goal.

Baseline Measures

	Aliskiren-based Regimen
Number of Participants [units: participants]	**256**
Age, Customized [units: participants]	
< 65 yrs	**203**
≥ 65 yrs	**53**
Gender [units: participants]	
Female	**113**
Male	**143**

Outcome Measures

Hide All Outcome Measures

1. Primary: Percentage of Participants (Defined as Estimated Cumulative Control Rate) Reaching Blood Pressure Target in a Stepped Care, Aliskiren-based Regimen [Time Frame: 24 weeks]

Measure Type	Primary
Measure Title	Percentage of Participants (Defined as Estimated Cumulative Control Rate) Reaching Blood Pressure Target in a Stepped Care, Aliskiren-based Regimen
Measure Description	For non diabetic patients the Blood Pressure target is defined as mean sitting Systolic Blood Pressure [msSBP] < 140 mmHg and mean sitting Diastolic Blood Pressure [msDBP] < 90 mmHg and for diabetic patients the Blood Pressure target is mean sitting Systolic Blood Pressure [msSBP] < 130 mmHg and mean sitting Diastolic Blood Pressure [msDBP] < 80 mmHg.
Time Frame	24 weeks
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

Reporting Groups

	Description
Aliskiren-based Regimen	Patients initiated treatment with aliskiren 150 mg (up-titrated to aliskiren 300 mg), followed by the addition of HCTZ 12.5 mg (up-titrated to 25 mg) and amlodipine 5 mg (up-titrated to 10 mg), as necessary to achieve the Blood Pressure goal.

Measured Values

	Aliskiren-based Regimen
Number of Participants Analyzed [units: participants]	**256**
Percentage of Participants (Defined as Estimated Cumulative Control Rate) Reaching Blood Pressure Target in a Stepped Care, Aliskiren-based Regimen [units: Percentage of participants]	**86.12**

No statistical analysis provided for Percentage of Participants (Defined as Estimated Cumulative Control Rate) Reaching Blood Pressure Target in a Stepped Care, Aliskiren-based Regimen

2. Secondary: Percentage of Patients (Defined as Estimated Cumulative Control Rate) Reaching Blood Pressure Target in a Stepped-care, Aliskiren-based Regimen by Patient Subgroups of Mild and Moderate Hypertensive Patients, and Non-diabetic and Diabetic Patients. [Time Frame: 24 weeks]

Measure Type	Secondary
Measure Title	Percentage of Patients (Defined as Estimated Cumulative Control Rate) Reaching Blood Pressure Target in a Stepped-care, Aliskiren-based Regimen by Patient Subgroups of Mild and Moderate Hypertensive Patients, and Non-diabetic and Diabetic Patients.
Measure Description	For non diabetic patients the Blood Pressure target is defined as mean sitting Systolic Blood Pressure [msSBP] < 140 mmHg and mean sitting Diastolic Blood Pressure [msDBP] < 90 mmHg and for diabetic patients the Blood Pressure target is mean sitting Systolic Blood Pressure [msSBP] < 130 mmHg and mean sitting Diastolic Blood Pressure [msDBP] < 80 mmHg.
Time Frame	24 weeks
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.
No text entered.

Reporting Groups

	Description
Aliskiren-based Regimen	Patients initiated treatment with aliskiren 150 mg (up-titrated to aliskiren 300 mg), followed by the addition of HCTZ 12.5 mg (up-titrated to 25 mg) and amlodipine 5 mg (up-titrated to 10 mg), as necessary to achieve the Blood Pressure goal.

Measured Values

	Aliskiren-based Regimen

Number of Participants Analyzed [units: participants]	**256**
Percentage of Patients (Defined as Estimated Cumulative Control Rate) Reaching Blood Pressure Target in a Stepped-care, Aliskiren-based Regimen by Patient Subgroups of Mild and Moderate Hypertensive Patients, and Non-diabetic and Diabetic Patients. [units: Percentage of Participants]	
Mild Hypertensive	**91.48**
Moderate Hypertensive	**79.24**
Non-diabetic	**92.74**
Diabetic	**72.58**

No statistical analysis provided for Percentage of Patients (Defined as Estimated Cumulative Control Rate) Reaching Blood Pressure Target in a Stepped-care, Aliskiren-based Regimen by Patient Subgroups of Mild and Moderate Hypertensive Patients, and Non-diabetic and Diabetic Patients.

3. Secondary: Changes From Baseline to Week 24 in Mean Sitting Systolic Blood Pressure [msSBP] and Mean Sitting Diastolic Blood Pressure [msDBP] [Time Frame: Baseline and Week 24]

Measure Type	Secondary
Measure Title	Changes From Baseline to Week 24 in Mean Sitting Systolic Blood Pressure [msSBP] and Mean Sitting Diastolic Blood Pressure [msDBP]
Measure Description	No text entered.
Time Frame	Baseline and Week 24
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

Reporting Groups

	Description
Aliskiren-based Regimen	Patients initiated treatment with aliskiren 150 mg (up-titrated to aliskiren 300 mg), followed by the addition of HCTZ 12.5 mg (up-titrated to 25 mg) and amlodipine 5 mg (up-titrated to 10 mg), as necessary to achieve the Blood Pressure goal.

