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Trial record **1 of 1** for: CSPP100AGB01

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Efficacy and Safety of Aliskiren/Ramipril/Amlodipine Compared With Ramipril/Amlodipine and Aliskiren/Amlodipine in Patients With Metabolic Syndrome (ALTO)

This study has been terminated.

(Early termination of the study due to slow recruitment.)

Sponsor:
Novartis

Information provided by:
Novartis

ClinicalTrials.gov Identifier:
NCT00542269

First received: October 9, 2007
Last updated: April 26, 2011
Last verified: April 2011
History of Changes

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Results First Received: January 6, 2011

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

Participant Flow

Hide Participant Flow

Recruitment Details

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

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment
No text entered.

Reporting Groups

	Description
Aliskiren / Ramipril / Amlodipine	6 weeks treatment with aliskiren 150 mg tablets, ramipril 5 mg capsules, and amlodipine 5-10 mg tablets followed by an additional 6 weeks treatment with aliskiren 300 mg tablets, ramipril 10 mg capsules, and amlodipine 5-10 mg tablets. Patients received amlodipine 5 mg (or 10 mg if they were receiving 10 mg prior to study start). Each dose was to be taken orally with water once daily at approximately 8:00 A.M. with or without food, except on the morning of an office/clinic visit, when the study drug was to be taken at the site after the visit procedures had been completed.
Aliskiren /Amlodipine	6 weeks treatment with aliskiren 150 mg tablets, ramipril 5 mg placebo capsules, and amlodipine 5-10 mg

	tablets followed by an additional 6 weeks treatment with aliskiren 300 mg tablets, ramipril 10 mg placebo capsules, and amlodipine 5-10 mg tablets. Patients received amlodipine 5 mg (or 10 mg if they were receiving 10 mg prior to study start). Each dose was to be taken orally with water once daily at approximately 8:00 A.M. with or without food, except on the morning of an office/clinic visit, when the study drug was to be taken at the site after the visit procedures had been completed.
Ramipril / Amlodipine	6 weeks treatment with aliskiren 150 mg placebo tablets, ramipril 5 mg capsules, and amlodipine 5-10 mg tablets followed by an additional 6 weeks treatment with aliskiren 300 mg placebo tablets, ramipril 10 mg capsules, and amlodipine 5-10 mg tablets. Patients received amlodipine 5 mg (or 10 mg if they were receiving 10 mg prior to study start). Each dose was to be taken orally with water once daily at approximately 8:00 A.M. with or without food, except on the morning of an office/clinic visit, when the study drug was to be taken at the site after the visit procedures had been completed.

Participant Flow: Overall Study

	Aliskiren / Ramipril / Amlodipine	Aliskiren /Amlodipine	Ramipril / Amlodipine
STARTED	61	60	57
COMPLETED	48	54	51
NOT COMPLETED	13	6	6
Adverse Event	10	4	5
Protocol Violation	1	1	0
Withdrawal by Subject	1	0	0
Administrative problems	1	1	1

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 / Ramipril / Amlodipine	6 weeks treatment with aliskiren 150 mg tablets, ramipril 5 mg capsules, and amlodipine 5-10 mg tablets followed by an additional 6 weeks treatment with aliskiren 300 mg tablets, ramipril 10 mg capsules, and amlodipine 5-10 mg tablets. Patients received amlodipine 5 mg (or 10 mg if they were receiving 10 mg prior to study start). Each dose was to be taken orally with water once daily at approximately 8:00 A.M. with or without food, except on the morning of an office/clinic visit, when the study drug was to be taken at the site after the visit procedures had been completed.
Aliskiren /Amlodipine	6 weeks treatment with aliskiren 150 mg tablets, ramipril 5 mg placebo capsules, and amlodipine 5-10 mg tablets followed by an additional 6 weeks treatment with aliskiren 300 mg tablets, ramipril 10 mg placebo capsules, and amlodipine 5-10 mg tablets. Patients received amlodipine 5 mg (or 10 mg if they were receiving 10 mg prior to study start). Each dose was to be taken orally with water once daily at approximately 8:00 A.M. with or without food, except on the morning of an office/clinic visit, when the study drug was to be taken at the site after the visit procedures had been completed.
Ramipril / Amlodipine	6 weeks treatment with aliskiren 150 mg placebo tablets, ramipril 5 mg capsules, and amlodipine 5-10 mg tablets followed by an additional 6 weeks treatment with aliskiren 300 mg placebo tablets, ramipril 10 mg capsules, and amlodipine 5-10 mg tablets. Patients received amlodipine 5 mg (or 10 mg if they were receiving 10 mg prior to study start). Each dose was to be taken orally with water once daily at approximately 8:00 A.M. with or without food, except on the morning of an office/clinic visit, when the study drug was to be taken at the site after the visit procedures had been completed.
Total	Total of all reporting groups

