ClinicalTrials.gov
A service of the U.S. National Institutes of Health

Trial record **1 of 1** for: CSPA100A2307

Previous Study | Return to List | Next Study

Aliskiren and the Calcium Channel Blocker Amlodipine Combination as an Initial Treatment Strategy for Hypertension (ACCELERATE)

This study has been completed.

Sponsor:
Novartis

Information provided by:
Novartis

ClinicalTrials.gov Identifier:
NCT00797862

First received: November 24, 2008
Last updated: October 7, 2011
Last verified: June 2011
History of Changes

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

Results First Received: April 21, 2011

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Investigator); Primary Purpose: Diagnostic
Condition:	Hypertension
Interventions:	Drug: Amlodipine Drug: hydrochlorothiazide Drug: Aliskiren

Participant Flow

Hide Participant Flow

Recruitment Details

Key information relevant to the recruitment process for the overall study, such as dates of the recruitment period and locations
No text entered.

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment
A 2-4 week single-blind placebo run in. 7 patients were assigned a randomization number in error (3 each in the aliskiren/amlodipine initial treatment and aliskiren based add-on regimens and 1 in the amlodipine based add-on regimen). These patients did not take any double-blind study medication and were excluded from the Full Analysis Set (FAS).

Reporting Groups

	Description
Aliskiren+Amlodipine	Eligible participants received oral aliskiren 150 mg + amlodipine 5 mg daily from week 1-8. From week 8 - 16, the dose of the combination treatment increased to aliskiren 300 mg + amlodipine 10 mg daily. From week 16-24, participants in this group continued combination treatment (aliskiren 300 mg + amlodipine 10 mg) for 8 weeks. At week 24, if blood pressure was not adequately controlled (systolic blood pressure >140 mmHg or diastolic blood pressure >90 mmHg) hydrochlorothiazide 12.5 mg was added to the combination (aliskiren 300 mg + amlodipine 10 mg) for an additional 8 weeks. Total treatment period =32 weeks.

Aliskiren Start-Amlodipine Add On	Eligible participants received oral aliskiren 150 mg daily from week 1-8. From week 8 - 16, the dose of aliskiren increased to 300 mg daily. From week 16-24, amlodipine 10 mg was added to the aliskiren 300 mg for 8 weeks (aliskiren 300 mg + amlodipine 10 mg). At week 24, if blood pressure was not adequately controlled (systolic blood pressure >140 mmHg or diastolic blood pressure >90 mmHg) hydrochlorothiazide 12.5 mg was added to the combination (aliskiren 300 mg + amlodipine 10 mg) for an additional 8 weeks. Total treatment period =32 weeks.
Amlodipine Start-Aliskiren Add On	Eligible participants received oral amlodipine 5 mg daily from week 1-8. From week 8 - 16, the dose of amlodipine increased to 10 mg daily. From week 16-24, aliskiren 300 mg was added to the amlodipine 10 mg for 8 weeks (amlodipine 10 mg + aliskiren 300 mg). At week 24, if blood pressure was not adequately controlled (systolic blood pressure > 140 mmHg or diastolic blood pressure >90 mmHg) hydrochlorothiazide 12.5 mg was added to the combination (amlodipine 10 mg + aliskiren 300 mg) for an additional 8 weeks. Total treatment period =32 weeks.

Participant Flow: Overall Study

	Aliskiren+Amlodipine	Aliskiren Start-Amlodipine Add On	Amlodipine Start-Aliskiren Add On
STARTED	620 [1]	318 [2]	316 [3]
Entered Double-Blind Treatment (FAS)	617	315	315
COMPLETED	496	250	230
NOT COMPLETED	124	68	86
Adverse Event	86	44	58
Abnormal Test Procedure Result	0	1	1
Lack of Efficacy	1	7	6
No longer required study medication	1	0	0
Withdrawal by Subject	14	7	7
Lost to Follow-up	11	0	5
Administrative Problem	4	0	0
Protocol Violation	4	6	8
Mis-randomized	3	3	1

[1] 3 participants were mis-randomized and discontinued. Only 617 participants received study drug.
[2] 3 participants were mis-randomized and discontinued. Only 315 participants received study drug.
[3] 1 participant was mis-randomized and discontinued. Only 315 participants received study drug.

Baseline Characteristics

Hide Baseline Characteristics

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
No text entered.

Reporting Groups

	Description
Aliskiren+Amlodipine	Eligible participants received oral aliskiren 150 mg + amlodipine 5 mg daily from week 1-8. From week 8 - 16, the dose of the combination treatment increased to aliskiren 300 mg + amlodipine 10 mg daily. From week 16-24, participants in this group continued combination treatment (aliskiren 300 mg + amlodipine 10 mg) for 8 weeks. At week 24, if blood pressure was not adequately controlled (systolic blood pressure >140 mmHg or diastolic blood pressure >90 mmHg) hydrochlorothiazide 12.5 mg was added to the combination (aliskiren 300 mg + amlodipine 10 mg) for an additional 8 weeks. Total

	treatment period =32 weeks.
Aliskiren Start-Amlodipine Add On	Eligible participants received oral aliskiren 150 mg daily from week 1-8. From week 8 - 16, the dose of aliskiren increased to 300 mg daily. From week 16-24, amlodipine 10 mg was added to the aliskiren 300 mg for 8 weeks (aliskiren 300 mg + amlodipine 10 mg). At week 24, if blood pressure was not adequately controlled (systolic blood pressure >140 mmHg or diastolic blood pressure >90 mmHg) hydrochlorothiazide 12.5 mg was added to the combination (aliskiren 300 mg + amlodipine 10 mg) for an additional 8 weeks. Total treatment period =32 weeks.
Amlodipine Start-Aliskiren Add On	Eligible participants received oral amlodipine 5 mg daily from week 1-8. From week 8 - 16, the dose of amlodipine increased to 10 mg daily. From week 16-24, aliskiren 300 mg was added to the amlodipine 10 mg for 8 weeks (amlodipine 10 mg + aliskiren 300 mg). At week 24, if blood pressure was not adequately controlled (systolic blood pressure > 140 mmHg or diastolic blood pressure >90 mmHg) hydrochlorothiazide 12.5 mg was added to the combination (amlodipine 10 mg + aliskiren 300 mg) for an additional 8 weeks. Total treatment period =32 weeks.
Total	Total of all reporting groups