Measured Values

	Aliskiren-based Regimen
Number of Participants Analyzed [units: participants]	**251**
Changes From Baseline to Week 24 in Mean Sitting Systolic Blood Pressure [msSBP] and Mean Sitting Diastolic Blood Pressure [msDBP] [units: mm Hg] Mean (Standard Deviation)	
msSBP	**-25.33 (13.942)**
msDBP	**-12.40 (9.371)**

No statistical analysis provided for Changes From Baseline to Week 24 in Mean Sitting Systolic Blood Pressure [msSBP] and Mean Sitting Diastolic Blood Pressure [msDBP]

4. Secondary: Percent of Responders for Mean Sitting Systolic Blood Pressure [msSBP] and for Mean Sitting Diastolic Blood Pressure [msDBP] [Time Frame: 24 weeks]

Measure Type	Secondary
Measure Title	Percent of Responders for Mean Sitting Systolic Blood Pressure [msSBP] and for Mean Sitting Diastolic Blood Pressure [msDBP]
Measure Description	Response for mean sitting Systolic Blood Pressure [msSBP] is defined as a reduction of ≥ 20 mmHg from baseline or mean sitting Systolic Blood Pressure [msSBP] < 140 mmHg (non diabetics) or < 130 mmHg (diabetics). Response for mean sitting Diastolic Blood Pressure [msDBP] is defined as a reduction of ≥10 mmHg from baseline or mean sitting Diastolic Blood Pressure [msDBP] < 90 mmHg (non diabetic) or < 80 mmHg (diabetics).
Time Frame	24 weeks
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.
No text entered.

Reporting Groups

	Description
Aliskiren-based Regimen	Patients initiated treatment with aliskiren 150 mg (up-titrated to aliskiren 300 mg), followed by the addition of HCTZ 12.5 mg (up-titrated to 25 mg) and amlodipine 5 mg (up-titrated to 10 mg), as necessary to achieve the Blood Pressure goal.

Measured Values

	Aliskiren-based Regimen
Number of Participants Analyzed [units: participants]	**256**
Percent of Responders for Mean Sitting Systolic Blood Pressure [msSBP] and for Mean Sitting Diastolic Blood Pressure [msDBP] [units: Percentage of Participants]	
msSBP	**96.80**
msDBP	**97.78**

No statistical analysis provided for Percent of Responders for Mean Sitting Systolic Blood Pressure [msSBP] and for Mean Sitting Diastolic Blood Pressure [msDBP]

5. Secondary: Overall Safety and Tolerability of Aliskiren Monotherapy and in Combination Treatment [Time Frame: 24 weeks]

Results not yet reported. **Anticipated Reporting Date:** No text entered. **Safety Issue:** No

Serious Adverse Events

Hide Serious Adverse Events

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

Reporting Groups

	Description
Aliskiren	Aliskiren treatment step
Aliskiren + HCTZ	Aliskiren and HCTZ treatment step
Aliskiren + HCTZ + Amlodipine	Aliskiren + HCTZ + Amlodipine treatment step

Serious Adverse Events

	Aliskiren	Aliskiren + HCTZ	Aliskiren + HCTZ + Amlodipine
Total, serious adverse events			
# participants affected / at risk	**3/256 (1.17%)**	**0/197 (0.00%)**	**0/119 (0.00%)**
Cardiac disorders			
Myocardial infarction † 1			
# participants affected / at risk	**1/256 (0.39%)**	**0/197 (0.00%)**	**0/119 (0.00%)**
General disorders			
Non-cardiac chest pain † 1			
# participants affected / at risk	**1/256 (0.39%)**	**0/197 (0.00%)**	**0/119 (0.00%)**
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Renal neoplasm † 1			
# participants affected / at risk	**1/256 (0.39%)**	**0/197 (0.00%)**	**0/119 (0.00%)**
Vascular disorders			
Hypertension † 1			
# participants affected / at risk	**1/256 (0.39%)**	**0/197 (0.00%)**	**0/119 (0.00%)**

† 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	Aliskiren treatment step
Aliskiren + HCTZ	Aliskiren and HCTZ treatment step
Aliskiren + HCTZ + Amlodipine	Aliskiren + HCTZ + Amlodipine treatment step

Other Adverse Events

	Aliskiren	Aliskiren + HCTZ	Aliskiren + HCTZ + Amlodipine
Total, other (not including serious) adverse events			

# participants affected / at risk	**0/256 (0.00%)**	**0/197 (0.00%)**	**0/119 (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:	External Affairs, Novartis
ClinicalTrials.gov Identifier:	NCT00765947 History of Changes
Other Study ID Numbers:	**CSPP100A2360**
Study First Received:	October 2, 2008
Results First Received:	December 13, 2010
Last Updated:	March 8, 2011
Health Authority:	United States: Food and Drug Administration France: Afssaps - Agence française de sécurité sanitaire des produits de santé (Saint-Denis) Hungary: National Institute of Pharmacy Slovakia: State Institute for Drug Control Romania: National Medicines Agency