Baseline Measures

	Aliskiren / Ramipril / Amlodipine	Aliskiren /Amlodipine	Ramipril / Amlodipine	Total
Number of Participants [units: participants]	61	60	57	178
Age [units: years] Mean (Standard Deviation)	61.3 (8.90)	58.3 (8.95)	59.1 (8.86)	59.6 (8.95)
Age, Customized [units: participants]				
< 65 years	37	47	42	126
≥ 65 years	24	13	15	52
Gender [units: participants]				
Female	17	18	19	54
Male	44	42	38	124

Outcome Measures

Hide All Outcome Measures

1. Primary: Change in Mean Sitting Systolic Blood Pressure (msSBP) From Baseline to End of Study - Aliskiren/Ramipril/Amlodipine vs Ramipril/Amlodipine) [Time Frame: Baseline to Week 12]

Measure Type	Primary
Measure Title	Change in Mean Sitting Systolic Blood Pressure (msSBP) From Baseline to End of Study - Aliskiren/Ramipril/Amlodipine vs Ramipril/Amlodipine)
Measure Description	Automated blood pressure determinations were made with the Omron HEM-705CP blood pressure monitor at trough (24 hours ± 3 hours post-dose) and recorded at all study visits following detailed directions specified in the study protocol. Three readings were made and msSBP was calculated as the average of the 3 readings. In the event of aberrant readings, ie, the lowest reading was ≥ 10 mmHg systolic or ≥ 5 mmHg diastolic lower than the highest of the 3 readings, 3 additional readings were obtained. A negative change indicates improvement.
Time Frame	Baseline to Week 12
Safety Issue	No

Population Description

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

Reporting Groups

	Description
Aliskiren / Ramipril / Amlodipine	6 weeks treatment with aliskiren 150 mg tablets, ramipril 5 mg capsules, and amlodipine 5-10 mg tablets followed by an additional 6 weeks treatment with aliskiren 300 mg tablets, ramipril 10 mg capsules, and amlodipine 5-10 mg tablets. Patients received amlodipine 5 mg (or 10 mg if they were receiving 10 mg prior to study start). Each dose was to be taken orally with water once daily at approximately 8:00 A.M. with or without food, except on the morning of an office/clinic visit, when the study drug was to be taken at the site after the visit procedures had been completed.
Ramipril / Amlodipine	6 weeks treatment with aliskiren 150 mg placebo tablets, ramipril 5 mg capsules, and amlodipine 5-10 mg tablets followed by an additional 6 weeks treatment with aliskiren 300 mg placebo tablets, ramipril 10 mg capsules, and amlodipine 5-10 mg tablets. Patients received amlodipine 5 mg (or 10 mg if they were receiving 10 mg prior to study start). Each dose was to be taken orally with water once daily at

	approximately 8:00 A.M. with or without food, except on the morning of an office/clinic visit, when the study drug was to be taken at the site after the visit procedures had been completed.