Baseline Measures

	Aliskiren+Amlodipine	Aliskiren Start-Amlodipine Add On	Amlodipine Start-Aliskiren Add On	Total
Number of Participants [units: participants]	**620**	**318**	**316**	**1254**
Age [units: years] Mean (Standard Deviation)	**58.1 (10.81)**	**58.4 (10.83)**	**58.1 (10.93)**	**58.1 (10.84)**
Gender [units: participants]				
Female	**305**	**154**	**160**	**619**
Male	**315**	**164**	**156**	**635**

Outcome Measures

Hide All Outcome Measures

1. Primary: Overall Mean Change From Baseline in Mean Sitting Systolic Blood Pressure (msSBP) Over 8, 16 and 24 Weeks [Time Frame: Baseline, 8 weeks, 16 weeks, and 24 weeks]

Measure Type	Primary
Measure Title	Overall Mean Change From Baseline in Mean Sitting Systolic Blood Pressure (msSBP) Over 8, 16 and 24 Weeks
Measure Description	Systolic Blood Pressure was measured in a sitting position using a validated automated blood pressure monitor (the Omron device) according to Guidelines of the British Hypertension Society, at Baseline and over 8, 16 and 24 weeks of study treatment. The overall mean change in msSBP from baseline was estimated over three time points: Week 8, Week 16, and Week 24. Analysis used a repeated measures Analysis of Covariance (ANCOVA) model with treatment, visit, and region as factors, treatment by visit interaction and baseline msSBP as a covariate.
Time Frame	Baseline, 8 weeks, 16 weeks, and 24 weeks
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The analysis population included participants in the Full Analysis Set, (randomized participants who received at least one dose of study drug) for whom efficacy data was available for this outcome measure.

Reporting Groups

	Description
Aliskiren+Amlodipine	Eligible participants received oral aliskiren 150 mg + amlodipine 5 mg daily from week 1-8. From week 8 - 16, the dose of the combination treatment increased to aliskiren 300 mg + amlodipine 10 mg daily. From week 16-24, participants in this group continued combination treatment (aliskiren 300 mg + amlodipine 10 mg) for 8 weeks. At week 24, if blood pressure was not adequately controlled (systolic blood pressure >140 mmHg or diastolic blood pressure >90 mmHg) hydrochlorothiazide 12.5 mg was added to the combination (aliskiren 300 mg + amlodipine 10 mg) for an additional 8 weeks. Total treatment period =32 weeks.
Aliskiren Start-Amlodipine Add On	Eligible participants received oral aliskiren 150 mg daily from week 1-8. From week 8 - 16, the dose of aliskiren increased to 300 mg daily. From week 16-24, amlodipine 10 mg was added to the aliskiren 300 mg for 8 weeks (aliskiren 300 mg + amlodipine 10 mg). At week 24, if blood pressure was not adequately controlled (systolic blood pressure >140 mmHg or diastolic blood pressure >90 mmHg) hydrochlorothiazide 12.5 mg was added to the combination (aliskiren 300 mg + amlodipine 10 mg) for an additional 8 weeks. Total treatment period =32 weeks.
Amlodipine Start-Aliskiren Add On	Eligible participants received oral amlodipine 5 mg daily from week 1-8. From week 8 - 16, the dose of amlodipine increased to 10 mg daily. From week 16-24, aliskiren 300 mg was added to the amlodipine 10 mg for 8 weeks (amlodipine 10 mg + aliskiren 300 mg). At week 24, if blood pressure was not adequately controlled (systolic blood pressure > 140 mmHg or diastolic blood pressure >90 mmHg) hydrochlorothiazide 12.5 mg was added to the combination (amlodipine 10 mg + aliskiren 300 mg) for an additional 8 weeks. Total treatment period =32 weeks.

Measured Values

	Aliskiren+Amlodipine	Aliskiren Start-Amlodipine Add On	Amlodipine Start-Aliskiren Add On
Number of Participants Analyzed [units: participants]	**604**	**312**	**313**
Overall Mean Change From Baseline in Mean Sitting Systolic Blood Pressure (msSBP) Over 8, 16 and 24 Weeks [units: mmHg] Least Squares Mean (Standard Error)	**-25.34 (0.436)**	**-17.94 (0.600)**	**-19.81 (0.611)**

No statistical analysis provided for Overall Mean Change From Baseline in Mean Sitting Systolic Blood Pressure (msSBP) Over 8, 16 and 24 Weeks

2. Primary: Change From Baseline in Mean Sitting Systolic Blood Pressure (msSBP) at Week 24 [Time Frame: Baseline to 24 weeks]

Measure Type	Primary
Measure Title	Change From Baseline in Mean Sitting Systolic Blood Pressure (msSBP) at Week 24
Measure Description	Systolic Blood pressure was measured in a sitting position using a validated automated blood pressure monitor (the Omron device) according to Guidelines of the British Hypertension Society, at Baseline and 24 weeks of study treatment. Analysis used a repeated measures ANCOVA model with treatment, visit and region as factors, treatment by visit interaction and baseline msSBP as a covariate.
Time Frame	Baseline to 24 weeks
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The analysis population included participants in the Full Analysis Set, (randomized participants who received at least one dose of study drug) for whom efficacy data was available for this outcome measure.

