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Trial record **1 of 1** for: CSPA100A2305

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Study to Evaluate the Efficacy and Safety of Aliskiren Alone and in Combination With Amlodipine in Essential Hypertension

This study has been completed.

Sponsor:
Novartis Pharmaceuticals

Information provided by:
Novartis

ClinicalTrials.gov Identifier:
NCT00739973

First received: August 20, 2008
Last updated: June 2, 2011
Last verified: June 2011
History of Changes

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Results First Received: January 13, 2011

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Factorial Assignment; Masking: Double Blind (Subject, Caregiver, Investigator); Primary Purpose: Treatment
Condition:	Hypertension
Interventions:	Drug: Placebo Drug: Aliskiren 150 mg tablet Drug: Aliskiren 300 mg tablet Drug: Amlodipine 5 mg capsule Drug: Amlodipine 10 mg capsule Drug: Aliskiren/amlodipine 150/5 mg tablet Drug: Aliskiren/amlodipine 150/10 mg tablet Drug: Aliskiren/amlodipine 300/5 mg tablet Drug: Aliskiren/amlodipine 300/10 mg tablet

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
A total of 2694 patients enrolled in the single-blind, placebo run-in period (2 to 4 weeks) of the study. A total of 1688 patients were randomized into the double-blind treatment period (8 weeks). Three patients were mis-randomized, as they were discontinued from the single-blind period and were not treated in the double-blind period.

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
Placebo	Each dose was to be taken orally with water at approximately 8:00 A.M., except on the morning of the next office/clinic visit, when the study medication was to be taken at the site after the visit procedures were completed. In order to adequately blind the study, patients were required to take a total of 4 tablets and 1 capsule of study medication throughout the study; for this arm all the 5 pills taken were placebos.
Aliskiren 150 mg	Each dose was to be taken orally with water at approximately 8:00 A.M., except on the morning of the next office/clinic visit, when the study medication was to be taken at the site after the visit procedures were completed. In order to adequately blind the study, patients were required to take a total of 4 tablets and 1 capsule of study medication throughout the study; 4 of the 5 pills taken were placebos.
Aliskiren 300 mg	Each dose was to be taken orally with water at approximately 8:00 A.M., except on the morning of the next office/clinic visit, when the study medication was to be taken at the site after the visit procedures were

	completed. In order to adequately blind the study, patients were required to take a total of 4 tablets and 1 capsule of study medication throughout the study; 4 of the 5 pills taken were placebos.
Amlodipine 5 mg	Each dose was to be taken orally with water at approximately 8:00 A.M., except on the morning of the next office/clinic visit, when the study medication was to be taken at the site after the visit procedures were completed. In order to adequately blind the study, patients were required to take a total of 4 tablets and 1 capsule of study medication throughout the study; 4 of the 5 pills taken were placebos.
Amlodipine 10 mg	Each dose was to be taken orally with water at approximately 8:00 A.M., except on the morning of the next office/clinic visit, when the study medication was to be taken at the site after the visit procedures were completed. In order to adequately blind the study, patients were required to take a total of 4 tablets and 1 capsule of study medication throughout the study; 4 of the 5 pills taken were placebos. Amlodipine 10 mg arm starts with 1 week of Amlodipine 5 mg, then force titrated to 10 mg.
Aliskiren/Amlodipine 150/5 mg	Each dose was to be taken orally with water at approximately 8:00 A.M., except on the morning of the next office/clinic visit, when the study medication was to be taken at the site after the visit procedures were completed. In order to adequately blind the study, patients were required to take a total of 4 tablets and 1 capsule of study medication throughout the study; 4 of the 5 pills taken were placebos.
Aliskiren/Amlodipine 150/10 mg	150/5 for 1 week, then up-titrated to 150/10 mg. Each dose was to be taken orally with water at approximately 8:00 A.M., except on the morning of the next office/clinic visit, when the study medication was to be taken at the site after the visit procedures were completed. In order to adequately blind the study, patients were required to take a total of 4 tablets and 1 capsule of study medication throughout the study; 4 of the 5 pills taken were placebos.
Aliskiren/Amlodipine 300/5 mg	Each dose was to be taken orally with water at approximately 8:00 A.M., except on the morning of the next office/clinic visit, when the study medication was to be taken at the site after the visit procedures were completed. In order to adequately blind the study, patients were required to take a total of 4 tablets and 1 capsule of study medication throughout the study; 4 of the 5 pills taken were placebos.
Aliskiren/Amlodipine 300/10 mg Tablet	300/5 for 1 week, then up-titrated to 300/10 mg. Each dose was to be taken orally with water at approximately 8:00 A.M., except on the morning of the next office/clinic visit, when the study medication was to be taken at the site after the visit procedures were completed. In order to adequately blind the study, patients were required to take a total of 4 tablets and 1 capsule of study medication throughout the study; 4 of the 5 pills taken were placebos.

Participant Flow for 2 periods

Period 1: Single-blind Period (2 to 4 Weeks)

	Placebo	Aliskiren 150 mg	Aliskiren 300 mg	Amlodipine 5 mg	Amlodipine 10 mg	Aliskiren/Amlodipine 150/5 mg	Aliskiren/Amlodipine 150/10 mg	Aliskiren/Amlodipine 300/5 mg	Aliskiren/ 300/10 m
STARTED	2694 [1]	0	0	0	0	0	0	0	
COMPLETED	1685	0	0	0	0	0	0	0	
NOT COMPLETED	1009	0	0	0	0	0	0	0	
Adverse Event	35	0	0	0	0	0	0	0	
Abnormal laboratory value(s)	38	0	0	0	0	0	0	0	
Abnormal test procedure result(s)	810	0	0	0	0	0	0	0	
Patient withdrew consent	86	0	0	0	0	0	0	0	
Lost to Follow-up	17	0	0	0	0	0	0	0	
Administrative problems	12	0	0	0	0	0	0	0	
Protocol deviation	11	0	0	0	0	0	0	0	

[1] In this period, participants were enrolled to only Placebo arm.

Period 2: Double-blind:Randomized Period (8 Weeks)

	Placebo	Aliskiren 150 mg	Aliskiren 300 mg	Amlodipine 5 mg	Amlodipine 10 mg	Aliskiren/Amlodipine 150/5 mg	Aliskiren/Amlodipine 150/10 mg	Aliskiren/Amlodipine 300/5 mg	Aliskiren/ 300/10 m

STARTED	198	195 [1]	203	185	181	181	183 [2]	178	1
COMPLETED	168	175	184	173	162	169	170	168	1
NOT COMPLETED	30	20	19	12	19	12	13	10	
Adverse Event	3	3	1	2	7	3	4	1	
Abnormal laboratory values	0	0	0	0	1	0	0	1	
Abnormal test procedure results	1	1	0	0	0	0	0	0	
Unsatisfactory therapeutic effect	17	8	8	4	2	2	1	1	
Patient no longer needs study drug	0	0	1	0	0	0	0	0	
Patient withdrew consent	4	2	4	3	4	4	3	2	
Lost to Follow-up	0	2	4	1	2	2	0	3	
Administrative problems	0	0	0	0	0	0	1	0	
Protocol deviation	5	3	1	2	3	1	2	2	
Discont. single-blind, Mis-randomized	0	1	0	0	0	0	2	0	

[1] One pt. was mis-randomized, so discontinued from single-blind and was untreated in the double-blind.
[2] 2 pts. were mis-randomized, so discontinued from single-blind and were untreated in double-blind.

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
Placebo	Each dose was to be taken orally with water at approximately 8:00 A.M., except on the morning of the next office/clinic visit, when the study medication was to be taken at the site after the visit procedures were completed. In order to adequately blind the study, patients were required to take a total of 4 tablets and 1 capsule of study medication throughout the study; for this arm all the 5 pills taken were placebos.
Aliskiren 150 mg	Each dose was to be taken orally with water at approximately 8:00 A.M., except on the morning of the next office/clinic visit, when the study medication was to be taken at the site after the visit procedures were completed. In order to adequately blind the study, patients were required to take a total of 4 tablets and 1 capsule of study medication throughout the study; 4 of the 5 pills taken were placebos.
Aliskiren 300 mg	Each dose was to be taken orally with water at approximately 8:00 A.M., except on the morning of the next office/clinic visit, when the study medication was to be taken at the site after the visit procedures were completed. In order to adequately blind the study, patients were required to take a total of 4 tablets and 1 capsule of study medication throughout the study; 4 of the 5 pills taken were placebos.
Amlodipine 5 mg	Each dose was to be taken orally with water at approximately 8:00 A.M., except on the morning of the next office/clinic visit, when the study medication was to be taken at the site after the visit procedures were completed. In order to adequately blind the study, patients were required to take a total of 4 tablets and 1 capsule of study medication throughout the study; 4 of the 5 pills taken were placebos.
Amlodipine 10 mg	Each dose was to be taken orally with water at approximately 8:00 A.M., except on the morning of the next

	office/clinic visit, when the study medication was to be taken at the site after the visit procedures were completed. In order to adequately blind the study, patients were required to take a total of 4 tablets and 1 capsule of study medication throughout the study; 4 of the 5 pills taken were placebos. Amlodipine 10 mg arm starts with 1 week of Amlodipine 5 mg, then force titrated to 10 mg.
Aliskiren/Amlodipine 150/5 mg	Each dose was to be taken orally with water at approximately 8:00 A.M., except on the morning of the next office/clinic visit, when the study medication was to be taken at the site after the visit procedures were completed. In order to adequately blind the study, patients were required to take a total of 4 tablets and 1 capsule of study medication throughout the study; 4 of the 5 pills taken were placebos.
Aliskiren/Amlodipine 150/10 mg	150/5 for 1 week, then up-titrated to 150/10 mg. Each dose was to be taken orally with water at approximately 8:00 A.M., except on the morning of the next office/clinic visit, when the study medication was to be taken at the site after the visit procedures were completed. In order to adequately blind the study, patients were required to take a total of 4 tablets and 1 capsule of study medication throughout the study; 4 of the 5 pills taken were placebos.
Aliskiren/Amlodipine 300/5 mg	Each dose was to be taken orally with water at approximately 8:00 A.M., except on the morning of the next office/clinic visit, when the study medication was to be taken at the site after the visit procedures were completed. In order to adequately blind the study, patients were required to take a total of 4 tablets and 1 capsule of study medication throughout the study; 4 of the 5 pills taken were placebos.
Aliskiren/Amlodipine 300/10 mg Tablet	300/5 for 1 week, then up-titrated to 300/10 mg. Each dose was to be taken orally with water at approximately 8:00 A.M., except on the morning of the next office/clinic visit, when the study medication was to be taken at the site after the visit procedures were completed. In order to adequately blind the study, patients were required to take a total of 4 tablets and 1 capsule of study medication throughout the study; 4 of the 5 pills taken were placebos.
Total	Total of all reporting groups

Baseline Measures

	Placebo	Aliskiren 150 mg	Aliskiren 300 mg	Amlodipine 5 mg	Amlodipine 10 mg	Aliskiren/Amlodipine 150/5 mg	Aliskiren/Amlodipine 150/10 mg	Aliskiren/Amlodipine 300/5 mg	Aliskire 300/10
Number of Participants [units: participants]	**198**	**195**	**203**	**185**	**181**	**181**	**183**	**178**	
Age [units: years] Mean (Standard Deviation)	**53.7 (10.32)**	**54.3 (11.07)**	**54.0 (9.99)**	**54.2 (11.61)**	**55.0 (10.34)**	**53.9 (10.82)**	**53.0 (10.59)**	**54.8 (10.29)**	**54.**
Gender [units: participants]									
Female	**108**	**76**	**108**	**86**	**94**	**84**	**96**	**100**	
Male	**90**	**119**	**95**	**99**	**87**	**97**	**87**	**78**	

Outcome Measures

Hide All Outcome Measures

1. Primary: Pairwise Comparison of Aliskiren/Amlodipine 150/5 mg vs. Aliskiren 150 mg on Change in Mean Sitting Diastolic Blood Pressure (msDBP) [Time Frame: Baseline to end of study (Week 8)]

Measure Type	Primary
Measure Title	Pairwise Comparison of Aliskiren/Amlodipine 150/5 mg vs. Aliskiren 150 mg on Change in Mean Sitting Diastolic Blood Pressure (msDBP)
Measure Description	The arm in which the highest sitting diastolic pressures were found at study entry was the arm used for all subsequent readings. An automated BP measurement device and appropriate size cuff were used to measure arterial sitting blood pressure (BP) at trough with the arm supported at the level of the heart. At each study visit, after having the patient in a sitting position for at least 5 minutes, diastolic BP were measured 3 times at 1-2 minute intervals. A mean was calculated from the 3 measurements.
Time Frame	Baseline to end of study (Week 8)
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Full Analysis Set (FAS): All participants who were randomized. Participants mis-randomized were excluded from the FAS. Mis-randomized participants refer to participants who were not qualified for randomization but were inadvertently randomized into the study. These participants did not receive study

drug.

Reporting Groups

	Description
Aliskiren 150 mg	Each dose was to be taken orally with water at approximately 8:00 A.M., except on the morning of the next office/clinic visit, when the study medication was to be taken at the site after the visit procedures were completed. In order to adequately blind the study, patients were required to take a total of 4 tablets and 1 capsule of study medication throughout the study; 4 of the 5 pills taken were placebos.
Aliskiren/Amlodipine 150/5 mg	Each dose was to be taken orally with water at approximately 8:00 A.M., except on the morning of the next office/clinic visit, when the study medication was to be taken at the site after the visit procedures were completed. In order to adequately blind the study, patients were required to take a total of 4 tablets and 1 capsule of study medication throughout the study; 4 of the 5 pills taken were placebos.