Measured Values

	Aliskiren / Ramipril / Amlodipine	Ramipril / Amlodipine
Number of Participants Analyzed [units: participants]	**61**	**57**
Change in Mean Sitting Systolic Blood Pressure (msSBP) From Baseline to End of Study - Aliskiren/Ramipril/Amlodipine vs Ramipril/Amlodipine) [units: mmHg] Least Squares Mean (Standard Error)	**-12.8 (1.56)**	**-10.9 (1.59)**

No statistical analysis provided for Change in Mean Sitting Systolic Blood Pressure (msSBP) From Baseline to End of Study - Aliskiren/Ramipril/Amlodipine vs Ramipril/Amlodipine)

2. Primary: Change in Mean Sitting Systolic Blood Pressure (msSBP) From Baseline to End of Study - Aliskiren/Amlodipine vs Ramipril/Amlodipine [Time Frame: Baseline to Week 12]

Measure Type	Primary
Measure Title	Change in Mean Sitting Systolic Blood Pressure (msSBP) From Baseline to End of Study - Aliskiren/Amlodipine vs Ramipril/Amlodipine
Measure Description	Automated blood pressure determinations were made with the Omron HEM-705CP blood pressure monitor at trough (24 hours ± 3 hours post-dose) and recorded at all study visits following detailed directions specified in the study protocol. Three readings were made and msSBP was calculated as the average of the 3 readings. In the event of aberrant readings, ie, the lowest reading was ≥ 10 mmHg systolic or ≥ 5 mmHg diastolic lower than the highest of the 3 readings, 3 additional readings were obtained. A negative change indicates improvement.
Time Frame	Baseline to Week 12
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Intent-to-treat (ITT) population. All patients that received at least 1 dose of study drug and had baseline and at least 1 post-baseline assessment of the variable.

Reporting Groups

	Description
Aliskiren / Amlodipine	6 weeks treatment with aliskiren 150 mg tablets, ramipril 5 mg placebo capsules, and amlodipine 5-10 mg tablets followed by an additional 6 weeks treatment with aliskiren 300 mg tablets, ramipril 10 mg placebo capsules, and amlodipine 5-10 mg tablets. Patients received amlodipine 5 mg (or 10 mg if they were receiving 10 mg prior to study start). Each dose was to be taken orally with water once daily at approximately 8:00 A.M. with or without food, except on the morning of an office/clinic visit, when the study drug was to be taken at the site after the visit procedures had been completed.
Ramipril / Amlodipine	6 weeks treatment with aliskiren 150 mg placebo tablets, ramipril 5 mg capsules, and amlodipine 5-10 mg tablets followed by an additional 6 weeks treatment with aliskiren 300 mg placebo tablets, ramipril 10 mg capsules, and amlodipine 5-10 mg tablets. Patients received amlodipine 5 mg (or 10 mg if they were receiving 10 mg prior to study start). Each dose was to be taken orally with water once daily at approximately 8:00 A.M. with or without food, except on the morning of an office/clinic visit, when the study drug was to be taken at the site after the visit procedures had been completed.

Measured Values

	Aliskiren /	Ramipril /

	Amlodipine	Amlodipine
Number of Participants Analyzed [units: participants]	**60**	**57**
Change in Mean Sitting Systolic Blood Pressure (msSBP) From Baseline to End of Study - Aliskiren/Amlodipine vs Ramipril/Amlodipine [units: mmHg] Least Squares Mean (Standard Error)	**-12.4 (1.36)**	**-10.0 (1.39)**

No statistical analysis provided for Change in Mean Sitting Systolic Blood Pressure (msSBP) From Baseline to End of Study - Aliskiren/Amlodipine vs Ramipril/Amlodipine

3. Secondary: Change in Mean Sitting Diastolic Blood Pressure (msDBP) From Baseline to End of Study - Aliskiren/Ramipril/Amlodipine vs Ramipril/Amlodipine [Time Frame: Baseline to Week 12]

Measure Type	Secondary
Measure Title	Change in Mean Sitting Diastolic Blood Pressure (msDBP) From Baseline to End of Study - Aliskiren/Ramipril/Amlodipine vs Ramipril/Amlodipine
Measure Description	Automated blood pressure determinations were made with the Omron HEM-705CP blood pressure monitor at trough (24 hours ± 3 hours post-dose) and recorded at all study visits following detailed directions specified in the study protocol. Three readings were made and msDBP was calculated as the average of the 3 readings. In the event of aberrant readings, ie, the lowest reading was ≥ 10 mmHg systolic or ≥ 5 mmHg diastolic lower than the highest of the 3 readings, 3 additional readings were obtained. A negative change indicates improvement.
Time Frame	Baseline to Week 12
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Intent-to-treat (ITT) population. All patients that received at least 1 dose of study drug and had baseline and at least 1 post-baseline assessment of the variable.

