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Trial record **1 of 1** for: CSPP100A2316

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Aliskiren in Combination With Losartan Compared to Losartan on the Regression of Left Ventricular Hypertrophy in Overweight Patients With Essential Hypertension (ALLAY)

This study has been completed.

Sponsor:
Novartis Pharmaceuticals

Information provided by:
Novartis

ClinicalTrials.gov Identifier:
NCT00219141

First received: September 12, 2005
Last updated: May 20, 2011
Last verified: May 2011
History of Changes

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Results First Received: January 11, 2011

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Efficacy Study; Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Investigator); Primary Purpose: Treatment
Conditions:	Hypertension Left Ventricular Hypertrophy Overweight
Interventions:	Drug: Aliskiren 150/300 mg Drug: Losartan 50/100 mg Drug: Aliskiren placebo Drug: Losartan 50/100 mg placebo

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 300 mg	Patients in this arm initially received 150 mg of aliskiren for two weeks and were then force-titrated up to 300 mg of aliskiren where they remained for 34 weeks.
Losartan 100 mg	Patients in this arm initially received 50 mg of losartan for two weeks and were then force-titrated up to 100 mg of losartan where they remained for 34 weeks.

Aliskiren/Losartan 300/100 mg	Patients in this arm initially received 150 mg of aliskiren in combination with 50 mg of losartan for two weeks and were then force-titrated up to 300 mg of aliskiren in combination with 100 mg of losartan where they remained for 34 weeks.

Participant Flow: Overall Study

	Aliskiren 300 mg	Losartan 100 mg	Aliskiren/Losartan 300/100 mg
STARTED	**154**	**152**	**154**
COMPLETED	**140**	**131**	**142**
NOT COMPLETED	**14**	**21**	**12**
Adverse Event	**4**	**10**	**5**
Lack of Efficacy	**3**	**2**	**0**
Administrative problems	**0**	**1**	**0**
Lost to Follow-up	**2**	**4**	**1**
Protocol Violation	**3**	**1**	**1**
Withdrawal by Subject	**1**	**3**	**5**
Condition no longer requires study drug	**1**	**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
Aliskiren 300 mg	Patients in this arm initially received 150 mg of aliskiren for two weeks and were then force-titrated up to 300 mg of aliskiren where they remained for 34 weeks.
Losartan 100 mg	Patients in this arm initially received 50 mg of losartan for two weeks and were then force-titrated up to 100 mg of losartan where they remained for 34 weeks.
Aliskiren/Losartan 300/100 mg	Patients in this arm initially received 150 mg of aliskiren in combination with 50 mg of losartan for two weeks and were then force-titrated up to 300 mg of aliskiren in combination with 100 mg of losartan where they remained for 34 weeks.
Total	Total of all reporting groups

Baseline Measures

	Aliskiren 300 mg	Losartan 100 mg	Aliskiren/Losartan 300/100 mg	Total
Number of Participants [units: participants]	**154**	**152**	**154**	**460**
Age [units: years] Mean (Standard Deviation)	**58.4 (9.61)**	**59.2 (11.00)**	**58.8 (10.62)**	**58.8 (10.41)**
Gender [units: participants]				
Female	**42**	**35**	**35**	**112**
Male	**112**	**117**	**119**	**348**

Outcome Measures

Hide All Outcome Measures

1. Primary: Change in Left Ventricular Mass Index (LVMI) From Baseline to End of Study (Week 36) [Time Frame: Baseline to end of study (Week 36)]

Measure Type	Primary
Measure Title	Change in Left Ventricular Mass Index (LVMI) From Baseline to End of Study (Week 36)
Measure Description	Left ventricular mass index (LVMI) was measured by magnetic resonance imaging (MRI). An increase in LVMI indicates hypertrophy of the left ventricle. This could be a normal reversible response to cardiovascular conditioning (athletic heart) or an abnormal irreversible response to chronically increased volume load (preload) or increased pressure load (afterload). Thickening of the ventricular muscle results in increased left ventricular pressure, increased end-systolic volume, and decreased end-diastolic volume, causing an overall reduction in cardiac output.
Time Frame	Baseline to end of study (Week 36)
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.
Efficacy population: All patients who had a baseline measurement and at least one post-baseline efficacy variable measurement patients and who had been treated for at least 28 weeks and had evaluable MRI assessments both at baseline and at the end of the study.

Reporting Groups

	Description
Aliskiren 300 mg	Patients in this arm initially received 150 mg of aliskiren for two weeks and were then force-titrated up to 300 mg of aliskiren where they remained for 34 weeks.
Losartan 100 mg	Patients in this arm initially received 50 mg of losartan for two weeks and were then force-titrated up to 100 mg of losartan where they remained for 34 weeks.
Aliskiren/Losartan 300/100 mg	Patients in this arm initially received 150 mg of aliskiren in combination with 50 mg of losartan for two weeks and were then force-titrated up to 300 mg of aliskiren in combination with 100 mg of losartan where they remained for 34 weeks.