Measured Values

	Aliskiren 150 mg	Aliskiren/Amlodipine 150/5 mg
Number of Participants Analyzed [units: participants]	**193**	**179**
Pairwise Comparison of Aliskiren/Amlodipine 150/5 mg vs. Aliskiren 150 mg on Change in Mean Sitting Diastolic Blood Pressure (msDBP) [units: mm Hg] Least Squares Mean (Standard Error)	**-7.99 (0.63)**	**-13.98 (0.66)**

Statistical Analysis 1 for Pairwise Comparison of Aliskiren/Amlodipine 150/5 mg vs. Aliskiren 150 mg on Change in Mean Sitting Diastolic Blood Pressure (msDBP)

Groups [1]	All groups
Method [2]	ANCOVA
P Value [3]	<0.001
Least Square Mean Difference [4]	-6.00
Standard Error of the mean	(0.90)
95% Confidence Interval	-7.77 to -4.22

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	A two-way analysis of covariance model with treatment and region as two factors, and the baseline as a covariate.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

2. Primary: Pairwise Comparison of Aliskiren/Amlodipine 150/5 mg vs. Amlodipine 5 mg on Change in Mean Sitting Diastolic Blood Pressure (msDBP) [Time Frame: Baseline to end of study (Week 8)]

Measure Type	Primary
Measure Title	Pairwise Comparison of Aliskiren/Amlodipine 150/5 mg vs. Amlodipine 5 mg on Change in Mean Sitting Diastolic Blood Pressure (msDBP)
Measure Description	The arm in which the highest sitting diastolic pressures were found at study entry was the arm used for all subsequent readings. An automated BP measurement device and appropriate size cuff were used to measure arterial sitting blood pressure (BP) at trough with the arm supported at the level of the heart. At each study visit, after having the patient in a sitting position for at least 5 minutes, diastolic BP were measured 3 times at 1-2 minute intervals. A mean was calculated from the 3 measurements.
Time Frame	Baseline to end of study (Week 8)
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Full Analysis Set (FAS): All participants who were randomized. Participants mis-randomized were excluded from the FAS. Mis-randomized participants refer to participants who were not qualified for randomization but were inadvertently randomized into the study. These participants did not receive study drug.

Reporting Groups

	Description
Amlodipine 5 mg	Each dose was to be taken orally with water at approximately 8:00 A.M., except on the morning of the next office/clinic visit, when the study medication was to be taken at the site after the visit procedures were completed. In order to adequately blind the study, patients were required to take a total of 4 tablets and 1 capsule of study medication throughout the study; 4 of the 5 pills taken were placebos.
Aliskiren/Amlodipine 150/5 mg	Each dose was to be taken orally with water at approximately 8:00 A.M., except on the morning of the next office/clinic visit, when the study medication was to be taken at the site after the visit procedures were completed. In order to adequately blind the study, patients were required to take a total of 4 tablets and 1 capsule of study medication throughout the study; 4 of the 5 pills taken were placebos.

Measured Values

	Amlodipine 5 mg	**Aliskiren/Amlodipine 150/5 mg**
Number of Participants Analyzed [units: participants]	**184**	**179**
Pairwise Comparison of Aliskiren/Amlodipine 150/5 mg vs. Amlodipine 5 mg on Change in Mean Sitting Diastolic Blood Pressure (msDBP) [units: mm Hg] Least Squares Mean (Standard Error)	**-11.0 (0.65)**	**-13.98 (0.66)**

Statistical Analysis 1 for Pairwise Comparison of Aliskiren/Amlodipine 150/5 mg vs. Amlodipine 5 mg on Change in Mean Sitting Diastolic Blood Pressure (msDBP)

Groups [1]	All groups
Method [2]	ANCOVA
P Value [3]	0.001
Least Square Mean Difference [4]	-2.98
Standard Error of the mean	(0.91)
95% Confidence Interval	-4.77 to -1.19

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	A two-way analysis of covariance model with treatment and region as two factors, and the baseline as a covariate.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

3. Primary: Pairwise Comparison of Aliskiren/Amlodipine 150/5 mg vs. Placebo on Change in Mean Sitting Diastolic Blood Pressure (msDBP) [Time Frame: Baseline to end of study (Week 8)]

Measure Type	Primary
Measure Title	Pairwise Comparison of Aliskiren/Amlodipine 150/5 mg vs. Placebo on Change in Mean Sitting Diastolic Blood Pressure (msDBP)
Measure Description	The arm in which the highest sitting diastolic pressures were found at study entry was the arm used for all subsequent readings. An automated BP measurement device and appropriate size cuff were used to measure arterial sitting blood pressure (BP) at trough with the arm supported at the level of the heart. At each study visit, after having the patient in a sitting position for at least 5 minutes, diastolic BP were measured 3 times at 1-2 minute intervals. A mean was calculated from the 3 measurements.

Time Frame	Baseline to end of study (Week 8)
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Full Analysis Set (FAS): All participants who were randomized. Participants mis-randomized were excluded from the FAS. Mis-randomized participants refer to participants who were not qualified for randomization but were inadvertently randomized into the study. These participants did not receive study drug.

Reporting Groups

	Description
Placebo	Each dose was to be taken orally with water at approximately 8:00 A.M., except on the morning of the next office/clinic visit, when the study medication was to be taken at the site after the visit procedures were completed. In order to adequately blind the study, patients were required to take a total of 4 tablets and 1 capsule of study medication throughout the study; for this arm all the 5 pills taken were placebos.
Aliskiren/Amlodipine 150/5 mg	Each dose was to be taken orally with water at approximately 8:00 A.M., except on the morning of the next office/clinic visit, when the study medication was to be taken at the site after the visit procedures were completed. In order to adequately blind the study, patients were required to take a total of 4 tablets and 1 capsule of study medication throughout the study; 4 of the 5 pills taken were placebos.

Measured Values

	Placebo	**Aliskiren/Amlodipine 150/5 mg**
Number of Participants Analyzed [units: participants]	**198**	**179**
Pairwise Comparison of Aliskiren/Amlodipine 150/5 mg vs. Placebo on Change in Mean Sitting Diastolic Blood Pressure (msDBP) [units: mm Hg] Least Squares Mean (Standard Error)	**-5.35 (0.62)**	**-13.98 (0.66)**

Statistical Analysis 1 for Pairwise Comparison of Aliskiren/Amlodipine 150/5 mg vs. Placebo on Change in Mean Sitting Diastolic Blood Pressure (msDBP)

Groups [1]	All groups
Method [2]	ANCOVA
P Value [3]	<0.001
Least Square Mean Difference [4]	-8.63
Standard Error of the mean	(0.90)
95% Confidence Interval	-10.39 to -6.87

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	A two-way analysis of covariance model with treatment and region as two factors, and the baseline as a covariate.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

4. Primary: Pairwise Comparison of Aliskiren/Amlodipine 150/10 mg vs. Aliskiren 150 mg on Change in Mean Sitting Diastolic Blood Pressure (msDBP) [Time Frame: Baseline to end of study (Week 8)]

Measure Type	Primary
Measure Title	Pairwise Comparison of Aliskiren/Amlodipine 150/10 mg vs. Aliskiren 150 mg on Change in Mean Sitting Diastolic Blood Pressure (msDBP)

Measure Description	The arm in which the highest sitting diastolic pressures were found at study entry was the arm used for all subsequent readings. An automated BP measurement device and appropriate size cuff were used to measure arterial sitting blood pressure (BP) at trough with the arm supported at the level of the heart. At each study visit, after having the patient in a sitting position for at least 5 minutes, diastolic BP were measured 3 times at 1-2 minute intervals. A mean was calculated from the 3 measurements.
Time Frame	Baseline to end of study (Week 8)
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Full Analysis Set (FAS): All participants who were randomized. Participants mis-randomized were excluded from the FAS. Mis-randomized participants refer to participants who were not qualified for randomization but were inadvertently randomized into the study. These participants did not receive study drug.

Reporting Groups

	Description
Aliskiren 150 mg	Each dose was to be taken orally with water at approximately 8:00 A.M., except on the morning of the next office/clinic visit, when the study medication was to be taken at the site after the visit procedures were completed. In order to adequately blind the study, patients were required to take a total of 4 tablets and 1 capsule of study medication throughout the study; 4 of the 5 pills taken were placebos.
Aliskiren/Amlodipine 150/10 mg	150/5 for 1 week, then up-titrated to 150/10 mg. Each dose was to be taken orally with water at approximately 8:00 A.M., except on the morning of the next office/clinic visit, when the study medication was to be taken at the site after the visit procedures were completed. In order to adequately blind the study, patients were required to take a total of 4 tablets and 1 capsule of study medication throughout the study; 4 of the 5 pills taken were placebos.

Measured Values

	Aliskiren 150 mg	**Aliskiren/Amlodipine 150/10 mg**
Number of Participants Analyzed [units: participants]	**193**	**179**
Pairwise Comparison of Aliskiren/Amlodipine 150/10 mg vs. Aliskiren 150 mg on Change in Mean Sitting Diastolic Blood Pressure (msDBP) [units: mm Hg] Least Squares Mean (Standard Error)	**-7.99 (0.63)**	**-16.16 (0.66)**

Statistical Analysis 1 for Pairwise Comparison of Aliskiren/Amlodipine 150/10 mg vs. Aliskiren 150 mg on Change in Mean Sitting Diastolic Blood Pressure (msDBP)

Groups [1]	All groups
Method [2]	ANCOVA
P Value [3]	<0.001
Least Square Mean Difference [4]	-8.17
Standard Error of the mean	(0.90)
95% Confidence Interval	-9.94 to -6.40

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	A two-way analysis of covariance model with treatment and region as two factors, and the baseline as a covariate.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

5. Primary: Pairwise Comparison of Aliskiren/Amlodipine 150/10 mg vs. Amlodipine 10 mg on Change in Mean Sitting Diastolic Blood Pressure (msDBP) [Time Frame: Baseline to end of study (Week 8)]

Measure Type	Primary
Measure Title	Pairwise Comparison of Aliskiren/Amlodipine 150/10 mg vs. Amlodipine 10 mg on Change in Mean Sitting Diastolic Blood Pressure (msDBP)
Measure Description	The arm in which the highest sitting diastolic pressures were found at study entry was the arm used for all subsequent readings. An automated BP measurement device and appropriate size cuff were used to measure arterial sitting blood pressure (BP) at trough with the arm supported at the level of the heart. At each study visit, after having the patient in a sitting position for at least 5 minutes, diastolic BP were measured 3 times at 1-2 minute intervals. A mean was calculated from the 3 measurements.
Time Frame	Baseline to end of study (Week 8)
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Full Analysis Set (FAS): All participants who were randomized. Participants mis-randomized were excluded from the FAS. Mis-randomized participants refer to participants who were not qualified for randomization but were inadvertently randomized into the study. These participants did not receive study drug.

Reporting Groups

	Description
Amlodipine 10 mg	Each dose was to be taken orally with water at approximately 8:00 A.M., except on the morning of the next office/clinic visit, when the study medication was to be taken at the site after the visit procedures were completed. In order to adequately blind the study, patients were required to take a total of 4 tablets and 1 capsule of study medication throughout the study; 4 of the 5 pills taken were placebos. Amlodipine 10 mg arm starts with 1 week of Amlodipine 5 mg, then force titrated to 10 mg.
Aliskiren/Amlodipine 150/10 mg	150/5 for 1 week, then up-titrated to 150/10 mg. Each dose was to be taken orally with water at approximately 8:00 A.M., except on the morning of the next office/clinic visit, when the study medication was to be taken at the site after the visit procedures were completed. In order to adequately blind the study, patients were required to take a total of 4 tablets and 1 capsule of study medication throughout the study; 4 of the 5 pills taken were placebos.

Measured Values

	Amlodipine 10 mg	**Aliskiren/Amlodipine 150/10 mg**
Number of Participants Analyzed [units: participants]	**179**	**179**
Pairwise Comparison of Aliskiren/Amlodipine 150/10 mg vs. Amlodipine 10 mg on Change in Mean Sitting Diastolic Blood Pressure (msDBP) [units: mm Hg] Least Squares Mean (Standard Error)	**-13.82 (0.66)**	**-16.16 (0.66)**

Statistical Analysis 1 for Pairwise Comparison of Aliskiren/Amlodipine 150/10 mg vs. Amlodipine 10 mg on Change in Mean Sitting Diastolic Blood Pressure (msDBP)

Groups [1]	All groups
Method [2]	ANCOVA
P Value [3]	0.011
Least Sqaure Mean Difference [4]	-2.33
Standard Error of the mean	(0.92)
95% Confidence Interval	-4.14 to -0.53

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	A two-way analysis of covariance model with treatment and region as two factors, and the baseline as a covariate.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:

	No text entered.

6. Primary: Pairwise Comparison of Aliskiren/Amlodipine 150/10 mg vs. Placebo on Change in Mean Sitting Diastolic Blood Pressure (msDBP) [Time Frame: Baseline to end of study (Week 8)]

Measure Type	Primary
Measure Title	Pairwise Comparison of Aliskiren/Amlodipine 150/10 mg vs. Placebo on Change in Mean Sitting Diastolic Blood Pressure (msDBP)
Measure Description	The arm in which the highest sitting diastolic pressures were found at study entry was the arm used for all subsequent readings. An automated BP measurement device and appropriate size cuff were used to measure arterial sitting blood pressure (BP) at trough with the arm supported at the level of the heart. At each study visit, after having the patient in a sitting position for at least 5 minutes, diastolic BP were measured 3 times at 1-2 minute intervals. A mean was calculated from the 3 measurements.
Time Frame	Baseline to end of study (Week 8)
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Full Analysis Set (FAS): All participants who were randomized. Participants mis-randomized were excluded from the FAS. Mis-randomized participants refer to participants who were not qualified for randomization but were inadvertently randomized into the study. These participants did not receive study drug.