Reporting Groups

	Description
Aliskiren+Amlodipine	Eligible participants received oral aliskiren 150 mg + amlodipine 5 mg daily from week 1-8. From week 8 - 16, the dose of the combination treatment increased to aliskiren 300 mg + amlodipine 10 mg daily. From week 16-24, participants in this group continued combination treatment (aliskiren 300 mg + amlodipine 10 mg) for 8 weeks. At week 24, if blood pressure was not adequately controlled (systolic blood pressure >140 mmHg or diastolic blood pressure >90 mmHg) hydrochlorothiazide 12.5 mg was added to the combination (aliskiren 300 mg + amlodipine 10 mg) for an additional 8 weeks. Total treatment period =32 weeks.
Aliskiren Start-Amlodipine Add On	Eligible participants received oral aliskiren 150 mg daily from week 1-8. From week 8 - 16, the dose of aliskiren increased to 300 mg daily. From week 16-24, amlodipine 10 mg was added to the aliskiren 300 mg for 8 weeks (aliskiren 300 mg + amlodipine 10 mg). At week 24, if blood pressure was not adequately controlled (systolic blood pressure >140 mmHg or diastolic blood pressure >90 mmHg) hydrochlorothiazide 12.5 mg was added to the combination (aliskiren 300 mg + amlodipine 10 mg) for an additional 8 weeks. Total treatment period =32 weeks.
Amlodipine Start-Aliskiren Add On	Eligible participants received oral amlodipine 5 mg daily from week 1-8. From week 8 - 16, the dose of amlodipine increased to 10 mg daily. From week 16-24, aliskiren 300 mg was added to the amlodipine 10 mg for 8 weeks (amlodipine 10 mg + aliskiren 300 mg). At week 24, if blood pressure was not adequately controlled (systolic blood pressure > 140 mmHg or diastolic blood pressure >90 mmHg) hydrochlorothiazide 12.5 mg was added to the combination (amlodipine 10 mg + aliskiren 300 mg) for an additional 8 weeks. Total treatment period =32 weeks.

Measured Values

	Aliskiren+Amlodipine	Aliskiren Start-Amlodipine Add On	Amlodipine Start-Aliskiren Add On
Number of Participants Analyzed [units: participants]	**604**	**312**	**313**
Change From Baseline in Mean Sitting Systolic Blood Pressure (msSBP) at Week 24 [units: mmHg] Least Squares Mean (Standard Error)	**-27.37 (0.546)**	**-26.34 (0.738)**	**-25.52 (0.782)**

No statistical analysis provided for Change From Baseline in Mean Sitting Systolic Blood Pressure (msSBP) at Week 24

3. Secondary: Change From Baseline in Mean Sitting Diastolic Blood Pressure (msDBP) at Week 32 [Time Frame: Baseline to 32 weeks]

Measure Type	Secondary
Measure Title	Change From Baseline in Mean Sitting Diastolic Blood Pressure (msDBP) at Week 32
Measure Description	Diastolic Blood Pressure was measured in a sitting position using a validated automated blood pressure monitor (the Omron device) according to Guidelines of the British Hypertension Society, at Baseline and 32 weeks of study treatment. Change at Week 32 used a separate repeated measures ANCOVA model containing Week 8, 16, 24 and 32 data. Treatment, visit and region were factors in the model, treatment by visit interaction and baseline msDBP a covariate.
Time Frame	Baseline to 32 weeks
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The analysis population included participants in the Full Analysis Set, (randomized participants who received at least one dose of study drug) for whom efficacy data was available for this outcome measure.

Reporting Groups

	Description

Aliskiren+Amlodipine	Eligible participants received oral aliskiren 150 mg + amlodipine 5 mg daily from week 1-8. From week 8 - 16, the dose of the combination treatment increased to aliskiren 300 mg + amlodipine 10 mg daily. From week 16-24, participants in this group continued combination treatment (aliskiren 300 mg + amlodipine 10 mg) for 8 weeks. At week 24, if blood pressure was not adequately controlled (systolic blood pressure >140 mmHg or diastolic blood pressure >90 mmHg) hydrochlorothiazide 12.5 mg was added to the combination (aliskiren 300 mg + amlodipine 10 mg) for an additional 8 weeks. Total treatment period =32 weeks.
Aliskiren Start-Amlodipine Add On	Eligible participants received oral aliskiren 150 mg daily from week 1-8. From week 8 - 16, the dose of aliskiren increased to 300 mg daily. From week 16-24, amlodipine 10 mg was added to the aliskiren 300 mg for 8 weeks (aliskiren 300 mg + amlodipine 10 mg). At week 24, if blood pressure was not adequately controlled (systolic blood pressure >140 mmHg or diastolic blood pressure >90 mmHg) hydrochlorothiazide 12.5 mg was added to the combination (aliskiren 300 mg + amlodipine 10 mg) for an additional 8 weeks. Total treatment period =32 weeks.
Amlodipine Start-Aliskiren Add On	Eligible participants received oral amlodipine 5 mg daily from week 1-8. From week 8 - 16, the dose of amlodipine increased to 10 mg daily. From week 16-24, aliskiren 300 mg was added to the amlodipine 10 mg for 8 weeks (amlodipine 10 mg + aliskiren 300 mg). At week 24, if blood pressure was not adequately controlled (systolic blood pressure > 140 mmHg or diastolic blood pressure >90 mmHg) hydrochlorothiazide 12.5 mg was added to the combination (amlodipine 10 mg + aliskiren 300 mg) for an additional 8 weeks. Total treatment period =32 weeks.