Measured Values

	Aliskiren 300 mg	**Losartan 100 mg**	**Aliskiren/Losartan 300/100 mg**
Number of Participants Analyzed [units: participants]	**132**	**123**	**136**
Change in Left Ventricular Mass Index (LVMI) From Baseline to End of Study (Week 36) [units: g/m^2] Least Squares Mean (Standard Error)	**-5.51 (0.95)**	**-4.81 (0.98)**	**-5.61 (0.93)**

No statistical analysis provided for Change in Left Ventricular Mass Index (LVMI) From Baseline to End of Study (Week 36)

2. Secondary: Change in the Left Ventricular Hypertrophy (LVH) Parameter Left Ventricular Mass Index as Measured by MRI From Baseline to End of Study (Week 36) [Time Frame: Baseline to end of study (Week 36)]

Measure Type	Secondary
Measure Title	Change in the Left Ventricular Hypertrophy (LVH) Parameter Left Ventricular Mass Index as Measured by MRI From

	Baseline to End of Study (Week 36)
Measure Description	No text entered.
Time Frame	Baseline to end of study (Week 36)
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.
Efficacy population: All patients who had a baseline measurement and at least one post-baseline efficacy variable measurement patients and who had been treated for at least 28 weeks and had evaluable MRI assessments both at baseline and at the end of the study.

Reporting Groups

	Description
Aliskiren 300 mg	Patients in this arm initially received 150 mg of aliskiren for two weeks and were then force-titrated up to 300 mg of aliskiren where they remained for 34 weeks.
Losartan 100 mg	Patients in this arm initially received 50 mg of losartan for two weeks and were then force-titrated up to 100 mg of losartan where they remained for 34 weeks.
Aliskiren/Losartan 300/100 mg	Patients in this arm initially received 150 mg of aliskiren in combination with 50 mg of losartan for two weeks and were then force-titrated up to 300 mg of aliskiren in combination with 100 mg of losartan where they remained for 34 weeks.

Measured Values

	Aliskiren 300 mg	**Losartan 100 mg**	**Aliskiren/Losartan 300/100 mg**
Number of Participants Analyzed [units: participants]	**132**	**123**	**136**
Change in the Left Ventricular Hypertrophy (LVH) Parameter Left Ventricular Mass Index as Measured by MRI From Baseline to End of Study (Week 36) [units: g/m^2] Mean (Standard Deviation)	**-4.87 (11.69)**	**-4.79 (11.87)**	**-5.81 (10.93)**

No statistical analysis provided for Change in the Left Ventricular Hypertrophy (LVH) Parameter Left Ventricular Mass Index as Measured by MRI From Baseline to End of Study (Week 36)

3. Secondary: Change in the Left Ventricular Hypertrophy (LVH) Parameter Left Ventricular End Diastolic Volume as Measured by MRI From Baseline to End of Study (Week 36) [Time Frame: Baseline to end of study (Week 36)]

Measure Type	Secondary
Measure Title	Change in the Left Ventricular Hypertrophy (LVH) Parameter Left Ventricular End Diastolic Volume as Measured by MRI From Baseline to End of Study (Week 36)
Measure Description	No text entered.
Time Frame	Baseline to end of study (Week 36)
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.
Efficacy population: All patients who had a baseline measurement and at least one post-baseline efficacy variable measurement patients and who had been treated for at least 28 weeks and had evaluable MRI assessments both at baseline and at the end of the study.

Reporting Groups

	Description
Aliskiren 300 mg	Patients in this arm initially received 150 mg of aliskiren for two weeks and were then force-titrated up to 300 mg of aliskiren where they remained for 34 weeks.
Losartan 100 mg	Patients in this arm initially received 50 mg of losartan for two weeks and were then force-titrated up to 100 mg of losartan where they remained for 34 weeks.
Aliskiren/Losartan 300/100 mg	Patients in this arm initially received 150 mg of aliskiren in combination with 50 mg of losartan for two weeks and were then force-titrated up to 300 mg of aliskiren in combination with 100 mg of losartan where they remained for 34 weeks.

Measured Values

	Aliskiren 300 mg	Losartan 100 mg	Aliskiren/Losartan 300/100 mg
Number of Participants Analyzed [units: participants]	**132**	**123**	**134**
Change in the Left Ventricular Hypertrophy (LVH) Parameter Left Ventricular End Diastolic Volume as Measured by MRI From Baseline to End of Study (Week 36) [units: mL] Mean (Standard Deviation)	**-7.05 (24.09)**	**-4.52 (25.15)**	**-7.03 (24.97)**

No statistical analysis provided for Change in the Left Ventricular Hypertrophy (LVH) Parameter Left Ventricular End Diastolic Volume as Measured by MRI From Baseline to End of Study (Week 36)

4. Secondary: Change in the Left Ventricular Hypertrophy (LVH) Parameter Left Ventricular End Systolic Volume as Measured by MRI From Baseline to End of Study (Week 36) [Time Frame: Baseline to end of study (Week 36)]

Measure Type	Secondary
Measure Title	Change in the Left Ventricular Hypertrophy (LVH) Parameter Left Ventricular End Systolic Volume as Measured by MRI From Baseline to End of Study (Week 36)
Measure Description	No text entered.
Time Frame	Baseline to end of study (Week 36)
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.
Efficacy population: All patients who had a baseline measurement and at least one post-baseline efficacy variable measurement patients and who had been treated for at least 28 weeks and had evaluable MRI assessments both at baseline and at the end of the study.