Reporting Groups

	Description
Placebo	Each dose was to be taken orally with water at approximately 8:00 A.M., except on the morning of the next office/clinic visit, when the study medication was to be taken at the site after the visit procedures were completed. In order to adequately blind the study, patients were required to take a total of 4 tablets and 1 capsule of study medication throughout the study; for this arm all the 5 pills taken were placebos.
Aliskiren/Amlodipine 150/10 mg	150/5 for 1 week, then up-titrated to 150/10 mg. Each dose was to be taken orally with water at approximately 8:00 A.M., except on the morning of the next office/clinic visit, when the study medication was to be taken at the site after the visit procedures were completed. In order to adequately blind the study, patients were required to take a total of 4 tablets and 1 capsule of study medication throughout the study; 4 of the 5 pills taken were placebos.

Measured Values

	Placebo	**Aliskiren/Amlodipine 150/10 mg**
Number of Participants Analyzed [units: participants]	**198**	**179**
Pairwise Comparison of Aliskiren/Amlodipine 150/10 mg vs. Placebo on Change in Mean Sitting Diastolic Blood Pressure (msDBP) [units: mm Hg] Least Squares Mean (Standard Error)	**-5.35 (0.62)**	**-16.16 (0.66)**

Statistical Analysis 1 for Pairwise Comparison of Aliskiren/Amlodipine 150/10 mg vs. Placebo on Change in Mean Sitting Diastolic Blood Pressure (msDBP)

Groups [1]	All groups
Method [2]	ANCOVA
P Value [3]	<0.001
Least Square Mean Difference [4]	-10.81
Standard Error of the mean	(0.90)
95% Confidence Interval	-12.57 to -9.05

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	A two-way analysis of covariance model with treatment and region as two factors, and the baseline as a covariate.

[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

7. Primary: Pairwise Comparison of Aliskiren/Amlodipine 300/5 mg vs. Aliskiren 300 mg on Change in Mean Sitting Diastolic Blood Pressure (msDBP) [Time Frame: Baseline to end of study (Week 8)]

Measure Type	Primary
Measure Title	Pairwise Comparison of Aliskiren/Amlodipine 300/5 mg vs. Aliskiren 300 mg on Change in Mean Sitting Diastolic Blood Pressure (msDBP)
Measure Description	The arm in which the highest sitting diastolic pressures were found at study entry was the arm used for all subsequent readings. An automated BP measurement device and appropriate size cuff were used to measure arterial sitting blood pressure (BP) at trough with the arm supported at the level of the heart. At each study visit, after having the patient in a sitting position for at least 5 minutes, diastolic BP were measured 3 times at 1-2 minute intervals. A mean was calculated from the 3 measurements.
Time Frame	Baseline to end of study (Week 8)
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Full Analysis Set (FAS): All participants who were randomized. Participants mis-randomized were excluded from the FAS. Mis-randomized participants refer to participants who were not qualified for randomization but were inadvertently randomized into the study. These participants did not receive study drug.

Reporting Groups

	Description
Aliskiren 300 mg	Each dose was to be taken orally with water at approximately 8:00 A.M., except on the morning of the next office/clinic visit, when the study medication was to be taken at the site after the visit procedures were completed. In order to adequately blind the study, patients were required to take a total of 4 tablets and 1 capsule of study medication throughout the study; 4 of the 5 pills taken were placebos.
Aliskiren/Amlodipine 300/5 mg	Each dose was to be taken orally with water at approximately 8:00 A.M., except on the morning of the next office/clinic visit, when the study medication was to be taken at the site after the visit procedures were completed. In order to adequately blind the study, patients were required to take a total of 4 tablets and 1 capsule of study medication throughout the study; 4 of the 5 pills taken were placebos.

Measured Values

	Aliskiren 300 mg	**Aliskiren/Amlodipine 300/5 mg**
Number of Participants Analyzed [units: participants]	**201**	**175**
Pairwise Comparison of Aliskiren/Amlodipine 300/5 mg vs. Aliskiren 300 mg on Change in Mean Sitting Diastolic Blood Pressure (msDBP) [units: mm Hg] Least Squares Mean (Standard Error)	**-10.19 (0.62)**	**-14.99 (0.66)**

Statistical Analysis 1 for Pairwise Comparison of Aliskiren/Amlodipine 300/5 mg vs. Aliskiren 300 mg on Change in Mean Sitting Diastolic Blood Pressure (msDBP)

Groups [1]	All groups
Method [2]	ANCOVA
P Value [3]	<0.001
Least Square Mean Difference [4]	-4.79
Standard Error of the mean	(0.90)
95% Confidence Interval	-6.56 to -3.03

[1]	Additional details about the analysis, such as null hypothesis and power calculation:

	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	A two-way analysis of covariance model with treatment and region as two factors, and the baseline as a covariate.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

8. Primary: Pairwise Comparison of Aliskiren/Amlodipine 300/5 mg vs. Amlodipine 5 mg on Change in Mean Sitting Diastolic Blood Pressure (msDBP) [Time Frame: Baseline to end of study (Week 8)]

Measure Type	Primary
Measure Title	Pairwise Comparison of Aliskiren/Amlodipine 300/5 mg vs. Amlodipine 5 mg on Change in Mean Sitting Diastolic Blood Pressure (msDBP)
Measure Description	The arm in which the highest sitting diastolic pressures were found at study entry was the arm used for all subsequent readings. An automated BP measurement device and appropriate size cuff were used to measure arterial sitting blood pressure (BP) at trough with the arm supported at the level of the heart. At each study visit, after having the patient in a sitting position for at least 5 minutes, diastolic BP were measured 3 times at 1-2 minute intervals. A mean was calculated from the 3 measurements.
Time Frame	Baseline to end of study (Week 8)
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Full Analysis Set (FAS): All participants who were randomized. Participants mis-randomized were excluded from the FAS. Mis-randomized participants refer to participants who were not qualified for randomization but were inadvertently randomized into the study. These participants did not receive study drug.

Reporting Groups

	Description
Amlodipine 5 mg	Each dose was to be taken orally with water at approximately 8:00 A.M., except on the morning of the next office/clinic visit, when the study medication was to be taken at the site after the visit procedures were completed. In order to adequately blind the study, patients were required to take a total of 4 tablets and 1 capsule of study medication throughout the study; 4 of the 5 pills taken were placebos.
Aliskiren/Amlodipine 300/5 mg	Each dose was to be taken orally with water at approximately 8:00 A.M., except on the morning of the next office/clinic visit, when the study medication was to be taken at the site after the visit procedures were completed. In order to adequately blind the study, patients were required to take a total of 4 tablets and 1 capsule of study medication throughout the study; 4 of the 5 pills taken were placebos.

Measured Values

	Amlodipine 5 mg	**Aliskiren/Amlodipine 300/5 mg**
Number of Participants Analyzed [units: participants]	**184**	**175**
Pairwise Comparison of Aliskiren/Amlodipine 300/5 mg vs. Amlodipine 5 mg on Change in Mean Sitting Diastolic Blood Pressure (msDBP) [units: mm Hg] Least Squares Mean (Standard Error)	**-11.0 (0.65)**	**-14.99 (0.66)**

Statistical Analysis 1 for Pairwise Comparison of Aliskiren/Amlodipine 300/5 mg vs. Amlodipine 5 mg on Change in Mean Sitting Diastolic Blood Pressure (msDBP)

Groups [1]	All groups
Method [2]	ANCOVA
P Value [3]	<0.001
Least Square Mean Difference [4]	-3.98

Standard Error of the mean	(0.92)
95% Confidence Interval	-5.78 to -2.18

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	A two-way analysis of covariance model with treatment and region as two factors, and the baseline as a covariate.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

9. Primary: Pairwise Comparison of Aliskiren/Amlodipine 300/5 mg vs. Placebo on Change in Mean Sitting Diastolic Blood Pressure (msDBP) [Time Frame: Baseline to end of study (Week 8)]

Measure Type	Primary
Measure Title	Pairwise Comparison of Aliskiren/Amlodipine 300/5 mg vs. Placebo on Change in Mean Sitting Diastolic Blood Pressure (msDBP)
Measure Description	The arm in which the highest sitting diastolic pressures were found at study entry was the arm used for all subsequent readings. An automated BP measurement device and appropriate size cuff were used to measure arterial sitting blood pressure (BP) at trough with the arm supported at the level of the heart. At each study visit, after having the patient in a sitting position for at least 5 minutes, diastolic BP were measured 3 times at 1-2 minute intervals. A mean was calculated from the 3 measurements.
Time Frame	Baseline to end of study (Week 8)
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Full Analysis Set (FAS): All participants who were randomized. Participants mis-randomized were excluded from the FAS. Mis-randomized participants refer to participants who were not qualified for randomization but were inadvertently randomized into the study. These participants did not receive study drug.

Reporting Groups

	Description
Placebo	Each dose was to be taken orally with water at approximately 8:00 A.M., except on the morning of the next office/clinic visit, when the study medication was to be taken at the site after the visit procedures were completed. In order to adequately blind the study, patients were required to take a total of 4 tablets and 1 capsule of study medication throughout the study; for this arm all the 5 pills taken were placebos.
Aliskiren/Amlodipine 300/5 mg	Each dose was to be taken orally with water at approximately 8:00 A.M., except on the morning of the next office/clinic visit, when the study medication was to be taken at the site after the visit procedures were completed. In order to adequately blind the study, patients were required to take a total of 4 tablets and 1 capsule of study medication throughout the study; 4 of the 5 pills taken were placebos.

Measured Values

	Placebo	**Aliskiren/Amlodipine 300/5 mg**
Number of Participants Analyzed [units: participants]	**198**	**175**
Pairwise Comparison of Aliskiren/Amlodipine 300/5 mg vs. Placebo on Change in Mean Sitting Diastolic Blood Pressure (msDBP) [units: mm Hg] Least Squares Mean (Standard Error)	**-5.35 (0.62)**	**-14.99 (0.66)**

Statistical Analysis 1 for Pairwise Comparison of Aliskiren/Amlodipine 300/5 mg vs. Placebo on Change in Mean Sitting Diastolic Blood Pressure (msDBP)

Groups [1]	All groups
Method [2]	ANCOVA

P Value [3]	<0.001
Least Square Mean Difference [4]	-9.64
Standard Error of the mean	(0.90)
95% Confidence Interval	-11.41 to -7.87

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	A two-way analysis of covariance model with treatment and region as two factors, and the baseline as a covariate.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

10. Primary: Pairwise Comparison of Aliskiren/Amlodipine 300/10 mg vs. Aliskiren 300 mg on Change in Mean Sitting Diastolic Blood Pressure (msDBP) [Time Frame: Baseline to end of study (Week 8)]

Measure Type	Primary
Measure Title	Pairwise Comparison of Aliskiren/Amlodipine 300/10 mg vs. Aliskiren 300 mg on Change in Mean Sitting Diastolic Blood Pressure (msDBP)
Measure Description	The arm in which the highest sitting diastolic pressures were found at study entry was the arm used for all subsequent readings. An automated BP measurement device and appropriate size cuff were used to measure arterial sitting blood pressure (BP) at trough with the arm supported at the level of the heart. At each study visit, after having the patient in a sitting position for at least 5 minutes, diastolic BP were measured 3 times at 1-2 minute intervals. A mean was calculated from the 3 measurements.
Time Frame	Baseline to end of study (Week 8)
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Full Analysis Set (FAS): All participants who were randomized. Participants mis-randomized were excluded from the FAS. Mis-randomized participants refer to participants who were not qualified for randomization but were inadvertently randomized into the study. These participants did not receive study drug.

Reporting Groups

	Description
Aliskiren 300 mg	Each dose was to be taken orally with water at approximately 8:00 A.M., except on the morning of the next office/clinic visit, when the study medication was to be taken at the site after the visit procedures were completed. In order to adequately blind the study, patients were required to take a total of 4 tablets and 1 capsule of study medication throughout the study; 4 of the 5 pills taken were placebos.
Aliskiren/Amlodipine 300/10 mg Tablet	300/5 for 1 week, then up-titrated to 300/10 mg. Each dose was to be taken orally with water at approximately 8:00 A.M., except on the morning of the next office/clinic visit, when the study medication was to be taken at the site after the visit procedures were completed. In order to adequately blind the study, patients were required to take a total of 4 tablets and 1 capsule of study medication throughout the study; 4 of the 5 pills taken were placebos.

Measured Values

	Aliskiren 300 mg	**Aliskiren/Amlodipine 300/10 mg Tablet**
Number of Participants Analyzed [units: participants]	**201**	**183**
Pairwise Comparison of Aliskiren/Amlodipine 300/10 mg vs. Aliskiren 300 mg on Change in Mean Sitting Diastolic Blood Pressure (msDBP) [units: mm Hg] Least Squares Mean (Standard Error)	**-10.19 (0.62)**	**-16.45 (0.65)**

Statistical Analysis 1 for Pairwise Comparison of Aliskiren/Amlodipine 300/10 mg vs. Aliskiren 300 mg on Change in Mean Sitting Diastolic Blood Pressure (msDBP)

Groups [1]	All groups
Method [2]	ANCOVA
P Value [3]	<0.001
Least Square Mean Difference [4]	-6.26
Standard Error of the mean	(0.89)
95% Confidence Interval	-8.00 to -4.51

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	A two-way analysis of covariance model with treatment and region as two factors, and the baseline as a covariate.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

11. Primary: Pairwise Comparison of Aliskiren/Amlodipine 300/10 mg vs. Amlodipine 10 mg on Change in Mean Sitting Diastolic Blood Pressure (msDBP) [Time Frame: Baseline to end of study (Week 8)]

Measure Type	Primary
Measure Title	Pairwise Comparison of Aliskiren/Amlodipine 300/10 mg vs. Amlodipine 10 mg on Change in Mean Sitting Diastolic Blood Pressure (msDBP)
Measure Description	The arm in which the highest sitting diastolic pressures were found at study entry was the arm used for all subsequent readings. An automated BP measurement device and appropriate size cuff were used to measure arterial sitting blood pressure (BP) at trough with the arm supported at the level of the heart. At each study visit, after having the patient in a sitting position for at least 5 minutes, diastolic BP were measured 3 times at 1-2 minute intervals. A mean was calculated from the 3 measurements.
Time Frame	Baseline to end of study (Week 8)
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Full Analysis Set (FAS): All participants who were randomized. Participants mis-randomized were excluded from the FAS. Mis-randomized participants refer to participants who were not qualified for randomization but were inadvertently randomized into the study. These participants did not receive study drug.