Measured Values

	Aliskiren+Amlodipine	Aliskiren Start-Amlodipine Add On	Amlodipine Start-Aliskiren Add On
Number of Participants Analyzed [units: participants]	**604**	**312**	**313**
Change From Baseline in Mean Sitting Diastolic Blood Pressure (msDBP) at Week 32 [units: mmHg] Least Squares Mean (Standard Error)	**-12.96 (0.323)**	**-12.96 (0.446)**	**-11.62 (0.467)**

No statistical analysis provided for Change From Baseline in Mean Sitting Diastolic Blood Pressure (msDBP) at Week 32

4. Secondary: Overall Mean Change From Baseline in Mean Sitting Diastolic Blood Pressure (msDBP) Over 8, 16, and 24 Weeks [Time Frame: Baseline, 8 weeks, 16 weeks and 24 weeks]

Measure Type	Secondary
Measure Title	Overall Mean Change From Baseline in Mean Sitting Diastolic Blood Pressure (msDBP) Over 8, 16, and 24 Weeks
Measure Description	Diastolic Blood pressure was measured in a sitting position using a validated automated blood pressure monitor (the Omron device) according to Guidelines of the British Hypertension Society, at Baseline and over 8, 16 and 24 weeks of study treatment. The overall mean change in msDBP from baseline was estimated over three time points: Week 8, Week 16, and Week 24. Analysis used a repeated measures ANCOVA model with treatment, visit and regions as factors, treatment by visit interaction and baseline msDBP as a covariate.
Time Frame	Baseline, 8 weeks, 16 weeks and 24 weeks
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The analysis population included participants in the Full Analysis Set, (randomized participants who received at least one dose of study drug) for whom efficacy data was available for this outcome measure.

Reporting Groups

	Description

Aliskiren+Amlodipine	Eligible participants received oral aliskiren 150 mg + amlodipine 5 mg daily from week 1-8. From week 8 - 16, the dose of the combination treatment increased to aliskiren 300 mg + amlodipine 10 mg daily. From week 16-24, participants in this group continued combination treatment (aliskiren 300 mg + amlodipine 10 mg) for 8 weeks. At week 24, if blood pressure was not adequately controlled (systolic blood pressure >140 mmHg or diastolic blood pressure >90 mmHg) hydrochlorothiazide 12.5 mg was added to the combination (aliskiren 300 mg + amlodipine 10 mg) for an additional 8 weeks. Total treatment period =32 weeks.
Aliskiren Start-Amlodipine Add On	Eligible participants received oral aliskiren 150 mg daily from week 1-8. From week 8 - 16, the dose of aliskiren increased to 300 mg daily. From week 16-24, amlodipine 10 mg was added to the aliskiren 300 mg for 8 weeks (aliskiren 300 mg + amlodipine 10 mg). At week 24, if blood pressure was not adequately controlled (systolic blood pressure >140 mmHg or diastolic blood pressure >90 mmHg) hydrochlorothiazide 12.5 mg was added to the combination (aliskiren 300 mg + amlodipine 10 mg) for an additional 8 weeks. Total treatment period =32 weeks.
Amlodipine Start-Aliskiren Add On	Eligible participants received oral amlodipine 5 mg daily from week 1-8. From week 8 - 16, the dose of amlodipine increased to 10 mg daily. From week 16-24, aliskiren 300 mg was added to the amlodipine 10 mg for 8 weeks (amlodipine 10 mg + aliskiren 300 mg). At week 24, if blood pressure was not adequately controlled (systolic blood pressure > 140 mmHg or diastolic blood pressure >90 mmHg) hydrochlorothiazide 12.5 mg was added to the combination (amlodipine 10 mg + aliskiren 300 mg) for an additional 8 weeks. Total treatment period =32 weeks.

Measured Values

	Aliskiren+Amlodipine	Aliskiren Start-Amlodipine Add On	Amlodipine Start-Aliskiren Add On
Number of Participants Analyzed [units: participants]	**604**	**312**	**313**
Overall Mean Change From Baseline in Mean Sitting Diastolic Blood Pressure (msDBP) Over 8, 16, and 24 Weeks [units: mmHg] Least Squares Mean (Standard Error)	**-12.39 (0.247)**	**-8.37 (0.340)**	**-9.02 (0.347)**

No statistical analysis provided for Overall Mean Change From Baseline in Mean Sitting Diastolic Blood Pressure (msDBP) Over 8, 16, and 24 Weeks

5. Secondary: Change From Baseline in Mean Sitting Diastolic Blood Pressure (msDBP) at Week 24 [Time Frame: Baseline to 24 weeks]

Measure Type	Secondary
Measure Title	Change From Baseline in Mean Sitting Diastolic Blood Pressure (msDBP) at Week 24
Measure Description	Diastolic Blood pressure was measured in a sitting position using a validated automated blood pressure monitor (the Omron device) according to Guidelines of the British Hypertension Society, at Baseline and 24 weeks of study treatment. Analysis used a repeated measures ANCOVA model with treatment, visit and region, as factors, treatment by visit interaction and baseline msDBP as a covariate.
Time Frame	Baseline to 24 weeks
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The analysis population included participants in the Full Analysis Set, (randomized participants who received at least one dose of study drug) for whom efficacy data was available for this outcome measure.