Reporting Groups

	Description
Aliskiren 300 mg	Patients in this arm initially received 150 mg of aliskiren for two weeks and were then force-titrated up to 300 mg of aliskiren where they remained for 34 weeks.
Losartan 100 mg	Patients in this arm initially received 50 mg of losartan for two weeks and were then force-titrated up to 100 mg of losartan where they remained for 34 weeks.
Aliskiren/Losartan 300/100 mg	Patients in this arm initially received 150 mg of aliskiren in combination with 50 mg of losartan for two weeks and were then force-titrated up to 300 mg of aliskiren in combination with 100 mg of losartan where they remained for 34 weeks.

Measured Values

	Aliskiren 300 mg	Losartan 100 mg	Aliskiren/Losartan 300/100 mg
Number of Participants Analyzed [units: participants]	**132**	**123**	**134**
Change in the Left Ventricular Hypertrophy (LVH) Parameter Left Ventricular End Systolic Volume as Measured by MRI From Baseline to End of Study (Week 36) [units: mL] Mean (Standard Deviation)	**-3.20 (16.64)**	**-4.73 (15.16)**	**-5.14 (15.35)**

No statistical analysis provided for Change in the Left Ventricular Hypertrophy (LVH) Parameter Left Ventricular End Systolic Volume as Measured by MRI From Baseline to End of Study (Week 36)

5. Secondary: Change in the Left Ventricular Hypertrophy (LVH) Parameter Left Ventricular Anteroseptal Wall Thickness as Measured by MRI From Baseline to End of Study (Week 36) [Time Frame: Baseline to end of study (Week 36)]

Measure Type	Secondary
Measure Title	Change in the Left Ventricular Hypertrophy (LVH) Parameter Left Ventricular Anteroseptal Wall Thickness as Measured by MRI From Baseline to End of Study (Week 36)
Measure Description	No text entered.
Time Frame	Baseline to end of study (Week 36)
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.
Efficacy population: All patients who had a baseline measurement and at least one post-baseline efficacy variable measurement patients and who had been treated for at least 28 weeks and had evaluable MRI assessments both at baseline and at the end of the study.

Reporting Groups

	Description
Aliskiren 300 mg	Patients in this arm initially received 150 mg of aliskiren for two weeks and were then force-titrated up to 300 mg of aliskiren where they remained for 34 weeks.
Losartan 100 mg	Patients in this arm initially received 50 mg of losartan for two weeks and were then force-titrated up to 100 mg of losartan where they remained for 34 weeks.
Aliskiren/Losartan 300/100 mg	Patients in this arm initially received 150 mg of aliskiren in combination with 50 mg of losartan for two weeks and were then force-titrated up to 300 mg of aliskiren in combination with 100 mg of losartan where they remained for 34 weeks.

Measured Values

	Aliskiren 300 mg	Losartan 100 mg	Aliskiren/Losartan 300/100 mg
Number of Participants Analyzed [units: participants]	**132**	**123**	**134**
Change in the Left Ventricular Hypertrophy (LVH) Parameter Left Ventricular Anteroseptal Wall Thickness as Measured by MRI From Baseline to End of Study (Week 36) [units: mm] Mean (Standard Deviation)	**-0.95 (2.71)**	**-1.20 (2.56)**	**-1.17 (2.61)**

No statistical analysis provided for Change in the Left Ventricular Hypertrophy (LVH) Parameter Left Ventricular Anteroseptal Wall Thickness as Measured by MRI From Baseline to End of Study (Week 36)

6. Secondary: Change in the Left Ventricular Hypertrophy (LVH) Parameter Left Ventricular Inferolateral Wall Thickness as Measured by MRI From Baseline to End of Study (Week 36) [Time Frame: Baseline to end of study (Week 36)]

Measure Type	Secondary
Measure Title	Change in the Left Ventricular Hypertrophy (LVH) Parameter Left Ventricular Inferolateral Wall Thickness as Measured by MRI From Baseline to End of Study (Week 36)
Measure Description	No text entered.
Time Frame	Baseline to end of study (Week 36)
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.
Efficacy population: All patients who had a baseline measurement and at least one post-baseline efficacy variable measurement patients and who had been treated for at least 28 weeks and had evaluable MRI assessments both at baseline and at the end of the study.

Reporting Groups

	Description
Aliskiren 300 mg	Patients in this arm initially received 150 mg of aliskiren for two weeks and were then force-titrated up to 300 mg of aliskiren where they remained for 34 weeks.
Losartan 100 mg	Patients in this arm initially received 50 mg of losartan for two weeks and were then force-titrated up to 100 mg of losartan where they remained for 34 weeks.
Aliskiren/Losartan 300/100 mg	Patients in this arm initially received 150 mg of aliskiren in combination with 50 mg of losartan for two weeks and were then force-titrated up to 300 mg of aliskiren in combination with 100 mg of losartan where they remained for 34 weeks.