Reporting Groups

	Description
Amlodipine 10 mg	Each dose was to be taken orally with water at approximately 8:00 A.M., except on the morning of the next office/clinic visit, when the study medication was to be taken at the site after the visit procedures were completed. In order to adequately blind the study, patients were required to take a total of 4 tablets and 1 capsule of study medication throughout the study; 4 of the 5 pills taken were placebos. Amlodipine 10 mg arm starts with 1 week of Amlodipine 5 mg, then force titrated to 10 mg.
Aliskiren/Amlodipine 300/10 mg Tablet	300/5 for 1 week, then up-titrated to 300/10 mg. Each dose was to be taken orally with water at approximately 8:00 A.M., except on the morning of the next office/clinic visit, when the study medication was to be taken at the site after the visit procedures were completed. In order to adequately blind the study, patients were required to take a total of 4 tablets and 1 capsule of study medication throughout the study; 4 of the 5 pills taken were placebos.

Measured Values

	Amlodipine 10 mg	**Aliskiren/Amlodipine 300/10 mg Tablet**
Number of Participants Analyzed		

[units: participants]	**179**	**183**
Pairwise Comparison of Aliskiren/Amlodipine 300/10 mg vs. Amlodipine 10 mg on Change in Mean Sitting Diastolic Blood Pressure (msDBP) [units: mm Hg] Least Squares Mean (Standard Error)	**-13.82 (0.66)**	**-16.45 (0.65)**

Statistical Analysis 1 for Pairwise Comparison of Aliskiren/Amlodipine 300/10 mg vs. Amlodipine 10 mg on Change in Mean Sitting Diastolic Blood Pressure (msDBP)

Groups [1]	All groups
Method [2]	ANCOVA
P Value [3]	0.004
Least Square Mean Difference [4]	-2.63
Standard Error of the mean	(0.92)
95% Confidence Interval	-4.42 to -0.83

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	A two-way analysis of covariance model with treatment and region as two factors, and the baseline as a covariate.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

12. Primary: Pairwise Comparison of Aliskiren/Amlodipine 300/10 mg vs. Placebo on Change in Mean Sitting Diastolic Blood Pressure (msDBP) [Time Frame: Baseline to end of study (Week 8)]

Measure Type	Primary
Measure Title	Pairwise Comparison of Aliskiren/Amlodipine 300/10 mg vs. Placebo on Change in Mean Sitting Diastolic Blood Pressure (msDBP)
Measure Description	The arm in which the highest sitting diastolic pressures were found at study entry was the arm used for all subsequent readings. An automated BP measurement device and appropriate size cuff were used to measure arterial sitting blood pressure (BP) at trough with the arm supported at the level of the heart. At each study visit, after having the patient in a sitting position for at least 5 minutes, diastolic BP were measured 3 times at 1-2 minute intervals. A mean was calculated from the 3 measurements.
Time Frame	Baseline to end of study (Week 8)
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Full Analysis Set (FAS): All participants who were randomized. Participants mis-randomized were excluded from the FAS. Mis-randomized participants refer to participants who were not qualified for randomization but were inadvertently randomized into the study. These participants did not receive study drug.

Reporting Groups

	Description
Placebo	Each dose was to be taken orally with water at approximately 8:00 A.M., except on the morning of the next office/clinic visit, when the study medication was to be taken at the site after the visit procedures were completed. In order to adequately blind the study, patients were required to take a total of 4 tablets and 1 capsule of study medication throughout the study; for this arm all the 5 pills taken were placebos.
Aliskiren/Amlodipine 300/10 mg Tablet	300/5 for 1 week, then up-titrated to 300/10 mg. Each dose was to be taken orally with water at approximately 8:00 A.M., except on the morning of the next office/clinic visit, when the study medication was to be taken at the site after the visit procedures were completed. In order to adequately blind the study, patients were required to take a total of 4 tablets and 1 capsule of study medication throughout the study; 4 of the 5 pills

	taken were placebos.

Measured Values

	Placebo	Aliskiren/Amlodipine 300/10 mg Tablet
Number of Participants Analyzed [units: participants]	**198**	**183**
Pairwise Comparison of Aliskiren/Amlodipine 300/10 mg vs. Placebo on Change in Mean Sitting Diastolic Blood Pressure (msDBP) [units: mm Hg] Least Squares Mean (Standard Error)	**-5.35 (0.62)**	**-16.45 (0.65)**

Statistical Analysis 1 for Pairwise Comparison of Aliskiren/Amlodipine 300/10 mg vs. Placebo on Change in Mean Sitting Diastolic Blood Pressure (msDBP)

Groups [1]	All groups
Method [2]	ANCOVA
P Value [3]	<0.001
Least Square Mean Difference [4]	-11.10
Standard Error of the mean	(0.89)
95% Confidence Interval	-12.85 to -9.35

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	A two-way analysis of covariance model with treatment and region as two factors, and the baseline as a covariate.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

13. Secondary: Pairwise Comparison of Aliskiren/Amlodipine 150/5 mg vs. Aliskiren 150 mg on Change in Mean Sitting Systolic Blood Pressure (msSBP) [Time Frame: Baseline to end of study (Week 8)]

Measure Type	Secondary
Measure Title	Pairwise Comparison of Aliskiren/Amlodipine 150/5 mg vs. Aliskiren 150 mg on Change in Mean Sitting Systolic Blood Pressure (msSBP)
Measure Description	The arm in which the highest sitting diastolic pressures were found at study entry was the arm used for all subsequent readings. An automated BP measurement device and appropriate size cuff were used to measure arterial sitting blood pressure (BP) at trough with the arm supported at the level of the heart. At each study visit, after having the patient in a sitting position for at least 5 minutes, systolic BP were measured 3 times at 1-2 minute intervals. A mean was calculated from the 3 measurements.
Time Frame	Baseline to end of study (Week 8)
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Full Analysis Set (FAS): All participants who were randomized. Participants mis-randomized were excluded from the FAS. Mis-randomized participants refer to participants who were not qualified for randomization but were inadvertently randomized into the study. These participants did not receive study drug.

Reporting Groups

	Description
Aliskiren 150 mg	Each dose was to be taken orally with water at approximately 8:00 A.M., except on the morning of the next office/clinic visit, when the study medication was to be taken at the site after the visit procedures were completed. In order to adequately blind the study, patients were required to take a total of 4 tablets and 1 capsule of study medication

	throughout the study; 4 of the 5 pills taken were placebos.
Aliskiren/Amlodipine 150/5 mg	Each dose was to be taken orally with water at approximately 8:00 A.M., except on the morning of the next office/clinic visit, when the study medication was to be taken at the site after the visit procedures were completed. In order to adequately blind the study, patients were required to take a total of 4 tablets and 1 capsule of study medication throughout the study; 4 of the 5 pills taken were placebos.

Measured Values

	Aliskiren 150 mg	Aliskiren/Amlodipine 150/5 mg
Number of Participants Analyzed [units: participants]	**193**	**179**
Pairwise Comparison of Aliskiren/Amlodipine 150/5 mg vs. Aliskiren 150 mg on Change in Mean Sitting Systolic Blood Pressure (msSBP) [units: mm Hg] Least Squares Mean (Standard Error)	**-10.67 (1.01)**	**-20.64 (1.05)**

Statistical Analysis 1 for Pairwise Comparison of Aliskiren/Amlodipine 150/5 mg vs. Aliskiren 150 mg on Change in Mean Sitting Systolic Blood Pressure (msSBP)

Groups [1]	All groups
Method [2]	ANCOVA
P Value [3]	<0.001
Least Square Mean Difference [4]	-9.97
Standard Error of the mean	(1.45)
95% Confidence Interval	-12.81 to -7.12

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	A two-way analysis of covariance model with treatment and region as two factors, and the baseline as a covariate.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

14. Secondary: Pairwise Comparison of Aliskiren/Amlodipine 150/5 mg vs. Amlodipine 5 mg on Change in Mean Sitting Systolic Blood Pressure (msSBP) [Time Frame: Baseline to end of study (Week 8)]

Measure Type	Secondary
Measure Title	Pairwise Comparison of Aliskiren/Amlodipine 150/5 mg vs. Amlodipine 5 mg on Change in Mean Sitting Systolic Blood Pressure (msSBP)
Measure Description	The arm in which the highest sitting diastolic pressures were found at study entry was the arm used for all subsequent readings. An automated BP measurement device and appropriate size cuff were used to measure arterial sitting blood pressure (BP) at trough with the arm supported at the level of the heart. At each study visit, after having the patient in a sitting position for at least 5 minutes, systolic BP were measured 3 times at 1-2 minute intervals. A mean was calculated from the 3 measurements.
Time Frame	Baseline to end of study (Week 8)
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Full Analysis Set (FAS): All participants who were randomized. Participants mis-randomized were excluded from the FAS. Mis-randomized participants refer to participants who were not qualified for randomization but were inadvertently randomized into the study. These participants did not receive study drug.

Reporting Groups

	Description
Amlodipine 5 mg	Each dose was to be taken orally with water at approximately 8:00 A.M., except on the morning of the next office/clinic visit, when the study medication was to be taken at the site after the visit procedures were completed. In order to adequately blind the study, patients were required to take a total of 4 tablets and 1 capsule of study medication throughout the study; 4 of the 5 pills taken were placebos.
Aliskiren/Amlodipine 150/5 mg	Each dose was to be taken orally with water at approximately 8:00 A.M., except on the morning of the next office/clinic visit, when the study medication was to be taken at the site after the visit procedures were completed. In order to adequately blind the study, patients were required to take a total of 4 tablets and 1 capsule of study medication throughout the study; 4 of the 5 pills taken were placebos.

Measured Values

	Amlodipine 5 mg	Aliskiren/Amlodipine 150/5 mg
Number of Participants Analyzed [units: participants]	**184**	**179**
Pairwise Comparison of Aliskiren/Amlodipine 150/5 mg vs. Amlodipine 5 mg on Change in Mean Sitting Systolic Blood Pressure (msSBP) [units: mm Hg] Least Squares Mean (Standard Error)	**-15.82 (1.04)**	**-20.64 (1.05)**

Statistical Analysis 1 for Pairwise Comparison of Aliskiren/Amlodipine 150/5 mg vs. Amlodipine 5 mg on Change in Mean Sitting Systolic Blood Pressure (msSBP)

Groups [1]	All groups
Method [2]	ANCOVA
P Value [3]	0.001
Least Square mean Difference [4]	-4.82
Standard Error of the mean	(1.47)
95% Confidence Interval	-7.70 to -1.94

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	A two-way analysis of covariance model with treatment and region as two factors, and the baseline as a covariate.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

15. Secondary: Pairwise Comparison of Aliskiren/Amlodipine 150/5 mg vs. Placebo on Change in Mean Sitting Systolic Blood Pressure (msSBP) [Time Frame: Baseline to end of study (Week 8)]

Measure Type	Secondary
Measure Title	Pairwise Comparison of Aliskiren/Amlodipine 150/5 mg vs. Placebo on Change in Mean Sitting Systolic Blood Pressure (msSBP)
Measure Description	The arm in which the highest sitting diastolic pressures were found at study entry was the arm used for all subsequent readings. An automated BP measurement device and appropriate size cuff were used to measure arterial sitting blood pressure (BP) at trough with the arm supported at the level of the heart. At each study visit, after having the patient in a sitting position for at least 5 minutes, systolic BP were measured 3 times at 1-2 minute intervals. A mean was calculated from the 3 measurements.
Time Frame	Baseline to end of study (Week 8)
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.

Full Analysis Set (FAS): All participants who were randomized. Participants mis-randomized were excluded from the FAS. Mis-randomized participants refer to participants who were not qualified for randomization but were inadvertently randomized into the study. These participants did not receive study drug.

Reporting Groups

	Description
Placebo	Each dose was to be taken orally with water at approximately 8:00 A.M., except on the morning of the next office/clinic visit, when the study medication was to be taken at the site after the visit procedures were completed. In order to adequately blind the study, patients were required to take a total of 4 tablets and 1 capsule of study medication throughout the study; for this arm all the 5 pills taken were placebos.
Aliskiren/Amlodipine 150/5 mg	Each dose was to be taken orally with water at approximately 8:00 A.M., except on the morning of the next office/clinic visit, when the study medication was to be taken at the site after the visit procedures were completed. In order to adequately blind the study, patients were required to take a total of 4 tablets and 1 capsule of study medication throughout the study; 4 of the 5 pills taken were placebos.