Reporting Groups

	Description

Aliskiren+Amlodipine	Eligible participants received oral aliskiren 150 mg + amlodipine 5 mg daily from week 1-8. From week 8 - 16, the dose of the combination treatment increased to aliskiren 300 mg + amlodipine 10 mg daily. From week 16-24, participants in this group continued combination treatment (aliskiren 300 mg + amlodipine 10 mg) for 8 weeks. At week 24, if blood pressure was not adequately controlled (systolic blood pressure >140 mmHg or diastolic blood pressure >90 mmHg) hydrochlorothiazide 12.5 mg was added to the combination (aliskiren 300 mg + amlodipine 10 mg) for an additional 8 weeks. Total treatment period =32 weeks.
Aliskiren Start-Amlodipine Add On	Eligible participants received oral aliskiren 150 mg daily from week 1-8. From week 8 - 16, the dose of aliskiren increased to 300 mg daily. From week 16-24, amlodipine 10 mg was added to the aliskiren 300 mg for 8 weeks (aliskiren 300 mg + amlodipine 10 mg). At week 24, if blood pressure was not adequately controlled (systolic blood pressure >140 mmHg or diastolic blood pressure >90 mmHg) hydrochlorothiazide 12.5 mg was added to the combination (aliskiren 300 mg + amlodipine 10 mg) for an additional 8 weeks. Total treatment period =32 weeks.
Amlodipine Start-Aliskiren Add On	Eligible participants received oral amlodipine 5 mg daily from week 1-8. From week 8 - 16, the dose of amlodipine increased to 10 mg daily. From week 16-24, aliskiren 300 mg was added to the amlodipine 10 mg for 8 weeks (amlodipine 10 mg + aliskiren 300 mg). At week 24, if blood pressure was not adequately controlled (systolic blood pressure > 140 mmHg or diastolic blood pressure >90 mmHg) hydrochlorothiazide 12.5 mg was added to the combination (amlodipine 10 mg + aliskiren 300 mg) for an additional 8 weeks. Total treatment period =32 weeks.

Measured Values

	Aliskiren+Amlodipine	**Aliskiren Start-Amlodipine Add On**	**Amlodipine Start-Aliskiren Add On**
Number of Participants Analyzed [units: participants]	**604**	**312**	**313**
Change From Baseline in Mean Sitting Diastolic Blood Pressure (msDBP) at Week 24 [units: mmHg] Least Squares Mean (Standard Error)	**-13.64 (0.319)**	**-13.22 (0.431)**	**-12.25 (0.457)**

No statistical analysis provided for Change From Baseline in Mean Sitting Diastolic Blood Pressure (msDBP) at Week 24

6. Secondary: Percentage of Participants Achieving Overall Blood Pressure Control at 8, 16, 24 and 32 Weeks Endpoints [Time Frame: Baseline to week 8, 16, 24 and 32 endpoints]

Measure Type	Secondary
Measure Title	Percentage of Participants Achieving Overall Blood Pressure Control at 8, 16, 24 and 32 Weeks Endpoints
Measure Description	Systolic & Diastolic Blood Pressure were measured in a sitting position using a validated automated blood pressure monitor (the Omron device) according to Guidelines of the British Hypertension Society, at Baseline and after 8, 16 , 24 and 32 weeks. Outcome is reported as percentage of participants achieving overall blood pressure control (msSBP <140 mmHg and msDBP <90 mmHg) at weeks 8, 16, 24 & 32 endpoints.
Time Frame	Baseline to week 8, 16, 24 and 32 endpoints
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The analysis population included participants in the Full Analysis Set, (randomized participants who received at least one dose of study drug) for whom efficacy data was available for this outcome measure. Last post-baseline observation was carried forward to each visit for the analysis of blood pressure control.

Reporting Groups

	Description

Aliskiren+Amlodipine	Eligible participants received oral aliskiren 150 mg + amlodipine 5 mg daily from week 1-8. From week 8 - 16, the dose of the combination treatment increased to aliskiren 300 mg + amlodipine 10 mg daily. From week 16-24, participants in this group continued combination treatment (aliskiren 300 mg + amlodipine 10 mg) for 8 weeks. At week 24, if blood pressure was not adequately controlled (systolic blood pressure >140 mmHg or diastolic blood pressure >90 mmHg) hydrochlorothiazide 12.5 mg was added to the combination (aliskiren 300 mg + amlodipine 10 mg) for an additional 8 weeks. Total treatment period =32 weeks.
Aliskiren Start-Amlodipine Add On	Eligible participants received oral aliskiren 150 mg daily from week 1-8. From week 8 - 16, the dose of aliskiren increased to 300 mg daily. From week 16-24, amlodipine 10 mg was added to the aliskiren 300 mg for 8 weeks (aliskiren 300 mg + amlodipine 10 mg). At week 24, if blood pressure was not adequately controlled (systolic blood pressure >140 mmHg or diastolic blood pressure >90 mmHg) hydrochlorothiazide 12.5 mg was added to the combination (aliskiren 300 mg + amlodipine 10 mg) for an additional 8 weeks. Total treatment period =32 weeks.
Amlodipine Start-Aliskiren Add On	Eligible participants received oral amlodipine 5 mg daily from week 1-8. From week 8 - 16, the dose of amlodipine increased to 10 mg daily. From week 16-24, aliskiren 300 mg was added to the amlodipine 10 mg for 8 weeks (amlodipine 10 mg + aliskiren 300 mg). At week 24, if blood pressure was not adequately controlled (systolic blood pressure > 140 mmHg or diastolic blood pressure >90 mmHg) hydrochlorothiazide 12.5 mg was added to the combination (amlodipine 10 mg + aliskiren 300 mg) for an additional 8 weeks. Total treatment period =32 weeks.