Measured Values

	Aliskiren 300 mg	**Losartan 100 mg**	**Aliskiren/Losartan 300/100 mg**
Number of Participants Analyzed [units: participants]	**132**	**123**	**134**
Change in the Left Ventricular Hypertrophy (LVH) Parameter Left Ventricular Inferolateral Wall Thickness as Measured by MRI From Baseline to End of Study (Week 36) [units: mm] Mean (Standard Deviation)	**-0.88 (2.03)**	**-0.89 (2.16)**	**-0.90 (2.22)**

No statistical analysis provided for Change in the Left Ventricular Hypertrophy (LVH) Parameter Left Ventricular Inferolateral Wall Thickness as Measured by MRI From Baseline to End of Study (Week 36)

7. Secondary: Change in the Left Ventricular Hypertrophy (LVH) Parameter Diameter of Ascending Aorta as Measured by MRI From Baseline to End of Study (Week 36) [Time Frame: Baseline to end of study (Week 36)]

Measure Type	Secondary
Measure Title	Change in the Left Ventricular Hypertrophy (LVH) Parameter Diameter of Ascending Aorta as Measured by MRI From Baseline to End of Study (Week 36)
Measure Description	No text entered.
Time Frame	Baseline to end of study (Week 36)

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.
Efficacy population: All patients who had a baseline measurement and at least one post-baseline efficacy variable measurement patients and who had been treated for at least 28 weeks and had evaluable MRI assessments both at baseline and at the end of the study.

Reporting Groups

	Description
Aliskiren 300 mg	Patients in this arm initially received 150 mg of aliskiren for two weeks and were then force-titrated up to 300 mg of aliskiren where they remained for 34 weeks.
Losartan 100 mg	Patients in this arm initially received 50 mg of losartan for two weeks and were then force-titrated up to 100 mg of losartan where they remained for 34 weeks.
Aliskiren/Losartan 300/100 mg	Patients in this arm initially received 150 mg of aliskiren in combination with 50 mg of losartan for two weeks and were then force-titrated up to 300 mg of aliskiren in combination with 100 mg of losartan where they remained for 34 weeks.

Measured Values

	Aliskiren 300 mg	**Losartan 100 mg**	**Aliskiren/Losartan 300/100 mg**
Number of Participants Analyzed [units: participants]	**133**	**129**	**137**
Change in the Left Ventricular Hypertrophy (LVH) Parameter Diameter of Ascending Aorta as Measured by MRI From Baseline to End of Study (Week 36) [units: mm] Mean (Standard Deviation)	**-0.71 (1.72)**	**-0.64 (2.16)**	**-0.86 (2.06)**

No statistical analysis provided for Change in the Left Ventricular Hypertrophy (LVH) Parameter Diameter of Ascending Aorta as Measured by MRI From Baseline to End of Study (Week 36)

8. Secondary: Change in the Left Ventricular Hypertrophy (LVH) Parameter Left Ventricular End Diastolic Mass as Measured by MRI From Baseline to End of Study (Week 36) [Time Frame: Baseline to end of study (Week 36)]

Measure Type	Secondary
Measure Title	Change in the Left Ventricular Hypertrophy (LVH) Parameter Left Ventricular End Diastolic Mass as Measured by MRI From Baseline to End of Study (Week 36)
Measure Description	No text entered.
Time Frame	Baseline to end of study (Week 36)
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.
Efficacy population: All patients who had a baseline measurement and at least one post-baseline efficacy variable measurement patients and who had been treated for at least 28 weeks and had evaluable MRI assessments both at baseline and at the end of the study.

Reporting Groups

	Description

Aliskiren 300 mg	Patients in this arm initially received 150 mg of aliskiren for two weeks and were then force-titrated up to 300 mg of aliskiren where they remained for 34 weeks.
Losartan 100 mg	Patients in this arm initially received 50 mg of losartan for two weeks and were then force-titrated up to 100 mg of losartan where they remained for 34 weeks.
Aliskiren/Losartan 300/100 mg	Patients in this arm initially received 150 mg of aliskiren in combination with 50 mg of losartan for two weeks and were then force-titrated up to 300 mg of aliskiren in combination with 100 mg of losartan where they remained for 34 weeks.

Measured Values

	Aliskiren 300 mg	**Losartan 100 mg**	**Aliskiren/Losartan 300/100 mg**
Number of Participants Analyzed [units: participants]	**132**	**123**	**134**
Change in the Left Ventricular Hypertrophy (LVH) Parameter Left Ventricular End Diastolic Mass as Measured by MRI From Baseline to End of Study (Week 36) [units: g] Mean (Standard Deviation)	**-9.81 (23.84)**	**-9.92 (24.24)**	**-12.29 (22.58)**

No statistical analysis provided for Change in the Left Ventricular Hypertrophy (LVH) Parameter Left Ventricular End Diastolic Mass as Measured by MRI From Baseline to End of Study (Week 36)

9. Secondary: Change in the Left Ventricular Hypertrophy (LVH) Parameter Left Ventricular Ejection Fraction as Measured by MRI From Baseline to End of Study (Week 36) [Time Frame: Baseline to end of study (Week 36)]

Measure Type	Secondary
Measure Title	Change in the Left Ventricular Hypertrophy (LVH) Parameter Left Ventricular Ejection Fraction as Measured by MRI From Baseline to End of Study (Week 36)
Measure Description	No text entered.
Time Frame	Baseline to end of study (Week 36)
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.
Efficacy population: All patients who had a baseline measurement and at least one post-baseline efficacy variable measurement patients and who had been treated for at least 28 weeks and had evaluable MRI assessments both at baseline and at the end of the study.