Measured Values

	Placebo	Aliskiren/Amlodipine 150/5 mg
Number of Participants Analyzed [units: participants]	**198**	**179**
Pairwise Comparison of Aliskiren/Amlodipine 150/5 mg vs. Placebo on Change in Mean Sitting Systolic Blood Pressure (msSBP) [units: mm Hg] Least Squares Mean (Standard Error)	**-6.79 (1.00)**	**-20.64 (1.05)**

Statistical Analysis 1 for Pairwise Comparison of Aliskiren/Amlodipine 150/5 mg vs. Placebo on Change in Mean Sitting Systolic Blood Pressure (msSBP)

Groups [1]	All groups
Method [2]	ANCOVA
P Value [3]	<0.001
Least Square Mean Difference [4]	-13.85
Standard Error of the mean	(1.44)
95% Confidence Interval	-16.68 to -11.0

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	A two-way analysis of covariance model with treatment and region as two factors, and the baseline as a covariate.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

16. Secondary: Pairwise Comparison of Aliskiren/Amlodipine 150/10 mg vs. Aliskiren 150 mg on Change in Mean Sitting Systolic Blood Pressure (mssBP) [Time Frame: Baseline to end of study (Week 8)]

Measure Type	Secondary
Measure Title	Pairwise Comparison of Aliskiren/Amlodipine 150/10 mg vs. Aliskiren 150 mg on Change in Mean Sitting Systolic Blood Pressure (mssBP)
Measure Description	The arm in which the highest sitting diastolic pressures were found at study entry was the arm used for all subsequent readings. An automated BP measurement device and appropriate size cuff were used to measure arterial sitting blood pressure (BP) at trough with the arm supported at the level of the heart. At each study visit, after having the patient in a sitting position for at least 5 minutes, systolic BP were measured 3 times at 1-2 minute intervals. A mean was calculated from the 3 measurements.
Time Frame	Baseline to end of study (Week 8)
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Full Analysis Set (FAS): All participants who were randomized. Participants mis-randomized were excluded from the FAS. Mis-randomized participants refer to participants who were not qualified for randomization but were inadvertently randomized into the study. These participants did not receive study drug.

Reporting Groups

	Description
Aliskiren 150 mg	Each dose was to be taken orally with water at approximately 8:00 A.M., except on the morning of the next office/clinic visit, when the study medication was to be taken at the site after the visit procedures were completed. In order to adequately blind the study, patients were required to take a total of 4 tablets and 1 capsule of study medication throughout the study; 4 of the 5 pills taken were placebos.
Aliskiren/Amlodipine 150/10 mg	150/5 for 1 week, then up-titrated to 150/10 mg. Each dose was to be taken orally with water at approximately 8:00 A.M., except on the morning of the next office/clinic visit, when the study medication was to be taken at the site after the visit procedures were completed. In order to adequately blind the study, patients were required to take a total of 4 tablets and 1 capsule of study medication throughout the study; 4 of the 5 pills taken were placebos.

Measured Values

	Aliskiren 150 mg	**Aliskiren/Amlodipine 150/10 mg**
Number of Participants Analyzed [units: participants]	**193**	**179**
Pairwise Comparison of Aliskiren/Amlodipine 150/10 mg vs. Aliskiren 150 mg on Change in Mean Sitting Systolic Blood Pressure (mssBP) [units: mm Hg] Least Squares Mean (Standard Error)	**-10.67 (1.01)**	**-23.87 (1.05)**

Statistical Analysis 1 for Pairwise Comparison of Aliskiren/Amlodipine 150/10 mg vs. Aliskiren 150 mg on Change in Mean Sitting Systolic Blood Pressure (mssBP)

Groups [1]	All groups
Method [2]	ANCOVA
P Value [3]	<0.001
Least Square Mean Difference [4]	-13.20
Standard Error of the mean	(1.45)
95% Confidence Interval	-16.04 to -10.4

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	A two-way analysis of covariance model with treatment and region as two factors, and the baseline as a covariate.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

17. Secondary: Pairwise Comparison of Aliskiren/Amlodipine 150/10 mg vs. Amlodipine 10 mg on Change in Mean Sitting Systolic Blood Pressure (msSBP) [Time Frame: Baseline to end of study (Week 8)]

Measure Type	Secondary
Measure Title	Pairwise Comparison of Aliskiren/Amlodipine 150/10 mg vs. Amlodipine 10 mg on Change in Mean Sitting Systolic Blood Pressure (msSBP)
Measure Description	The arm in which the highest sitting diastolic pressures were found at study entry was the arm used for all subsequent readings. An automated BP measurement device and appropriate size cuff were used to measure arterial sitting blood pressure (BP) at

	trough with the arm supported at the level of the heart. At each study visit, after having the patient in a sitting position for at least 5 minutes, systolic BP were measured 3 times at 1-2 minute intervals. A mean was calculated from the 3 measurements.
Time Frame	Baseline to end of study (Week 8)
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Full Analysis Set (FAS): All randomized patients who received the study medication.

Reporting Groups

	Description
Amlodipine 10 mg	Each dose was to be taken orally with water at approximately 8:00 A.M., except on the morning of the next office/clinic visit, when the study medication was to be taken at the site after the visit procedures were completed. In order to adequately blind the study, patients were required to take a total of 4 tablets and 1 capsule of study medication throughout the study; 4 of the 5 pills taken were placebos. Amlodipine 10 mg arm starts with 1 week of Amlodipine 5 mg, then force titrated to 10 mg.
Aliskiren/Amlodipine 150/10 mg	150/5 for 1 week, then up-titrated to 150/10 mg. Each dose was to be taken orally with water at approximately 8:00 A.M., except on the morning of the next office/clinic visit, when the study medication was to be taken at the site after the visit procedures were completed. In order to adequately blind the study, patients were required to take a total of 4 tablets and 1 capsule of study medication throughout the study; 4 of the 5 pills taken were placebos.

Measured Values

	Amlodipine 10 mg	**Aliskiren/Amlodipine 150/10 mg**
Number of Participants Analyzed [units: participants]	**179**	**179**
Pairwise Comparison of Aliskiren/Amlodipine 150/10 mg vs. Amlodipine 10 mg on Change in Mean Sitting Systolic Blood Pressure (msSBP) [units: mm Hg] Least Squares Mean (Standard Error)	**-21.04 (1.05)**	**-23.87 (1.05)**

Statistical Analysis 1 for Pairwise Comparison of Aliskiren/Amlodipine 150/10 mg vs. Amlodipine 10 mg on Change in Mean Sitting Systolic Blood Pressure (msSBP)

Groups [1]	All groups
Method [2]	ANCOVA
P Value [3]	0.056
Least Square Mean Difference [4]	-2.83
Standard Error of the mean	(1.48)
95% Confidence Interval	-5.73 to -0.07

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	A two-way analysis of covariance model with treatment and region as two factors, and the baseline as a covariate.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

18. Secondary: Pairwise Comparison of Aliskiren/Amlodipine 150/10 mg vs. Placebo on Change in Mean Sitting Systolic Blood Pressure (msSBP) [Time Frame: Baseline to end of study (Week 8)]

Measure Type	Secondary

Measure Title	Pairwise Comparison of Aliskiren/Amlodipine 150/10 mg vs. Placebo on Change in Mean Sitting Systolic Blood Pressure (msSBP)
Measure Description	The arm in which the highest sitting diastolic pressures were found at study entry was the arm used for all subsequent readings. An automated BP measurement device and appropriate size cuff were used to measure arterial sitting blood pressure (BP) at trough with the arm supported at the level of the heart. At each study visit, after having the patient in a sitting position for at least 5 minutes, systolic BP were measured 3 times at 1-2 minute intervals. A mean was calculated from the 3 measurements.
Time Frame	Baseline to end of study (Week 8)
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Full Analysis Set (FAS): All participants who were randomized. Participants mis-randomized were excluded from the FAS. Mis-randomized participants refer to participants who were not qualified for randomization but were inadvertently randomized into the study. These participants did not receive study drug.

Reporting Groups

	Description
Placebo	Each dose was to be taken orally with water at approximately 8:00 A.M., except on the morning of the next office/clinic visit, when the study medication was to be taken at the site after the visit procedures were completed. In order to adequately blind the study, patients were required to take a total of 4 tablets and 1 capsule of study medication throughout the study; for this arm all the 5 pills taken were placebos.
Aliskiren/Amlodipine 150/10 mg	150/5 for 1 week, then up-titrated to 150/10 mg. Each dose was to be taken orally with water at approximately 8:00 A.M., except on the morning of the next office/clinic visit, when the study medication was to be taken at the site after the visit procedures were completed. In order to adequately blind the study, patients were required to take a total of 4 tablets and 1 capsule of study medication throughout the study; 4 of the 5 pills taken were placebos.

Measured Values

	Placebo	**Aliskiren/Amlodipine 150/10 mg**
Number of Participants Analyzed [units: participants]	**198**	**179**
Pairwise Comparison of Aliskiren/Amlodipine 150/10 mg vs. Placebo on Change in Mean Sitting Systolic Blood Pressure (msSBP) [units: mm Hg] Least Squares Mean (Standard Error)	**-6.79 (1.00)**	**-23.87 (1.05)**

Statistical Analysis 1 for Pairwise Comparison of Aliskiren/Amlodipine 150/10 mg vs. Placebo on Change in Mean Sitting Systolic Blood Pressure (msSBP)

Groups [1]	All groups
Method [2]	ANCOVA
P Value [3]	<0.001
Least Square Mean Difference [4]	-17.08
Standard Error of the mean	(1.44)
95% Confidence Interval	-19.91 to -14.3

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	A two-way analysis of covariance model with treatment and region as two factors, and the baseline as a covariate.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

19. Secondary: Pairwise Comparison of Aliskiren/Amlodipine 300/5 mg vs. Aliskiren 300 mg on Change in Mean Sitting Systolic Blood Pressure (msSBP)

[Time Frame: Baseline to end of study (Week 8)]

Measure Type	Secondary
Measure Title	Pairwise Comparison of Aliskiren/Amlodipine 300/5 mg vs. Aliskiren 300 mg on Change in Mean Sitting Systolic Blood Pressure (msSBP)
Measure Description	The arm in which the highest sitting diastolic pressures were found at study entry was the arm used for all subsequent readings. An automated BP measurement device and appropriate size cuff were used to measure arterial sitting blood pressure (BP) at trough with the arm supported at the level of the heart. At each study visit, after having the patient in a sitting position for at least 5 minutes, systolic BP were measured 3 times at 1-2 minute intervals. A mean was calculated from the 3 measurements.
Time Frame	Baseline to end of study (Week 8)
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Full Analysis Set (FAS): All participants who were randomized. Participants mis-randomized were excluded from the FAS. Mis-randomized participants refer to participants who were not qualified for randomization but were inadvertently randomized into the study. These participants did not receive study drug.

Reporting Groups

	Description
Aliskiren 300 mg	Each dose was to be taken orally with water at approximately 8:00 A.M., except on the morning of the next office/clinic visit, when the study medication was to be taken at the site after the visit procedures were completed. In order to adequately blind the study, patients were required to take a total of 4 tablets and 1 capsule of study medication throughout the study; 4 of the 5 pills taken were placebos.
Aliskiren/Amlodipine 300/5 mg	Each dose was to be taken orally with water at approximately 8:00 A.M., except on the morning of the next office/clinic visit, when the study medication was to be taken at the site after the visit procedures were completed. In order to adequately blind the study, patients were required to take a total of 4 tablets and 1 capsule of study medication throughout the study; 4 of the 5 pills taken were placebos.

Measured Values

	Aliskiren 300 mg	**Aliskiren/Amlodipine 300/5 mg**
Number of Participants Analyzed [units: participants]	**201**	**175**
Pairwise Comparison of Aliskiren/Amlodipine 300/5 mg vs. Aliskiren 300 mg on Change in Mean Sitting Systolic Blood Pressure (msSBP) [units: mm Hg] Least Squares Mean (Standard Error)	**-15.37 (0.99)**	**-21.82 (1.06)**

Statistical Analysis 1 for Pairwise Comparison of Aliskiren/Amlodipine 300/5 mg vs. Aliskiren 300 mg on Change in Mean Sitting Systolic Blood Pressure (msSBP)

Groups [1]	All groups
Method [2]	ANCOVA
P Value [3]	<0.001
Least Square Mean Difference [4]	-6.45
Standard Error of the mean	(1.45)
95% Confidence Interval	-9.29 to -3.62

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	A two-way analysis of covariance model with treatment and region as two factors, and the baseline as a covariate.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:

	No text entered.

20. Secondary: Pairwise Comparison of Aliskiren/Amlodipine 300/5 mg vs. Amlodipine 5 mg on Change in Mean Sitting Systolic Blood Pressure (msSBP) [Time Frame: Baseline to end of study (Week 8)]

Measure Type	Secondary
Measure Title	Pairwise Comparison of Aliskiren/Amlodipine 300/5 mg vs. Amlodipine 5 mg on Change in Mean Sitting Systolic Blood Pressure (msSBP)
Measure Description	The arm in which the highest sitting diastolic pressures were found at study entry was the arm used for all subsequent readings. An automated BP measurement device and appropriate size cuff were used to measure arterial sitting blood pressure (BP) at trough with the arm supported at the level of the heart. At each study visit, after having the patient in a sitting position for at least 5 minutes, systolic BP were measured 3 times at 1-2 minute intervals. A mean was calculated from the 3 measurements.
Time Frame	Baseline to end of study (Week 8)
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Full Analysis Set (FAS): All participants who were randomized. Participants mis-randomized were excluded from the FAS. Mis-randomized participants refer to participants who were not qualified for randomization but were inadvertently randomized into the study. These participants did not receive study drug.

Reporting Groups

	Description
Amlodipine 5 mg	Each dose was to be taken orally with water at approximately 8:00 A.M., except on the morning of the next office/clinic visit, when the study medication was to be taken at the site after the visit procedures were completed. In order to adequately blind the study, patients were required to take a total of 4 tablets and 1 capsule of study medication throughout the study; 4 of the 5 pills taken were placebos.
Aliskiren/Amlodipine 300/5 mg	Each dose was to be taken orally with water at approximately 8:00 A.M., except on the morning of the next office/clinic visit, when the study medication was to be taken at the site after the visit procedures were completed. In order to adequately blind the study, patients were required to take a total of 4 tablets and 1 capsule of study medication throughout the study; 4 of the 5 pills taken were placebos.