Measured Values

	Aliskiren+Amlodipine	Aliskiren Start-Amlodipine Add On	Amlodipine Start-Aliskiren Add On
Number of Participants Analyzed [units: participants]	**604**	**312**	**313**
Percentage of Participants Achieving Overall Blood Pressure Control at 8, 16, 24 and 32 Weeks Endpoints [units: Percentage of Participants]			
Week 8 endpoint	**46.5**	**22.8**	**25.2**
Week 16 endpoint	**65.9**	**33.3**	**40.9**
Week 24 endpoint	**63.4**	**62.8**	**57.8**
Week 32 endpoint	**61.6**	**59.0**	**53.4**

No statistical analysis provided for Percentage of Participants Achieving Overall Blood Pressure Control at 8, 16, 24 and 32 Weeks Endpoints

7. Post-Hoc: Change From Baseline in Mean Sitting Systolic Blood Pressure (msSBP) at Week 32 [Time Frame: Baseline to 32 weeks]

Measure Type	Post-Hoc
Measure Title	Change From Baseline in Mean Sitting Systolic Blood Pressure (msSBP) at Week 32
Measure Description	Systolic Blood pressure was measured in a sitting position using a validated automated blood pressure monitor (the Omron device) according to Guidelines of the British Hypertension Society, at Baseline and 32 weeks of study treatment. Change at week 32 used a separate repeated measures ANCOVA model containing Week 8, 16, 24 & 32 data. Treatment, visit and region were factors in the model, treatment by visit interaction and baseline msSBP was a covariate.
Time Frame	Baseline to 32 weeks
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The analysis population included participants in the Full Analysis Set, (randomized participants who received at least one dose of study drug) for whom efficacy data was available for this outcome measure.

Reporting Groups

	Description
Aliskiren+Amlodipine	Eligible participants received oral aliskiren 150 mg + amlodipine 5 mg daily from week 1-8. From week 8 - 16, the dose of the combination treatment increased to aliskiren 300 mg + amlodipine 10 mg daily. From week 16-24, participants in this group continued combination treatment (aliskiren 300 mg + amlodipine 10 mg) for 8 weeks. At week 24, if blood pressure was not adequately controlled (systolic blood pressure >140 mmHg or diastolic blood pressure >90 mmHg) hydrochlorothiazide 12.5 mg was added to the combination (aliskiren 300 mg + amlodipine 10 mg) for an additional 8 weeks. Total treatment period =32 weeks.
Aliskiren Start-Amlodipine Add On	Eligible participants received oral aliskiren 150 mg daily from week 1-8. From week 8 - 16, the dose of aliskiren increased to 300 mg daily. From week 16-24, amlodipine 10 mg was added to the aliskiren 300 mg for 8 weeks (aliskiren 300 mg + amlodipine 10 mg). At week 24, if blood pressure was not adequately controlled (systolic blood pressure >140 mmHg or diastolic blood pressure >90 mmHg) hydrochlorothiazide 12.5 mg was added to the combination (aliskiren 300 mg + amlodipine 10 mg) for an additional 8 weeks. Total treatment period =32 weeks.
Amlodipine Start-Aliskiren Add On	Eligible participants received oral amlodipine 5 mg daily from week 1-8. From week 8 - 16, the dose of amlodipine increased to 10 mg daily. From week 16-24, aliskiren 300 mg was added to the amlodipine 10 mg for 8 weeks (amlodipine 10 mg + aliskiren 300 mg). At week 24, if blood pressure was not adequately controlled (systolic blood pressure > 140 mmHg or diastolic blood pressure >90 mmHg) hydrochlorothiazide 12.5 mg was added to the combination (amlodipine 10 mg + aliskiren 300 mg) for an additional 8 weeks. Total treatment period =32 weeks.

Measured Values

	Aliskiren+Amlodipine	Aliskiren Start-Amlodipine Add On	Amlodipine Start-Aliskiren Add On
Number of Participants Analyzed [units: participants]	**604**	**312**	**313**
Change From Baseline in Mean Sitting Systolic Blood Pressure (msSBP) at Week 32 [units: mmHg] Least Squares Mean (Standard Error)	**-26.42 (0.566)**	**-25.75 (0.781)**	**-24.32 (0.816)**

No statistical analysis provided for Change From Baseline in Mean Sitting Systolic Blood Pressure (msSBP) at Week 32

Serious Adverse Events

Hide Serious Adverse Events

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

Reporting Groups

	Description
Aliskiren + Amlodipine	Eligible participants received oral aliskiren 150 mg + amlodipine 5 mg daily from week 1-8. From week 8 - 16, the dose of the combination treatment increased to aliskiren 300 mg + amlodipine 10 mg daily. From week 16-24, participants in this group continued combination treatment (aliskiren 300 mg + amlodipine 10 mg) for 8 weeks. At week 24, if blood pressure was not adequately controlled (systolic blood pressure >140 mmHg or diastolic blood pressure >90 mmHg) hydrochlorothiazide 12.5 mg was added to the combination (aliskiren 300 mg + amlodipine 10 mg) for an additional 8 weeks. Total treatment period =32 weeks.
Aliskiren	Eligible participants received oral aliskiren 150 mg daily from week 1-8. From week 8 - 16, the dose of aliskiren increased to 300 mg daily. From week 16-24, amlodipine 10 mg was added to the aliskiren 300 mg for 8 weeks (aliskiren 300 mg + amlodipine 10 mg). At week 24, if blood pressure was not adequately controlled (systolic blood pressure >140 mmHg or diastolic blood pressure >90 mmHg) hydrochlorothiazide 12.5 mg was added to the

	combination (aliskiren 300 mg + amlodipine 10 mg) for an additional 8 weeks. Total treatment period =32 weeks.
Amlodipine	Eligible participants received oral amlodipine 5 mg daily from week 1-8. From week 8 - 16, the dose of amlodipine increased to 10 mg daily. From week 16-24, aliskiren 300 mg was added to the amlodipine 10 mg for 8 weeks (amlodipine 10 mg + aliskiren 300 mg). At week 24, if blood pressure was not adequately controlled (systolic blood pressure >140 mmHg or diastolic blood pressure >90 mmHg) hydrochlorothiazide 12.5 mg was added to the combination (amlodipine 10 mg + aliskiren 300 mg) for an additional 8 weeks. Total treatment period =32 weeks.