Reporting Groups

	Description
Aliskiren 300 mg	Patients in this arm initially received 150 mg of aliskiren for two weeks and were then force-titrated up to 300 mg of aliskiren where they remained for 34 weeks.
Losartan 100 mg	Patients in this arm initially received 50 mg of losartan for two weeks and were then force-titrated up to 100 mg of losartan where they remained for 34 weeks.
Aliskiren/Losartan 300/100 mg	Patients in this arm initially received 150 mg of aliskiren in combination with 50 mg of losartan for two weeks and were then force-titrated up to 300 mg of aliskiren in combination with 100 mg of losartan where they remained for 34 weeks.

Measured Values

	Aliskiren	**Losartan**	**Aliskiren/Losartan**

	300 mg	100 mg	300/100 mg
Number of Participants Analyzed [units: participants]	**132**	**123**	**133**
Change in the Left Ventricular Hypertrophy (LVH) Parameter Left Ventricular Ejection Fraction as Measured by MRI From Baseline to End of Study (Week 36) [units: percent] Mean (Standard Deviation)	**0.62 (7.73)**	**2.02 (6.70)**	**1.92 (7.00)**

No statistical analysis provided for Change in the Left Ventricular Hypertrophy (LVH) Parameter Left Ventricular Ejection Fraction as Measured by MRI From Baseline to End of Study (Week 36)

10. Secondary: Change in the Left Ventricular Hypertrophy (LVH) Parameter Left Ventricular Stroke Volume as Measured by MRI From Baseline to End of Study (Week 36) [Time Frame: Baseline to end of study (Week 36)]

Measure Type	Secondary
Measure Title	Change in the Left Ventricular Hypertrophy (LVH) Parameter Left Ventricular Stroke Volume as Measured by MRI From Baseline to End of Study (Week 36)
Measure Description	No text entered.
Time Frame	Baseline to end of study (Week 36)
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.
Efficacy population: All patients who had a baseline measurement and at least one post-baseline efficacy variable measurement patients and who had been treated for at least 28 weeks and had evaluable MRI assessments both at baseline and at the end of the study.

Reporting Groups

	Description
Aliskiren 300 mg	Patients in this arm initially received 150 mg of aliskiren for two weeks and were then force-titrated up to 300 mg of aliskiren where they remained for 34 weeks.
Losartan 100 mg	Patients in this arm initially received 50 mg of losartan for two weeks and were then force-titrated up to 100 mg of losartan where they remained for 34 weeks.
Aliskiren/Losartan 300/100 mg	Patients in this arm initially received 150 mg of aliskiren in combination with 50 mg of losartan for two weeks and were then force-titrated up to 300 mg of aliskiren in combination with 100 mg of losartan where they remained for 34 weeks.

Measured Values

	Aliskiren 300 mg	Losartan 100 mg	Aliskiren/Losartan 300/100 mg
Number of Participants Analyzed [units: participants]	**132**	**123**	**133**
Change in the Left Ventricular Hypertrophy (LVH) Parameter Left Ventricular Stroke Volume as Measured by MRI From Baseline to End of Study (Week 36) [units: mL] Mean (Standard Deviation)	**-3.89 (17.83)**	**0.24 (17.53)**	**-2.24 (17.25)**

No statistical analysis provided for Change in the Left Ventricular Hypertrophy (LVH) Parameter Left Ventricular Stroke Volume as Measured by MRI From Baseline to End of Study (Week 36)

11. Secondary: Change in the Left Ventricular Hypertrophy (LVH) Parameter Sokolow-Lyon Voltage as Measured by Electrocardiogram From Baseline to End of Study (Week 36) [Time Frame: Baseline to end of study (Week 36)]

Measure Type	Secondary
Measure Title	Change in the Left Ventricular Hypertrophy (LVH) Parameter Sokolow-Lyon Voltage as Measured by Electrocardiogram From Baseline to End of Study (Week 36)
Measure Description	No text entered.
Time Frame	Baseline to end of study (Week 36)
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.
Intent-to-treat population: All patients who had a baseline measurement and at least one post-baseline efficacy variable measurement.

Reporting Groups

	Description
Aliskiren 300 mg	Patients in this arm initially received 150 mg of aliskiren for two weeks and were then force-titrated up to 300 mg of aliskiren where they remained for 34 weeks.
Losartan 100 mg	Patients in this arm initially received 50 mg of losartan for two weeks and were then force-titrated up to 100 mg of losartan where they remained for 34 weeks.
Aliskiren/Losartan 300/100 mg	Patients in this arm initially received 150 mg of aliskiren in combination with 50 mg of losartan for two weeks and were then force-titrated up to 300 mg of aliskiren in combination with 100 mg of losartan where they remained for 34 weeks.