Measured Values

	Amlodipine 5 mg	**Aliskiren/Amlodipine 300/5 mg**
Number of Participants Analyzed [units: participants]	**184**	**175**
Pairwise Comparison of Aliskiren/Amlodipine 300/5 mg vs. Amlodipine 5 mg on Change in Mean Sitting Systolic Blood Pressure (msSBP) [units: mm Hg] Least Squares Mean (Standard Error)	**-15.82 (1.04)**	**-21.82 (1.06)**

Statistical Analysis 1 for Pairwise Comparison of Aliskiren/Amlodipine 300/5 mg vs. Amlodipine 5 mg on Change in Mean Sitting Systolic Blood Pressure (msSBP)

Groups [1]	All groups
Method [2]	ANCOVA
P Value [3]	<0.001
Least Square Mean Difference [4]	-6.00
Standard Error of the mean	(1.48)
95% Confidence Interval	-8.90 to -3.11

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:

	A two-way analysis of covariance model with treatment and region asntwo factors, and the baseline as a covariate.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

21. Secondary: Pairwise Comparison of Aliskiren/Amlodipine 300/5 mg vs. Placebo on Change in Mean Sitting Systolic Blood Pressure (msSBP) [Time Frame: Baseline to end of study (Week 8)]

Measure Type	Secondary
Measure Title	Pairwise Comparison of Aliskiren/Amlodipine 300/5 mg vs. Placebo on Change in Mean Sitting Systolic Blood Pressure (msSBP)
Measure Description	The arm in which the highest sitting diastolic pressures were found at study entry was the arm used for all subsequent readings. An automated BP measurement device and appropriate size cuff were used to measure arterial sitting blood pressure (BP) at trough with the arm supported at the level of the heart. At each study visit, after having the patient in a sitting position for at least 5 minutes, systolic BP were measured 3 times at 1-2 minute intervals. A mean was calculated from the 3 measurements.
Time Frame	Baseline to end of study (Week 8)
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Full Analysis Set (FAS): All participants who were randomized. Participants mis-randomized were excluded from the FAS. Mis-randomized participants refer to participants who were not qualified for randomization but were inadvertently randomized into the study. These participants did not receive study drug.

Reporting Groups

	Description
Placebo	Each dose was to be taken orally with water at approximately 8:00 A.M., except on the morning of the next office/clinic visit, when the study medication was to be taken at the site after the visit procedures were completed. In order to adequately blind the study, patients were required to take a total of 4 tablets and 1 capsule of study medication throughout the study; for this arm all the 5 pills taken were placebos.
Aliskiren/Amlodipine 300/5 mg	Each dose was to be taken orally with water at approximately 8:00 A.M., except on the morning of the next office/clinic visit, when the study medication was to be taken at the site after the visit procedures were completed. In order to adequately blind the study, patients were required to take a total of 4 tablets and 1 capsule of study medication throughout the study; 4 of the 5 pills taken were placebos.

Measured Values

	Placebo	**Aliskiren/Amlodipine 300/5 mg**
Number of Participants Analyzed [units: participants]	**198**	**175**
Pairwise Comparison of Aliskiren/Amlodipine 300/5 mg vs. Placebo on Change in Mean Sitting Systolic Blood Pressure (msSBP) [units: mm Hg] Least Squares Mean (Standard Error)	**-6.79 (1.00)**	**-21.82 (1.06)**

Statistical Analysis 1 for Pairwise Comparison of Aliskiren/Amlodipine 300/5 mg vs. Placebo on Change in Mean Sitting Systolic Blood Pressure (msSBP)

Groups [1]	All groups
Method [2]	ANCOVA
P Value [3]	<0.001
Least Square Mean Difference [4]	-15.03
Standard Error of the mean	(1.45)
95% Confidence Interval	-17.88 to -12.2

[1]	Additional details about the analysis, such as null hypothesis and power calculation:

	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

22. Secondary: Pairwise Comparison of Aliskiren/Amlodipine 300/10 mg vs. Aliskiren 300 mg on Change in Mean Sitting Systolic Blood Pressure (msSBP) [Time Frame: Baseline to end of study (Week 8)]

Measure Type	Secondary
Measure Title	Pairwise Comparison of Aliskiren/Amlodipine 300/10 mg vs. Aliskiren 300 mg on Change in Mean Sitting Systolic Blood Pressure (msSBP)
Measure Description	The arm in which the highest sitting diastolic pressures were found at study entry was the arm used for all subsequent readings. An automated BP measurement device and appropriate size cuff were used to measure arterial sitting blood pressure (BP) at trough with the arm supported at the level of the heart. At each study visit, after having the patient in a sitting position for at least 5 minutes, systolic BP were measured 3 times at 1-2 minute intervals. A mean was calculated from the 3 measurements.
Time Frame	Baseline to end of study (Week 8)
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Full Analysis Set (FAS): All participants who were randomized. Participants mis-randomized were excluded from the FAS. Mis-randomized participants refer to participants who were not qualified for randomization but were inadvertently randomized into the study. These participants did not receive study drug.

Reporting Groups

	Description
Aliskiren 300 mg	Each dose was to be taken orally with water at approximately 8:00 A.M., except on the morning of the next office/clinic visit, when the study medication was to be taken at the site after the visit procedures were completed. In order to adequately blind the study, patients were required to take a total of 4 tablets and 1 capsule of study medication throughout the study; 4 of the 5 pills taken were placebos.
Aliskiren/Amlodipine 300/10 mg Tablet	300/5 for 1 week, then up-titrated to 300/10 mg. Each dose was to be taken orally with water at approximately 8:00 A.M., except on the morning of the next office/clinic visit, when the study medication was to be taken at the site after the visit procedures were completed. In order to adequately blind the study, patients were required to take a total of 4 tablets and 1 capsule of study medication throughout the study; 4 of the 5 pills taken were placebos.

Measured Values

	Aliskiren 300 mg	**Aliskiren/Amlodipine 300/10 mg Tablet**
Number of Participants Analyzed [units: participants]	**201**	**183**
Pairwise Comparison of Aliskiren/Amlodipine 300/10 mg vs. Aliskiren 300 mg on Change in Mean Sitting Systolic Blood Pressure (msSBP) [units: mm Hg] Least Squares Mean (Standard Error)	**-15.37 (0.99)**	**-23.19 (1.04)**

Statistical Analysis 1 for Pairwise Comparison of Aliskiren/Amlodipine 300/10 mg vs. Aliskiren 300 mg on Change in Mean Sitting Systolic Blood Pressure (msSBP)

Groups [1]	All groups
Method [2]	ANCOVA
P Value [3]	<0.001

Least Square Mean Difference [4]	-7.82
Standard Error of the mean	(1.43)
95% Confidence Interval	-10.63 to -5.02

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	A two-way analysis of covariance model with treatment and region as two factors, and the baseline as a covariate.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

23. Secondary: Pairwise Comparison of Aliskiren/Amlodipine 300/10 mg vs. Amlodipine 10 mg on Change in Mean Sitting Systolic Blood Pressure (msSBP) [Time Frame: Baseline to end of study (Week 8)]

Measure Type	Secondary
Measure Title	Pairwise Comparison of Aliskiren/Amlodipine 300/10 mg vs. Amlodipine 10 mg on Change in Mean Sitting Systolic Blood Pressure (msSBP)
Measure Description	The arm in which the highest sitting diastolic pressures were found at study entry was the arm used for all subsequent readings. An automated BP measurement device and appropriate size cuff were used to measure arterial sitting blood pressure (BP) at trough with the arm supported at the level of the heart. At each study visit, after having the patient in a sitting position for at least 5 minutes, systolic BP were measured 3 times at 1-2 minute intervals. A mean was calculated from the 3 measurements.
Time Frame	Baseline to end of study (Week 8)
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Full Analysis Set (FAS): All participants who were randomized. Participants mis-randomized were excluded from the FAS. Mis-randomized participants refer to participants who were not qualified for randomization but were inadvertently randomized into the study. These participants did not receive study drug.

Reporting Groups

	Description
Amlodipine 10 mg	Each dose was to be taken orally with water at approximately 8:00 A.M., except on the morning of the next office/clinic visit, when the study medication was to be taken at the site after the visit procedures were completed. In order to adequately blind the study, patients were required to take a total of 4 tablets and 1 capsule of study medication throughout the study; 4 of the 5 pills taken were placebos. Amlodipine 10 mg arm starts with 1 week of Amlodipine 5 mg, then force titrated to 10 mg.
Aliskiren/Amlodipine 300/10 mg Tablet	300/5 for 1 week, then up-titrated to 300/10 mg. Each dose was to be taken orally with water at approximately 8:00 A.M., except on the morning of the next office/clinic visit, when the study medication was to be taken at the site after the visit procedures were completed. In order to adequately blind the study, patients were required to take a total of 4 tablets and 1 capsule of study medication throughout the study; 4 of the 5 pills taken were placebos.

Measured Values

	Amlodipine 10 mg	**Aliskiren/Amlodipine 300/10 mg Tablet**
Number of Participants Analyzed [units: participants]	**179**	**183**
Pairwise Comparison of Aliskiren/Amlodipine 300/10 mg vs. Amlodipine 10 mg on Change in Mean Sitting Systolic Blood Pressure (msSBP) [units: mm Hg] Least Squares Mean (Standard Error)	**-21.04 (1.05)**	**-23.19 (1.04)**

Statistical Analysis 1 for Pairwise Comparison of Aliskiren/Amlodipine 300/10 mg vs. Amlodipine 10 mg on Change in Mean Sitting Systolic Blood Pressure

(msSBP)

Groups [1]	All groups
Method [2]	ANCOVA
P Value [3]	0.143
Least Square Mean Difference [4]	-2.16
Standard Error of the mean	(1.47)
95% Confidence Interval	-5.04 to 0.73

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	A two-way analysis of covariance model with treatment and region as two factors, and the baseline as a covariate.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

24. Secondary: Pairwise Comparison of Aliskiren/Amlodipine 300/10 mg vs. Placebo on Change in Mean Sitting Systolic Blood Pressure (msSBP) [Time Frame: Baseline to end of study (Week 8)]

Measure Type	Secondary
Measure Title	Pairwise Comparison of Aliskiren/Amlodipine 300/10 mg vs. Placebo on Change in Mean Sitting Systolic Blood Pressure (msSBP)
Measure Description	The arm in which the highest sitting diastolic pressures were found at study entry was the arm used for all subsequent readings. An automated BP measurement device and appropriate size cuff were used to measure arterial sitting blood pressure (BP) at trough with the arm supported at the level of the heart. At each study visit, after having the patient in a sitting position for at least 5 minutes, systolic BP were measured 3 times at 1-2 minute intervals. A mean was calculated from the 3 measurements.
Time Frame	Baseline to end of study (Week 8)
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Full Analysis Set (FAS): All participants who were randomized. Participants mis-randomized were excluded from the FAS. Mis-randomized participants refer to participants who were not qualified for randomization but were inadvertently randomized into the study. These participants did not receive study drug.

Reporting Groups

	Description
Placebo	Each dose was to be taken orally with water at approximately 8:00 A.M., except on the morning of the next office/clinic visit, when the study medication was to be taken at the site after the visit procedures were completed. In order to adequately blind the study, patients were required to take a total of 4 tablets and 1 capsule of study medication throughout the study; for this arm all the 5 pills taken were placebos.
Aliskiren/Amlodipine 300/10 mg Tablet	300/5 for 1 week, then up-titrated to 300/10 mg. Each dose was to be taken orally with water at approximately 8:00 A.M., except on the morning of the next office/clinic visit, when the study medication was to be taken at the site after the visit procedures were completed. In order to adequately blind the study, patients were required to take a total of 4 tablets and 1 capsule of study medication throughout the study; 4 of the 5 pills taken were placebos.

Measured Values

	Placebo	**Aliskiren/Amlodipine 300/10 mg Tablet**
Number of Participants Analyzed [units: participants]	**198**	**183**
Pairwise Comparison of Aliskiren/Amlodipine 300/10 mg vs. Placebo on Change in Mean Sitting Systolic Blood Pressure (msSBP)	**-6.79**	

[units: mm Hg] **Least Squares Mean (Standard Error)**	**(1.00)**	**-23.19 (1.04)**

Statistical Analysis 1 for Pairwise Comparison of Aliskiren/Amlodipine 300/10 mg vs. Placebo on Change in Mean Sitting Systolic Blood Pressure (msSBP)

Groups [1]	All groups
Method [2]	ANCOVA
P Value [3]	<0.001
Least Square Mean Difference [4]	-16.40
Standard Error of the mean	(1.43)
95% Confidence Interval	-19.21 to -13.6

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	A two-way analysis of covariance model with treatment and region as two factors, and the baseline as a covariate.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

25. Secondary: Percentage of Patients With Blood Pressure Control (msSBP < 140 mm Hg and msDBP < 90 mm Hg) at End of Study [Time Frame: End of study (Week 8)]

Measure Type	Secondary
Measure Title	Percentage of Patients With Blood Pressure Control (msSBP < 140 mm Hg and msDBP < 90 mm Hg) at End of Study
Measure Description	Blood pressure control defined as msSBP < 140 mm Hg and msDBP < 90 mm Hg. The arm in which the highest sitting diastolic pressures were found at study entry was the arm used for all subsequent readings. A calibrated sphygmomanometer and appropriate size cuff were used to measure arterial sitting blood pressure (BP) at trough with the arm supported at the level of the heart. At each study visit, after having the patient in a sitting position for at least 5 minutes, systolic/diastolic BP were measured 3 times at 1-2 minute intervals. A mean was calculated from the 3 measurements.
Time Frame	End of study (Week 8)
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
All patients who were randomized. Following the intent-to-treat principle, patients will be analyzed according to the treatment they were assigned to at randomization. Patients with baseline and Endpoint msDBP values were included in this analysis.