Serious Adverse Events

	Aliskiren + Amlodipine	Aliskiren	Amlodipine
Total, serious adverse events			
# participants affected / at risk	**14/617 (2.27%)**	**9/315 (2.86%)**	**9/315 (2.86%)**
Cardiac disorders			
Angina pectoris † 1			
# participants affected / at risk	**0/617 (0.00%)**	**0/315 (0.00%)**	**1/315 (0.32%)**
Atrial fibrillation † 1			
# participants affected / at risk	**0/617 (0.00%)**	**1/315 (0.32%)**	**0/315 (0.00%)**
Cardiac failure † 1			
# participants affected / at risk	**0/617 (0.00%)**	**0/315 (0.00%)**	**1/315 (0.32%)**
Cardiac failure congestive † 1			
# participants affected / at risk	**1/617 (0.16%)**	**0/315 (0.00%)**	**0/315 (0.00%)**
Hypertensive heart disease † 1			
# participants affected / at risk	**0/617 (0.00%)**	**1/315 (0.32%)**	**0/315 (0.00%)**
Mitral valve incompetence † 1			
# participants affected / at risk	**0/617 (0.00%)**	**0/315 (0.00%)**	**1/315 (0.32%)**
Myocardial ischaemia † 1			
# participants affected / at risk	**0/617 (0.00%)**	**0/315 (0.00%)**	**1/315 (0.32%)**
Supraventricular tachycardia † 1			
# participants affected / at risk	**0/617 (0.00%)**	**1/315 (0.32%)**	**0/315 (0.00%)**
Gastrointestinal disorders			
Abdominal pain † 1			
# participants affected / at risk	**1/617 (0.16%)**	**0/315 (0.00%)**	**0/315 (0.00%)**
Abdominal pain upper † 1			
# participants affected / at risk	**1/617 (0.16%)**	**0/315 (0.00%)**	**0/315 (0.00%)**
Gastric haemorrhage † 1			
# participants affected / at risk	**1/617 (0.16%)**	**0/315 (0.00%)**	**0/315 (0.00%)**
Gastritis † 1			
# participants affected / at risk	**1/617 (0.16%)**	**0/315 (0.00%)**	**0/315 (0.00%)**
Gastrointestinal haemorrhage † 1			
# participants affected / at risk	**1/617 (0.16%)**	**0/315 (0.00%)**	**0/315 (0.00%)**
Gastrooesophageal reflux disease † 1			
# participants affected / at risk	**0/617 (0.00%)**	**0/315 (0.00%)**	**1/315 (0.32%)**
Intestinal obstruction † 1			
# participants affected / at risk	**0/617 (0.00%)**	**0/315 (0.00%)**	**1/315 (0.32%)**
Parotid gland enlargement † 1			
# participants affected / at risk	**1/617 (0.16%)**	**0/315 (0.00%)**	**0/315 (0.00%)**

Sigmoiditis † 1			
# participants affected / at risk	**1/617 (0.16%)**	**0/315 (0.00%)**	**0/315 (0.00%)**
General disorders			
Chest pain † 1			
# participants affected / at risk	**0/617 (0.00%)**	**1/315 (0.32%)**	**0/315 (0.00%)**
Oedema peripheral † 1			
# participants affected / at risk	**1/617 (0.16%)**	**0/315 (0.00%)**	**0/315 (0.00%)**
Hepatobiliary disorders			
Cholelithiasis † 1			
# participants affected / at risk	**1/617 (0.16%)**	**0/315 (0.00%)**	**0/315 (0.00%)**
Infections and infestations			
Pyelonephritis † 1			
# participants affected / at risk	**1/617 (0.16%)**	**0/315 (0.00%)**	**0/315 (0.00%)**
Injury, poisoning and procedural complications			
Accidental overdose † 1			
# participants affected / at risk	**0/617 (0.00%)**	**1/315 (0.32%)**	**0/315 (0.00%)**
Foot fracture † 1			
# participants affected / at risk	**0/617 (0.00%)**	**0/315 (0.00%)**	**1/315 (0.32%)**
Musculoskeletal and connective tissue disorders			
Joint swelling † 1			
# participants affected / at risk	**1/617 (0.16%)**	**0/315 (0.00%)**	**0/315 (0.00%)**
Osteoarthritis † 1			
# participants affected / at risk	**0/617 (0.00%)**	**0/315 (0.00%)**	**1/315 (0.32%)**
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Bladder cancer † 1			
# participants affected / at risk	**1/617 (0.16%)**	**0/315 (0.00%)**	**0/315 (0.00%)**
Breast cancer † 1			
# participants affected / at risk	**1/617 (0.16%)**	**1/315 (0.32%)**	**0/315 (0.00%)**
Nervous system disorders			
Ischaemic stroke † 1			
# participants affected / at risk	**0/617 (0.00%)**	**0/315 (0.00%)**	**1/315 (0.32%)**
Transient ischaemic attack † 1			
# participants affected / at risk	**0/617 (0.00%)**	**1/315 (0.32%)**	**1/315 (0.32%)**
Renal and urinary disorders			
Haematuria † 1			
# participants affected / at risk	**1/617 (0.16%)**	**0/315 (0.00%)**	**0/315 (0.00%)**
Nephrolithiasis † 1			
# participants affected / at risk	**0/617 (0.00%)**	**1/315 (0.32%)**	**0/315 (0.00%)**
Renal colic † 1			
# participants affected / at risk	**1/617 (0.16%)**	**0/315 (0.00%)**	**0/315 (0.00%)**
Stress urinary incontinence † 1			
# participants affected / at risk	**0/617 (0.00%)**	**0/315 (0.00%)**	**1/315 (0.32%)**
Urinary bladder polyp † 1			