Measured Values

	Aliskiren 300 mg	**Losartan 100 mg**	**Aliskiren/Losartan 300/100 mg**
Number of Participants Analyzed [units: participants]	**145**	**146**	**146**
Change in the Left Ventricular Hypertrophy (LVH) Parameter Sokolow-Lyon Voltage as Measured by Electrocardiogram From Baseline to End of Study (Week 36) [units: mm] Mean (Standard Deviation)	**-1.07 (3.78)**	**-0.97 (4.22)**	**-1.43 (3.81)**

No statistical analysis provided for Change in the Left Ventricular Hypertrophy (LVH) Parameter Sokolow-Lyon Voltage as Measured by Electrocardiogram From Baseline to End of Study (Week 36)

12. Secondary: Change in the Left Ventricular Hypertrophy (LVH) Parameter Cornell Voltage Duration Product as Measured by Electrocardiogram From Baseline to End of Study (Week 36) [Time Frame: Baseline to end of study (Week 36)]

Measure Type	Secondary
Measure Title	Change in the Left Ventricular Hypertrophy (LVH) Parameter Cornell Voltage Duration Product as Measured by Electrocardiogram From Baseline to End of Study (Week 36)
Measure Description	No text entered.
Time Frame	Baseline to end of study (Week 36)
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.
Intent-to-treat population: All patients who had a baseline measurement and at least one post-baseline efficacy variable measurement.

Reporting Groups

	Description
Aliskiren 300 mg	Patients in this arm initially received 150 mg of aliskiren for two weeks and were then force-titrated up to 300 mg of aliskiren where they remained for 34 weeks.
Losartan 100 mg	Patients in this arm initially received 50 mg of losartan for two weeks and were then force-titrated up to 100 mg of losartan where they remained for 34 weeks.
Aliskiren/Losartan 300/100 mg	Patients in this arm initially received 150 mg of aliskiren in combination with 50 mg of losartan for two weeks and were then force-titrated up to 300 mg of aliskiren in combination with 100 mg of losartan where they remained for 34 weeks.

Measured Values

	Aliskiren 300 mg	**Losartan 100 mg**	**Aliskiren/Losartan 300/100 mg**
Number of Participants Analyzed [units: participants]	**140**	**144**	**146**
Change in the Left Ventricular Hypertrophy (LVH) Parameter Cornell Voltage Duration Product as Measured by Electrocardiogram From Baseline to End of Study (Week 36) [units: mm * ms] Mean (Standard Deviation)	**-104.97 (376.30)**	**-150.31 (439.81)**	**-130.65 (453.17)**

No statistical analysis provided for Change in the Left Ventricular Hypertrophy (LVH) Parameter Cornell Voltage Duration Product as Measured by Electrocardiogram From Baseline to End of Study (Week 36)

13. Secondary: Change From Baseline in Mean 24-hour Ambulatory Diastolic and Systolic Blood Pressure From Baseline to the End of the Study (Week 36) [Time Frame: Baseline the end of study (Week 36)]

Measure Type	Secondary
Measure Title	Change From Baseline in Mean 24-hour Ambulatory Diastolic and Systolic Blood Pressure From Baseline to the End of the Study (Week 36)
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. A correlation was made between the ABPM device readings and measurements taken with a mercury sphygmomanometer and stethoscope. Following the correlation procedure, blood pressure was measured at study specified intervals.
Time Frame	Baseline the end of study (Week 36)
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

Aliskiren 300 mg	Patients in this arm initially received 150 mg of aliskiren for two weeks and were then force-titrated up to 300 mg of aliskiren where they remained for 34 weeks.
Losartan 100 mg	Patients in this arm initially received 50 mg of losartan for two weeks and were then force-titrated up to 100 mg of losartan where they remained for 34 weeks.
Aliskiren/Losartan 300/100 mg	Patients in this arm initially received 150 mg of aliskiren in combination with 50 mg of losartan for two weeks and were then force-titrated up to 300 mg of aliskiren in combination with 100 mg of losartan where they remained for 34 weeks.

Measured Values

	Aliskiren 300 mg	Losartan 100 mg	Aliskiren/Losartan 300/100 mg
Number of Participants Analyzed [units: participants]	**83**	**89**	**84**
Change From Baseline in Mean 24-hour Ambulatory Diastolic and Systolic Blood Pressure From Baseline to the End of the Study (Week 36) [units: mm Hg] Least Squares Mean (Standard Error)			
Systolic	**-2.67 (1.19)**	**-3.81 (1.17)**	**-6.97 (1.21)**
Diastolic	**-1.31 (0.82)**	**-1.92 (0.81)**	**-4.11 (0.83)**

No statistical analysis provided for Change From Baseline in Mean 24-hour Ambulatory Diastolic and Systolic Blood Pressure From Baseline to the End of the Study (Week 36)

Serious Adverse Events

Hide Serious Adverse Events

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

Reporting Groups

	Description
Aliskiren 300 mg	Patients in this arm initially received 150 mg of aliskiren for two weeks and were then force-titrated up to 300 mg of aliskiren where they remained for 34 weeks.
Losartan 100 mg	Patients in this arm initially received 50 mg of losartan for two weeks and were then force-titrated up to 100 mg of losartan where they remained for 34 weeks.
Aliskiren/Losartan 300/100 mg	Patients in this arm initially received 150 mg of aliskiren in combination with 50 mg of losartan for two weeks and were then force-titrated up to 300 mg of aliskiren in combination with 100 mg of losartan where they remained for 34 weeks.