Reporting Groups

	Description
Placebo	Each dose was to be taken orally with water at approximately 8:00 A.M., except on the morning of the next office/clinic visit, when the study medication was to be taken at the site after the visit procedures were completed. In order to adequately blind the study, patients were required to take a total of 4 tablets and 1 capsule of study medication throughout the study; for this arm all the 5 pills taken were placebos.
Aliskiren 150 mg	Each dose was to be taken orally with water at approximately 8:00 A.M., except on the morning of the next office/clinic visit, when the study medication was to be taken at the site after the visit procedures were completed. In order to adequately blind the study, patients were required to take a total of 4 tablets and 1 capsule of study medication throughout the study; 4 of the 5 pills taken were placebos.
Aliskiren 300 mg	Each dose was to be taken orally with water at approximately 8:00 A.M., except on the morning of the next office/clinic visit, when the study medication was to be taken at the site after the visit procedures were completed. In order to adequately blind the study, patients were required to take a total of 4 tablets and 1 capsule of study medication throughout the study; 4 of the 5 pills taken were placebos.
Amlodipine 5 mg	Each dose was to be taken orally with water at approximately 8:00 A.M., except on the morning of the next

	office/clinic visit, when the study medication was to be taken at the site after the visit procedures were completed. In order to adequately blind the study, patients were required to take a total of 4 tablets and 1 capsule of study medication throughout the study; 4 of the 5 pills taken were placebos.
Amlodipine 10 mg	Each dose was to be taken orally with water at approximately 8:00 A.M., except on the morning of the next office/clinic visit, when the study medication was to be taken at the site after the visit procedures were completed. In order to adequately blind the study, patients were required to take a total of 4 tablets and 1 capsule of study medication throughout the study; 4 of the 5 pills taken were placebos. Amlodipine 10 mg arm starts with 1 week of Amlodipine 5 mg, then force titrated to 10 mg.
Aliskiren/Amlodipine 150/5 mg	Each dose was to be taken orally with water at approximately 8:00 A.M., except on the morning of the next office/clinic visit, when the study medication was to be taken at the site after the visit procedures were completed. In order to adequately blind the study, patients were required to take a total of 4 tablets and 1 capsule of study medication throughout the study; 4 of the 5 pills taken were placebos.
Aliskiren/Amlodipine 150/10 mg	150/5 for 1 week, then up-titrated to 150/10 mg. Each dose was to be taken orally with water at approximately 8:00 A.M., except on the morning of the next office/clinic visit, when the study medication was to be taken at the site after the visit procedures were completed. In order to adequately blind the study, patients were required to take a total of 4 tablets and 1 capsule of study medication throughout the study; 4 of the 5 pills taken were placebos.
Aliskiren/Amlodipine 300/5 mg	Each dose was to be taken orally with water at approximately 8:00 A.M., except on the morning of the next office/clinic visit, when the study medication was to be taken at the site after the visit procedures were completed. In order to adequately blind the study, patients were required to take a total of 4 tablets and 1 capsule of study medication throughout the study; 4 of the 5 pills taken were placebos.
Aliskiren/Amlodipine 300/10 mg Tablet	300/5 for 1 week, then up-titrated to 300/10 mg. Each dose was to be taken orally with water at approximately 8:00 A.M., except on the morning of the next office/clinic visit, when the study medication was to be taken at the site after the visit procedures were completed. In order to adequately blind the study, patients were required to take a total of 4 tablets and 1 capsule of study medication throughout the study; 4 of the 5 pills taken were placebos.

Measured Values

	Placebo	Aliskiren 150 mg	Aliskiren 300 mg	Amlodipine 5 mg	Amlodipine 10 mg	Aliskiren/Amlodipine 150/5 mg	Aliskiren/Amlodipine 150/10 mg	Aliskiren/Amlodi 300/5 mg
Number of Participants Analyzed [units: participants]	**198**	**193**	**201**	**184**	**179**	**179**	**179**	**175**
Percentage of Patients With Blood Pressure Control (msSBP < 140 mm Hg and msDBP < 90 mm Hg) at End of Study [units: Percentage of Participants]	**19.2**	**26.9**	**36.3**	**35.9**	**50.3**	**49.2**	**65.4**	**56.5**

No statistical analysis provided for Percentage of Patients With Blood Pressure Control (msSBP < 140 mm Hg and msDBP < 90 mm Hg) at End of Study

26. Secondary: Percentage of Patients Achieving a Successful Diastolic Blood Pressure Response [Time Frame: End of study (Week 8)]

Measure Type	Secondary
Measure Title	Percentage of Patients Achieving a Successful Diastolic Blood Pressure Response
Measure Description	Blood pressure response in msDBP is defined as a mean sitting diastolic blood pressure < 90 mmHg or a >=10 mmHg reduction from baseline. A calibrated sphygmomanometer and appropriate size cuff were used to measure arterial sitting blood pressure (BP) at trough with the arm supported at the level of the heart. At each study visit, after having the patient in a sitting position for at least 5 minutes, systolic/diastolic BP were measured 3 times at 1-2 minute intervals. A mean was calculated from the 3 measurements.
Time Frame	End of study (Week 8)
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
All patients who were randomized. Following the intent-to-treat principle, patients will be analyzed according to the treatment they were assigned to at randomization. Patients with baseline and Endpoint msDBP values were included in this analysis.

Reporting Groups

	Description

Placebo	Each dose was to be taken orally with water at approximately 8:00 A.M., except on the morning of the next office/clinic visit, when the study medication was to be taken at the site after the visit procedures were completed. In order to adequately blind the study, patients were required to take a total of 4 tablets and 1 capsule of study medication throughout the study; for this arm all the 5 pills taken were placebos.
Aliskiren 150 mg	Each dose was to be taken orally with water at approximately 8:00 A.M., except on the morning of the next office/clinic visit, when the study medication was to be taken at the site after the visit procedures were completed. In order to adequately blind the study, patients were required to take a total of 4 tablets and 1 capsule of study medication throughout the study; 4 of the 5 pills taken were placebos.
Aliskiren 300 mg	Each dose was to be taken orally with water at approximately 8:00 A.M., except on the morning of the next office/clinic visit, when the study medication was to be taken at the site after the visit procedures were completed. In order to adequately blind the study, patients were required to take a total of 4 tablets and 1 capsule of study medication throughout the study; 4 of the 5 pills taken were placebos.
Amlodipine 5 mg	Each dose was to be taken orally with water at approximately 8:00 A.M., except on the morning of the next office/clinic visit, when the study medication was to be taken at the site after the visit procedures were completed. In order to adequately blind the study, patients were required to take a total of 4 tablets and 1 capsule of study medication throughout the study; 4 of the 5 pills taken were placebos.
Amlodipine 10 mg	Each dose was to be taken orally with water at approximately 8:00 A.M., except on the morning of the next office/clinic visit, when the study medication was to be taken at the site after the visit procedures were completed. In order to adequately blind the study, patients were required to take a total of 4 tablets and 1 capsule of study medication throughout the study; 4 of the 5 pills taken were placebos. Amlodipine 10 mg arm starts with 1 week of Amlodipine 5 mg, then force titrated to 10 mg.
Aliskiren/Amlodipine 150/5 mg	Each dose was to be taken orally with water at approximately 8:00 A.M., except on the morning of the next office/clinic visit, when the study medication was to be taken at the site after the visit procedures were completed. In order to adequately blind the study, patients were required to take a total of 4 tablets and 1 capsule of study medication throughout the study; 4 of the 5 pills taken were placebos.
Aliskiren/Amlodipine 150/10 mg	150/5 for 1 week, then up-titrated to 150/10 mg. Each dose was to be taken orally with water at approximately 8:00 A.M., except on the morning of the next office/clinic visit, when the study medication was to be taken at the site after the visit procedures were completed. In order to adequately blind the study, patients were required to take a total of 4 tablets and 1 capsule of study medication throughout the study; 4 of the 5 pills taken were placebos.
Aliskiren/Amlodipine 300/5 mg	Each dose was to be taken orally with water at approximately 8:00 A.M., except on the morning of the next office/clinic visit, when the study medication was to be taken at the site after the visit procedures were completed. In order to adequately blind the study, patients were required to take a total of 4 tablets and 1 capsule of study medication throughout the study; 4 of the 5 pills taken were placebos.
Aliskiren/Amlodipine 300/10 mg Tablet	300/5 for 1 week, then up-titrated to 300/10 mg. Each dose was to be taken orally with water at approximately 8:00 A.M., except on the morning of the next office/clinic visit, when the study medication was to be taken at the site after the visit procedures were completed. In order to adequately blind the study, patients were required to take a total of 4 tablets and 1 capsule of study medication throughout the study; 4 of the 5 pills taken were placebos.

Measured Values

	Placebo	Aliskiren 150 mg	Aliskiren 300 mg	Amlodipine 5 mg	Amlodipine 10 mg	Aliskiren/Amlodipine 150/5 mg	Aliskiren/Amlodipine 150/10 mg	Aliskiren/Amlodi 300/5 mg
Number of Participants Analyzed [units: participants]	198	193	201	184	179	179	179	175
Percentage of Patients Achieving a Successful Diastolic Blood Pressure Response [units: Percentage of Participants]	34.3	50.3	54.2	62.0	74.3	73.2	83.8	73.7

No statistical analysis provided for Percentage of Patients Achieving a Successful Diastolic Blood Pressure Response

27. Secondary: Percentage of Patients Achieving a Successful Systolic Blood Pressure Response [Time Frame: End of study (Week 8)]

Measure Type	Secondary
Measure Title	Percentage of Patients Achieving a Successful Systolic Blood Pressure Response
Measure Description	Blood pressure response in msSBP is defined as a mean sitting systolic blood pressure < 140 mmHg or a >= 20 mmHg reduction from baseline. A calibrated sphygmomanometer and appropriate size cuff were used to measure arterial sitting blood pressure (BP) at trough with the arm supported at the level of the heart. At each study visit, after having the patient in a sitting position for at least 5 minutes, systolic/diastolic BP were measured 3 times at 1-2 minute intervals. A mean was calculated from the 3 measurements.
Time Frame	End of study (Week 8)

Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
All patients who were randomized. Following the intent-to-treat principle, patients will be analyzed according to the treatment they were assigned to at randomization. Patients with baseline and Endpoint msDBP values were included in this analysis.

Reporting Groups

	Description
Placebo	Each dose was to be taken orally with water at approximately 8:00 A.M., except on the morning of the next office/clinic visit, when the study medication was to be taken at the site after the visit procedures were completed. In order to adequately blind the study, patients were required to take a total of 4 tablets and 1 capsule of study medication throughout the study; for this arm all the 5 pills taken were placebos.
Aliskiren 150 mg	Each dose was to be taken orally with water at approximately 8:00 A.M., except on the morning of the next office/clinic visit, when the study medication was to be taken at the site after the visit procedures were completed. In order to adequately blind the study, patients were required to take a total of 4 tablets and 1 capsule of study medication throughout the study; 4 of the 5 pills taken were placebos.
Aliskiren 300 mg	Each dose was to be taken orally with water at approximately 8:00 A.M., except on the morning of the next office/clinic visit, when the study medication was to be taken at the site after the visit procedures were completed. In order to adequately blind the study, patients were required to take a total of 4 tablets and 1 capsule of study medication throughout the study; 4 of the 5 pills taken were placebos.
Amlodipine 5 mg	Each dose was to be taken orally with water at approximately 8:00 A.M., except on the morning of the next office/clinic visit, when the study medication was to be taken at the site after the visit procedures were completed. In order to adequately blind the study, patients were required to take a total of 4 tablets and 1 capsule of study medication throughout the study; 4 of the 5 pills taken were placebos.
Amlodipine 10 mg	Each dose was to be taken orally with water at approximately 8:00 A.M., except on the morning of the next office/clinic visit, when the study medication was to be taken at the site after the visit procedures were completed. In order to adequately blind the study, patients were required to take a total of 4 tablets and 1 capsule of study medication throughout the study; 4 of the 5 pills taken were placebos. Amlodipine 10 mg arm starts with 1 week of Amlodipine 5 mg, then force titrated to 10 mg.
Aliskiren/Amlodipine 150/5 mg	Each dose was to be taken orally with water at approximately 8:00 A.M., except on the morning of the next office/clinic visit, when the study medication was to be taken at the site after the visit procedures were completed. In order to adequately blind the study, patients were required to take a total of 4 tablets and 1 capsule of study medication throughout the study; 4 of the 5 pills taken were placebos.
Aliskiren/Amlodipine 150/10 mg	150/5 for 1 week, then up-titrated to 150/10 mg. Each dose was to be taken orally with water at approximately 8:00 A.M., except on the morning of the next office/clinic visit, when the study medication was to be taken at the site after the visit procedures were completed. In order to adequately blind the study, patients were required to take a total of 4 tablets and 1 capsule of study medication throughout the study; 4 of the 5 pills taken were placebos.
Aliskiren/Amlodipine 300/5 mg	Each dose was to be taken orally with water at approximately 8:00 A.M., except on the morning of the next office/clinic visit, when the study medication was to be taken at the site after the visit procedures were completed. In order to adequately blind the study, patients were required to take a total of 4 tablets and 1 capsule of study medication throughout the study; 4 of the 5 pills taken were placebos.
Aliskiren/Amlodipine 300/10 mg Tablet	300/5 for 1 week, then up-titrated to 300/10 mg. Each dose was to be taken orally with water at approximately 8:00 A.M., except on the morning of the next office/clinic visit, when the study medication was to be taken at the site after the visit procedures were completed. In order to adequately blind the study, patients were required to take a total of 4 tablets and 1 capsule of study medication throughout the study; 4 of the 5 pills taken were placebos.