Reporting Groups

	Description
Aliskiren / Ramipril / Amlodipine	6 weeks treatment with aliskiren 150 mg tablets, ramipril 5 mg capsules, and amlodipine 5-10 mg tablets followed by an additional 6 weeks treatment with aliskiren 300 mg tablets, ramipril 10 mg capsules, and amlodipine 5-10 mg tablets. Patients received amlodipine 5 mg (or 10 mg if they were receiving 10 mg prior to study start). Each dose was to be taken orally with water once daily at approximately 8:00 A.M. with or without food, except on the morning of an office/clinic visit, when the study drug was to be taken at the site after the visit procedures had been completed.
Ramipril / Amlodipine	6 weeks treatment with aliskiren 150 mg placebo tablets, ramipril 5 mg capsules, and amlodipine 5-10 mg tablets followed by an additional 6 weeks treatment with aliskiren 300 mg placebo tablets, ramipril 10 mg capsules, and amlodipine 5-10 mg tablets. Patients received amlodipine 5 mg (or 10 mg if they were receiving 10 mg prior to study start). Each dose was to be taken orally with water once daily at approximately 8:00 A.M. with or without food, except on the morning of an office/clinic visit, when the study drug was to be taken at the site after the visit procedures had been completed.

Measured Values

	Aliskiren / Ramipril / Amlodipine	Ramipril / Amlodipine
Number of Participants Analyzed [units: participants]	**61**	**57**
Change in Mean Sitting Diastolic Blood Pressure (msDBP) From Baseline to End of Study - Aliskiren/Ramipril/Amlodipine vs Ramipril/Amlodipine		

[units: mmHg] Least Squares Mean (Standard Error)	**-6.0 (0.94)**	**-4.1 (0.96)**

No statistical analysis provided for Change in Mean Sitting Diastolic Blood Pressure (msDBP) From Baseline to End of Study - Aliskiren/Ramipril/Amlodipine vs Ramipril/Amlodipine

4. Secondary: Change in Mean Sitting Diastolic Blood Pressure (msDBP) From Baseline to End of Study - Aliskiren/Amlodipine vs Ramipril/Amlodipine [Time Frame: Baseline to Week 12]

Measure Type	Secondary
Measure Title	Change in Mean Sitting Diastolic Blood Pressure (msDBP) From Baseline to End of Study - Aliskiren/Amlodipine vs Ramipril/Amlodipine
Measure Description	Automated blood pressure determinations were made with the Omron HEM-705CP blood pressure monitor at trough (24 hours ± 3 hours post-dose) and recorded at all study visits following detailed directions specified in the study protocol. Three readings were made and msDBP was calculated as the average of the 3 readings. In the event of aberrant readings, ie, the lowest reading was ≥ 10 mmHg systolic or ≥ 5 mmHg diastolic lower than the highest of the 3 readings, 3 additional readings were obtained. A negative change indicates improvement.
Time Frame	Baseline to Week 12
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Intent-to-treat (ITT) population. All patients that received at least 1 dose of study drug and had baseline and at least 1 post-baseline assessment of the variable.

Reporting Groups

	Description
Aliskiren / Amlodipine	6 weeks treatment with aliskiren 150 mg tablets, ramipril 5 mg placebo capsules, and amlodipine 5-10 mg tablets followed by an additional 6 weeks treatment with aliskiren 300 mg tablets, ramipril 10 mg placebo capsules, and amlodipine 5-10 mg tablets. Patients received amlodipine 5 mg (or 10 mg if they were receiving 10 mg prior to study start). Each dose was to be taken orally with water once daily at approximately 8:00 A.M. with or without food, except on the morning of an office/clinic visit, when the study drug was to be taken at the site after the visit procedures had been completed.
Ramipril / Amlodipine	6 weeks treatment with aliskiren 150 mg placebo tablets, ramipril 5 mg capsules, and amlodipine 5-10 mg tablets followed by an additional 6 weeks treatment with aliskiren 300 mg placebo tablets, ramipril 10 mg capsules, and amlodipine 5-10 mg tablets. Patients received amlodipine 5 mg (or 10 mg if they were receiving 10 mg prior to study start). Each dose was to be taken orally with water once daily at approximately 8:00 A.M. with or without food, except on the morning of an office/clinic visit, when the study drug was to be taken at the site after the visit procedures had been completed.