# participants affected / at risk	**0/617 (0.00%)**	**1/315 (0.32%)**	**0/315 (0.00%)**
Reproductive system and breast disorders			
Varicocele † 1			
# participants affected / at risk	**0/617 (0.00%)**	**1/315 (0.32%)**	**0/315 (0.00%)**
Respiratory, thoracic and mediastinal disorders			
Dyspnoea † 1			
# participants affected / at risk	**0/617 (0.00%)**	**1/315 (0.32%)**	**0/315 (0.00%)**
Skin and subcutaneous tissue disorders			
Angioedema † 1			
# participants affected / at risk	**1/617 (0.16%)**	**0/315 (0.00%)**	**0/315 (0.00%)**
Vascular disorders			
Hypertensive crisis † 1			
# participants affected / at risk	**0/617 (0.00%)**	**1/315 (0.32%)**	**0/315 (0.00%)**

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

Other Adverse Events

Hide Other Adverse Events

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

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
Aliskiren + Amlodipine	Eligible participants received oral aliskiren 150 mg + amlodipine 5 mg daily from week 1-8. From week 8 - 16, the dose of the combination treatment increased to aliskiren 300 mg + amlodipine 10 mg daily. From week 16-24, participants in this group continued combination treatment (aliskiren 300 mg + amlodipine 10 mg) for 8 weeks. At week 24, if blood pressure was not adequately controlled (systolic blood pressure >140 mmHg or diastolic blood pressure >90 mmHg) hydrochlorothiazide 12.5 mg was added to the combination (aliskiren 300 mg + amlodipine 10 mg) for an additional 8 weeks. Total treatment period =32 weeks.
Aliskiren	Eligible participants received oral aliskiren 150 mg daily from week 1-8. From week 8 - 16, the dose of aliskiren increased to 300 mg daily. From week 16-24, amlodipine 10 mg was added to the aliskiren 300 mg for 8 weeks (aliskiren 300 mg + amlodipine 10 mg). At week 24, if blood pressure was not adequately controlled (systolic blood pressure >140 mmHg or diastolic blood pressure >90 mmHg) hydrochlorothiazide 12.5 mg was added to the combination (aliskiren 300 mg + amlodipine 10 mg) for an additional 8 weeks. Total treatment period =32 weeks.
Amlodipine	Eligible participants received oral amlodipine 5 mg daily from week 1-8. From week 8 - 16, the dose of amlodipine increased to 10 mg daily. From week 16-24, aliskiren 300 mg was added to the amlodipine 10 mg for 8 weeks (amlodipine 10 mg + aliskiren 300 mg). At week 24, if blood pressure was not adequately controlled (systolic blood pressure >140 mmHg or diastolic blood pressure >90 mmHg) hydrochlorothiazide 12.5 mg was added to the combination (amlodipine 10 mg + aliskiren 300 mg) for an additional 8 weeks. Total treatment period =32 weeks.

Other Adverse Events

	Aliskiren + Amlodipine	**Aliskiren**	**Amlodipine**
Total, other (not including serious) adverse events			
# participants affected / at risk	**196/617 (31.77%)**	**81/315 (25.71%)**	**104/315 (33.02%)**

General disorders			
Oedema peripheral † 1			
# participants affected / at risk	**131/617 (21.23%)**	**53/315 (16.83%)**	**76/315 (24.13%)**
Musculoskeletal and connective tissue disorders			
Joint swelling † 1			
# participants affected / at risk	**46/617 (7.46%)**	**20/315 (6.35%)**	**21/315 (6.67%)**
Nervous system disorders			
Headache † 1			
# participants affected / at risk	**31/617 (5.02%)**	**20/315 (6.35%)**	**16/315 (5.08%)**

† 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 it's investigators may vary. However, Novartis does not prohibit any investigator from publishing. Any publications from a single-site are postponed until publication of pooled data (i.e., data from all sites) in the clinical trial.

Results Point of Contact:

Name/Title: Study Director
Organization: Novartis Pharmaceuticals
phone: 862- 778- 8300

No publications provided by Novartis

Publications automatically indexed to this study:

Brown MJ, McInnes GT, Papst CC, Zhang J, MacDonald TM. Aliskiren and the calcium channel blocker amlodipine combination as an initial treatment strategy for hypertension control (ACCELERATE): a randomised, parallel-group trial. Lancet. 2011 Jan 22;377(9762):312-20. doi:

10.1016/S0140-6736(10)62003-X. Epub 2011 Jan 12.

Responsible Party:	External Affairs, Novartis Pharmaceuticals
ClinicalTrials.gov Identifier:	NCT00797862 History of Changes
Other Study ID Numbers:	**CSPA100A2307**
Study First Received:	November 24, 2008
Results First Received:	April 21, 2011
Last Updated:	October 7, 2011
Health Authority:	Canada: Health Canada Costa Rica: Ministry of Health Costa Rica France: Afssaps - Agence française de sécurité sanitaire des produits de santé (Saint-Denis) Germany: Federal Institute for Drugs and Medical Devices Guatemala: Ministry of Public Health and Social Assistance Greece: National Organization of Medicines South Africa: Medicines Control Council Switzerland: Swissmedic United Kingdom: Medicines and Healthcare Products Regulatory Agency Venezuela: Ministry of Health and Social Development