Measured Values

	Placebo	**Aliskiren 150 mg**	**Aliskiren 300 mg**	**Amlodipine 5 mg**	**Amlodipine 10 mg**	**Aliskiren/Amlodipine 150/5 mg**	**Aliskiren/Amlodipine 150/10 mg**	**Aliskiren/Amlodi 300/5 mg**
Number of Participants Analyzed [units: participants]	**198**	**193**	**201**	**184**	**179**	**179**	**179**	**175**
Percentage of Patients Achieving a Successful Systolic Blood Pressure Response [units: Percentage of Participants]	**32.3**	**41.5**	**53.2**	**54.9**	**72.1**	**67.6**	**77.1**	**69.7**

No statistical analysis provided for Percentage of Patients Achieving a Successful Systolic Blood Pressure Response

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	Baseline to end of study (Week 8)
Additional Description	No text entered.

Reporting Groups

	Description
Placebo	Each dose was to be taken orally with water at approximately 8:00 A.M., except on the morning of the next office/clinic visit, when the study medication was to be taken at the site after the visit procedures were completed. In order to adequately blind the study, patients were required to take a total of 4 tablets and 1 capsule of study medication throughout the study; for this arm all the 5 pills taken were placebos.
Aliskiren 150 mg Tablet	Each dose was to be taken orally with water at approximately 8:00 A.M., except on the morning of the next office/clinic visit, when the study medication was to be taken at the site after the visit procedures were completed. In order to adequately blind the study, patients were required to take a total of 4 tablets and 1 capsule of study medication throughout the study; 4 of the 5 pills taken were placebos.
Aliskiren 300 mg Tablet	Each dose was to be taken orally with water at approximately 8:00 A.M., except on the morning of the next office/clinic visit, when the study medication was to be taken at the site after the visit procedures were completed. In order to adequately blind the study, patients were required to take a total of 4 tablets and 1 capsule of study medication throughout the study; 4 of the 5 pills taken were placebos.
Amlodipine 5 mg Capsule	Each dose was to be taken orally with water at approximately 8:00 A.M., except on the morning of the next office/clinic visit, when the study medication was to be taken at the site after the visit procedures were completed. In order to adequately blind the study, patients were required to take a total of 4 tablets and 1 capsule of study medication throughout the study; 4 of the 5 pills taken were placebos.
Amlodipine 10 mg Capsule	Each dose was to be taken orally with water at approximately 8:00 A.M., except on the morning of the next office/clinic visit, when the study medication was to be taken at the site after the visit procedures were completed. In order to adequately blind the study, patients were required to take a total of 4 tablets and 1 capsule of study medication throughout the study; 4 of the 5 pills taken were placebos. Amlodipine 10 mg arm starts with 1 week of Amlodipine 5 mg, then force titrated to 10 mg.
Aliskiren/Amlodipine 150/5 mg Tablet	Each dose was to be taken orally with water at approximately 8:00 A.M., except on the morning of the next office/clinic visit, when the study medication was to be taken at the site after the visit procedures were completed. In order to adequately blind the study, patients were required to take a total of 4 tablets and 1 capsule of study medication throughout the study; 4 of the 5 pills taken were placebos.
Aliskiren/Amlodipine 150/10 mg Tablet	150/5 for 1 week, then up-titrated to 150/10 mg. Each dose was to be taken orally with water at approximately 8:00 A.M., except on the morning of the next office/clinic visit, when the study medication was to be taken at the site after the visit procedures were completed. In order to adequately blind the study, patients were required to take a total of 4 tablets and 1 capsule of study medication throughout the study; 4 of the 5 pills taken were placebos.
Aliskiren/Amlodipine 300/5 mg Tablet	Each dose was to be taken orally with water at approximately 8:00 A.M., except on the morning of the next office/clinic visit, when the study medication was to be taken at the site after the visit procedures were completed. In order to adequately blind the study, patients were required to take a total of 4 tablets and 1 capsule of study medication throughout the study; 4 of the 5 pills taken were placebos.
Aliskiren/Amlodipine 300/10 mg Tablet	300/5 for 1 week, then up-titrated to 300/10 mg. Each dose was to be taken orally with water at approximately 8:00 A.M., except on the morning of the next office/clinic visit, when the study medication was to be taken at the site after the visit procedures were completed. In order to adequately blind the study, patients were required to take a total of 4 tablets and 1 capsule of study medication throughout the study; 4 of the 5 pills taken were placebos.

Serious Adverse Events

	Placebo	Aliskiren 150 mg Tablet	Aliskiren 300 mg Tablet	Amlodipine 5 mg Capsule	Amlodipine 10 mg Capsule	Aliskiren/Amlodipine 150/5 mg Tablet	Aliskiren/Amlodipine 150/10 mg Tablet	Aliskiren/Amlod 300/5 mg Tabl
Total, serious adverse events								
# participants affected / at risk	**2/198 (1.01%)**	**0/194 (0.00%)**	**0/203 (0.00%)**	**1/185 (0.54%)**	**1/181 (0.55%)**	**1/181 (0.55%)**	**2/181 (1.10%)**	**1/178 (0.56%**
Eye disorders								
Retinal detachment † 1								
# participants	**0/198 (0.00%)**	**0/194 (0.00%)**	**0/203 (0.00%)**	**0/185 (0.00%)**	**0/181 (0.00%)**	**0/181 (0.00%)**	**0/181 (0.00%)**	**0/178 (0.00%**

affected / at risk								
Gastrointestinal disorders								
Abdominal mass † 1								
# participants affected / at risk	1/198 (0.51%)	0/194 (0.00%)	0/203 (0.00%)	0/185 (0.00%)	0/181 (0.00%)	0/181 (0.00%)	0/181 (0.00%)	0/178 (0.00%
Infections and infestations								
Bronchitis † 1								
# participants affected / at risk	0/198 (0.00%)	0/194 (0.00%)	0/203 (0.00%)	0/185 (0.00%)	0/181 (0.00%)	0/181 (0.00%)	1/181 (0.55%)	0/178 (0.00%
Gastroenteritis † 1								
# participants affected / at risk	0/198 (0.00%)	0/194 (0.00%)	0/203 (0.00%)	0/185 (0.00%)	0/181 (0.00%)	0/181 (0.00%)	0/181 (0.00%)	1/178 (0.56%
Pneumonia † 1								
# participants affected / at risk	0/198 (0.00%)	0/194 (0.00%)	0/203 (0.00%)	1/185 (0.54%)	1/181 (0.55%)	0/181 (0.00%)	0/181 (0.00%)	0/178 (0.00%
Injury, poisoning and procedural complications								
Hand fracture † 1								
# participants affected / at risk	1/198 (0.51%)	0/194 (0.00%)	0/203 (0.00%)	0/185 (0.00%)	0/181 (0.00%)	0/181 (0.00%)	0/181 (0.00%)	0/178 (0.00%
Nervous system disorders								
Cerebrovascular accident † 1								
# participants affected / at risk	0/198 (0.00%)	0/194 (0.00%)	0/203 (0.00%)	0/185 (0.00%)	0/181 (0.00%)	1/181 (0.55%)	0/181 (0.00%)	0/178 (0.00%
Renal and urinary disorders								
Calculus ureteric † 1								
# participants affected / at risk	0/198 (0.00%)	0/194 (0.00%)	0/203 (0.00%)	0/185 (0.00%)	0/181 (0.00%)	0/181 (0.00%)	1/181 (0.55%)	0/178 (0.00%
Hydronephrosis † 1								
# participants affected / at risk	0/198 (0.00%)	0/194 (0.00%)	0/203 (0.00%)	0/185 (0.00%)	0/181 (0.00%)	0/181 (0.00%)	1/181 (0.55%)	0/178 (0.00%

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

Other Adverse Events

Hide Other Adverse Events

Time Frame	Baseline to end of study (Week 8)
Additional Description	No text entered.

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
Placebo	Each dose was to be taken orally with water at approximately 8:00 A.M., except on the morning of the next office/clinic visit, when the study medication was to be taken at the site after the visit procedures were completed. In order to adequately blind the study, patients were required to take a total of 4 tablets and 1 capsule of study medication throughout the study; for this arm all the 5 pills taken were placebos.
Aliskiren 150 mg Tablet	Each dose was to be taken orally with water at approximately 8:00 A.M., except on the morning of the next office/clinic visit, when the study medication was to be taken at the site after the visit procedures were completed. In order to adequately blind the study, patients were required to take a total of 4 tablets and 1 capsule of study medication throughout the study; 4 of the 5 pills taken were placebos.
Aliskiren 300 mg Tablet	Each dose was to be taken orally with water at approximately 8:00 A.M., except on the morning of the next office/clinic visit, when the study medication was to be taken at the site after the visit procedures were completed. In order to adequately blind the study, patients were required to take a total of 4 tablets and 1 capsule of study medication throughout the study; 4 of the 5 pills taken were placebos.
Amlodipine 5 mg Capsule	Each dose was to be taken orally with water at approximately 8:00 A.M., except on the morning of the next office/clinic visit, when the study medication was to be taken at the site after the visit procedures were completed. In order to adequately blind the study, patients were required to take a total of 4 tablets and 1 capsule of study medication throughout the study; 4 of the 5 pills taken were placebos.
Amlodipine 10 mg Capsule	Each dose was to be taken orally with water at approximately 8:00 A.M., except on the morning of the next office/clinic visit, when the study medication was to be taken at the site after the visit procedures were completed. In order to adequately blind the study, patients were required to take a total of 4 tablets and 1 capsule of study medication throughout the study; 4 of the 5 pills taken were placebos. Amlodipine 10 mg arm starts with 1 week of Amlodipine 5 mg, then force titrated to 10 mg.
Aliskiren/Amlodipine 150/5 mg Tablet	Each dose was to be taken orally with water at approximately 8:00 A.M., except on the morning of the next office/clinic visit, when the study medication was to be taken at the site after the visit procedures were completed. In order to adequately blind the study, patients were required to take a total of 4 tablets and 1 capsule of study medication throughout the study; 4 of the 5 pills taken were placebos.
Aliskiren/Amlodipine 150/10 mg Tablet	150/5 for 1 week, then up-titrated to 150/10 mg. Each dose was to be taken orally with water at approximately 8:00 A.M., except on the morning of the next office/clinic visit, when the study medication was to be taken at the site after the visit procedures were completed. In order to adequately blind the study, patients were required to take a total of 4 tablets and 1 capsule of study medication throughout the study; 4 of the 5 pills taken were placebos.
Aliskiren/Amlodipine 300/5 mg Tablet	Each dose was to be taken orally with water at approximately 8:00 A.M., except on the morning of the next office/clinic visit, when the study medication was to be taken at the site after the visit procedures were completed. In order to adequately blind the study, patients were required to take a total of 4 tablets and 1 capsule of study medication throughout the study; 4 of the 5 pills taken were placebos.
Aliskiren/Amlodipine 300/10 mg Tablet	300/5 for 1 week, then up-titrated to 300/10 mg. Each dose was to be taken orally with water at approximately 8:00 A.M., except on the morning of the next office/clinic visit, when the study medication was to be taken at the site after the visit procedures were completed. In order to adequately blind the study, patients were required to take a total of 4 tablets and 1 capsule of study medication throughout the study; 4 of the 5 pills taken were placebos.

Other Adverse Events

	Placebo	Aliskiren 150 mg Tablet	Aliskiren 300 mg Tablet	Amlodipine 5 mg Capsule	Amlodipine 10 mg Capsule	Aliskiren/Amlodipine 150/5 mg Tablet	Aliskiren/Amlodipine 150/10 mg Tablet	Aliskiren 300/5 m
Total, other (not including serious) adverse events								
# participants affected / at risk	**22/198 (11.11%)**	**15/194 (7.73%)**	**18/203 (8.87%)**	**18/185 (9.73%)**	**32/181 (17.68%)**	**15/181 (8.29%)**	**19/181 (10.50%)**	**8/178**
General disorders								
Oedema								

peripheral † 1								
# participants affected / at risk	2/198 (1.01%)	2/194 (1.03%)	3/203 (1.48%)	8/185 (4.32%)	25/181 (13.81%)	4/181 (2.21%)	14/181 (7.73%)	2/178
Nervous system disorders								
Headache † 1								
# participants affected / at risk	20/198 (10.10%)	13/194 (6.70%)	15/203 (7.39%)	11/185 (5.95%)	8/181 (4.42%)	11/181 (6.08%)	8/181 (4.42%)	6/178

† 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:	External Affairs, Novartis Pharmaceuticals
ClinicalTrials.gov Identifier:	NCT00739973 History of Changes
Other Study ID Numbers:	**CSPA100A2305**
Study First Received:	August 20, 2008
Results First Received:	January 13, 2011
Last Updated:	June 2, 2011
Health Authority:	Argentina: Administracion Nacional de Medicamentos, Alimentos y Tecnologia Medica Canada: Health Canada Colombia: INVIMA Instituto Nacional de Vigilancia de Medicamentos y Alimentos Denmark: Danish Medicines Agency Finland: Finnish Medicines Agency Greece: National Organization of Medicines Peru: General Directorate of Pharmaceuticals, Devices, and Drugs

Italy: National Institute of Health
Russia: Ministry of Health of the Russian Federation
Spain: Spanish Agency of Medicines
Sweden: Medical Products Agency
South Africa: Medicines Control Council
Taiwan: Department of Health
United States: Food and Drug Administration
Dominican Republic: Consejo Nacional de Bioetica en Salud
Panama: Commemorative Institute GORGAS of Studies of Health
Mexico: National Institute of Public Health, Health Secretariat
Romania: National Medicines Agency
Australia: Department of Health and Ageing Therapeutic Goods Administration