Serious Adverse Events

	Aliskiren 300 mg	Losartan 100 mg	Aliskiren/Losartan 300/100 mg
Total, serious adverse events			
# participants affected / at risk	**10/154 (6.49%)**	**13/152 (8.55%)**	**10/154 (6.49%)**
Blood and lymphatic system disorders			
Leukocytosis † [1]			
# participants affected / at risk	**1/154 (0.65%)**	**0/152 (0.00%)**	**0/154 (0.00%)**

Thrombocythaemia † 1			
# participants affected / at risk	1/154 (0.65%)	0/152 (0.00%)	0/154 (0.00%)
Cardiac disorders			
Acute myocardial infarction † 1			
# participants affected / at risk	1/154 (0.65%)	0/152 (0.00%)	1/154 (0.65%)
Angina pectoris † 1			
# participants affected / at risk	1/154 (0.65%)	1/152 (0.66%)	0/154 (0.00%)
Atrial fibrillation † 1			
# participants affected / at risk	2/154 (1.30%)	2/152 (1.32%)	1/154 (0.65%)
Coronary artery stenosis † 1			
# participants affected / at risk	0/154 (0.00%)	1/152 (0.66%)	0/154 (0.00%)
Myocardial infarction † 1			
# participants affected / at risk	1/154 (0.65%)	0/152 (0.00%)	0/154 (0.00%)
Palpitations † 1			
# participants affected / at risk	1/154 (0.65%)	0/152 (0.00%)	0/154 (0.00%)
Sick sinus syndrome † 1			
# participants affected / at risk	1/154 (0.65%)	0/152 (0.00%)	0/154 (0.00%)
Ear and labyrinth disorders			
Vestibular disorder † 1			
# participants affected / at risk	0/154 (0.00%)	0/152 (0.00%)	1/154 (0.65%)
Endocrine disorders			
Hyperthyroidism † 1			
# participants affected / at risk	0/154 (0.00%)	0/152 (0.00%)	1/154 (0.65%)
Eye disorders			
Conjunctivitis † 1			
# participants affected / at risk	0/154 (0.00%)	1/152 (0.66%)	0/154 (0.00%)
Gastrointestinal disorders			
Diverticular perforation † 1			
# participants affected / at risk	1/154 (0.65%)	0/152 (0.00%)	0/154 (0.00%)
General disorders			
Non-cardiac chest pain † 1			
# participants affected / at risk	0/154 (0.00%)	1/152 (0.66%)	0/154 (0.00%)
Infections and infestations			
Bronchitis † 1			
# participants affected / at risk	0/154 (0.00%)	0/152 (0.00%)	1/154 (0.65%)
Diverticulitis † 1			
# participants affected / at risk	1/154 (0.65%)	0/152 (0.00%)	0/154 (0.00%)
Erysipelas † 1			
# participants affected / at risk	0/154 (0.00%)	1/152 (0.66%)	0/154 (0.00%)
Herpes zoster † 1			
# participants affected / at risk	0/154 (0.00%)	1/152 (0.66%)	0/154 (0.00%)
Otitis media † 1			
# participants affected / at risk	1/154 (0.65%)	0/152 (0.00%)	0/154 (0.00%)

Pneumonia † 1			
# participants affected / at risk	**1/154 (0.65%)**	**0/152 (0.00%)**	**0/154 (0.00%)**
Sepsis † 1			
# participants affected / at risk	**0/154 (0.00%)**	**1/152 (0.66%)**	**0/154 (0.00%)**
Sinusitis † 1			
# participants affected / at risk	**0/154 (0.00%)**	**0/152 (0.00%)**	**1/154 (0.65%)**
Urinary tract infection † 1			
# participants affected / at risk	**0/154 (0.00%)**	**1/152 (0.66%)**	**0/154 (0.00%)**
Injury, poisoning and procedural complications			
Brain contusion † 1			
# participants affected / at risk	**1/154 (0.65%)**	**0/152 (0.00%)**	**0/154 (0.00%)**
Head injury † 1			
# participants affected / at risk	**1/154 (0.65%)**	**0/152 (0.00%)**	**0/154 (0.00%)**
Joint dislocation † 1			
# participants affected / at risk	**0/154 (0.00%)**	**0/152 (0.00%)**	**1/154 (0.65%)**
Multiple injuries † 1			
# participants affected / at risk	**0/154 (0.00%)**	**1/152 (0.66%)**	**0/154 (0.00%)**
Radius fracture † 1			
# participants affected / at risk	**0/154 (0.00%)**	**1/152 (0.66%)**	**0/154 (0.00%)**
Road traffic accident † 1			
# participants affected / at risk	**0/154 (0.00%)**	**1/152 (0.66%)**	**0/154 (0.00%)**
Skin injury † 1			
# participants affected / at risk	**0/154 (0.00%)**	**1/152 (0.66%)**	**0/154 (0.00%)**
Tendon rupture † 1			
# participants affected / at risk	**0/154 (0.00%)**	**1/152 (0.66%)**	**0/154 (0.00%)**
Upper limb fracture † 1			
# participants affected / at risk	**0/154 (0.00%)**	**1/152 (0.66%)**	**0/154 (0.00%)**
Investigations			
Blood creatine phosphokinase increased † 1			
# participants affected / at risk	**0/154 (0.00%)**	**1/152 (0.66%)**	**0/154 (0.00%)**
Metabolism and nutrition disorders			
Hypercalcaemia † 1			
# participants affected / at risk	**0/154 (0.00%)**	**0/152 (0.00%)**	**1/154 (0.65%)**
Musculoskeletal and connective tissue disorders			
Osteoarthritis † 1			
# participants affected / at risk	**0/154 (0.00%)**	**0/152 (0.00%)**	**1/154 (0.65%)**
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Pelvic neoplasm † 1			
# participants affected / at risk	**0/154 (0.00%)**	**1/152 (0.66%)**	**0/154 (0.00%)**
Prostate cancer † 1			
# participants affected / at risk	**0/154 (0.00%)**	**1/152 (0.66%)**	**0/154 (0.00%)**
Nervous system disorders			
Loss of consciousness † 1			

# participants affected / at risk	0/154 (0.00%)	0/152 (0.00%)	1/154 (0.65%)
Neuropathy † 1			
# participants affected / at risk	1/154 (0.65%)	0/152 (0.00%)	0/154 (0.00%)
Subarachnoid haemorrhage † 1			
# participants affected / at risk	0/154 (0.00%)	1/152 (0.66%)	0/154 (0.00%)
Trigeminal neuralgia † 1			
# participants affected / at risk	1/154 (0.65%)	0/152 (0.00%)	0/154 (0.00%)
Psychiatric disorders			
Alcohol withdrawal syndrome † 1			
# participants affected / at risk	0/154 (0.00%)	0/152 (0.00%)	1/154 (0.65%)
Depression † 1			
# participants affected / at risk	0/154 (0.00%)	0/152 (0.00%)	1/154 (0.65%)
Renal and urinary disorders			
Renal impairment † 1			
# participants affected / at risk	0/154 (0.00%)	1/152 (0.66%)	0/154 (0.00%)
Respiratory, thoracic and mediastinal disorders			
Bronchopneumopathy † 1			
# participants affected / at risk	1/154 (0.65%)	0/152 (0.00%)	0/154 (0.00%)
Nasal polyps † 1			
# participants affected / at risk	0/154 (0.00%)	0/152 (0.00%)	1/154 (0.65%)
Vascular disorders			
Haematoma † 1			
# participants affected / at risk	0/154 (0.00%)	1/152 (0.66%)	0/154 (0.00%)
Thrombosis † 1			
# participants affected / at risk	0/154 (0.00%)	0/152 (0.00%)	1/154 (0.65%)

† 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 300 mg	Patients in this arm initially received 150 mg of aliskiren for two weeks and were then force-titrated up to 300 mg of aliskiren where they remained for 34 weeks.
Losartan 100 mg	Patients in this arm initially received 50 mg of losartan for two weeks and were then force-titrated up to 100 mg of losartan where they remained for 34 weeks.
Aliskiren/Losartan 300/100 mg	Patients in this arm initially received 150 mg of aliskiren in combination with 50 mg of losartan for two weeks and were then force-titrated up to 300 mg of aliskiren in combination with 100 mg of losartan where they

	remained for 34 weeks.

Other Adverse Events

	Aliskiren 300 mg	Losartan 100 mg	Aliskiren/Losartan 300/100 mg
Total, other (not including serious) adverse events			
# participants affected / at risk	**31/154 (20.13%)**	**31/152 (20.39%)**	**29/154 (18.83%)**
Gastrointestinal disorders			
Diarrhoea † 1			
# participants affected / at risk	**6/154 (3.90%)**	**9/152 (5.92%)**	**7/154 (4.55%)**
Infections and infestations			
Nasopharyngitis † 1			
# participants affected / at risk	**11/154 (7.14%)**	**13/152 (8.55%)**	**11/154 (7.14%)**
Nervous system disorders			
Dizziness † 1			
# participants affected / at risk	**5/154 (3.25%)**	**3/152 (1.97%)**	**8/154 (5.19%)**
Headache † 1			
# participants affected / at risk	**14/154 (9.09%)**	**8/152 (5.26%)**	**10/154 (6.49%)**

† 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 by Novartis

Publications automatically indexed to this study:

Pouleur AC, Uno H, Prescott MF, Desai A, Appelbaum E, Lukashevich V, Smith BA, Dahlöf B, Solomon SD; ALLAY Investigators. Suppression of aldosterone mediates regression of left ventricular hypertrophy in patients with hypertension. J Renin Angiotensin Aldosterone Syst. 2011 Dec;12(4):483-90. doi: 10.1177/1470320311414453. Epub 2011 Jul 11.

Responsible Party:	Novartis Pharmaceuticals, External Affairs
ClinicalTrials.gov Identifier:	NCT00219141 History of Changes
Other Study ID Numbers:	**CSPP100A2316**
Study First Received:	September 12, 2005
Results First Received:	January 11, 2011
Last Updated:	May 20, 2011
Health Authority:	United States: Food and Drug Administration Argentina: Administracion Nacional de Medicamentos, Alimentos y Tecnologia Medica