Measured Values

	Aliskiren / Amlodipine	**Ramipril / Amlodipine**
Number of Participants Analyzed [units: participants]	**60**	**57**
Change in Mean Sitting Diastolic Blood Pressure (msDBP) From Baseline to End of Study - Aliskiren/Amlodipine vs Ramipril/Amlodipine [units: mmHg] Least Squares Mean (Standard Error)	**-5.8 (0.98)**	**-4.5 (1.00)**

No statistical analysis provided for Change in Mean Sitting Diastolic Blood Pressure (msDBP) From Baseline to End of Study - Aliskiren/Amlodipine vs Ramipril/Amlodipine

5. Secondary: Percentage of Patients Who Achieved Normalized Blood Pressure at End of Study [Time Frame: Week 12]

Measure Type	Secondary
Measure Title	Percentage of Patients Who Achieved Normalized Blood Pressure at End of Study
Measure Description	Normalized was defined as a msSBP < 140 mmHg and/or a msDBP < 90 mmHg.
Time Frame	Week 12
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Intent-to-treat (ITT) population. All patients that received at least 1 dose of study drug and had baseline and at least 1 post-baseline assessment of the variable.

Reporting Groups

	Description
Aliskiren / Ramipril / Amlodipine	6 weeks treatment with aliskiren 150 mg tablets, ramipril 5 mg capsules, and amlodipine 5-10 mg tablets followed by an additional 6 weeks treatment with aliskiren 300 mg tablets, ramipril 10 mg capsules, and amlodipine 5-10 mg tablets. Patients received amlodipine 5 mg (or 10 mg if they were receiving 10 mg prior to study start). Each dose was to be taken orally with water once daily at approximately 8:00 A.M. with or without food, except on the morning of an office/clinic visit, when the study drug was to be taken at the site after the visit procedures had been completed.
Aliskiren /Amlodipine	6 weeks treatment with aliskiren 150 mg tablets, ramipril 5 mg placebo capsules, and amlodipine 5-10 mg tablets followed by an additional 6 weeks treatment with aliskiren 300 mg tablets, ramipril 10 mg placebo capsules, and amlodipine 5-10 mg tablets. Patients received amlodipine 5 mg (or 10 mg if they were receiving 10 mg prior to study start). Each dose was to be taken orally with water once daily at approximately 8:00 A.M. with or without food, except on the morning of an office/clinic visit, when the study drug was to be taken at the site after the visit procedures had been completed.
Ramipril / Amlodipine	6 weeks treatment with aliskiren 150 mg placebo tablets, ramipril 5 mg capsules, and amlodipine 5-10 mg tablets followed by an additional 6 weeks treatment with aliskiren 300 mg placebo tablets, ramipril 10 mg capsules, and amlodipine 5-10 mg tablets. Patients received amlodipine 5 mg (or 10 mg if they were receiving 10 mg prior to study start). Each dose was to be taken orally with water once daily at approximately 8:00 A.M. with or without food, except on the morning of an office/clinic visit, when the study drug was to be taken at the site after the visit procedures had been completed.

Measured Values

	Aliskiren / Ramipril / Amlodipine	**Aliskiren /Amlodipine**	**Ramipril / Amlodipine**
Number of Participants Analyzed [units: participants]	**61**	**60**	**57**
Percentage of Patients Who Achieved Normalized Blood Pressure at End of Study [units: Percentage of patients]	**45.90**	**43.33**	**42.11**

No statistical analysis provided for Percentage of Patients Who Achieved Normalized Blood Pressure at End of Study

6. Secondary: Change in HOMA-IR From Baseline to End of Study [Time Frame: Baseline to Week 12]

Measure Type	Secondary

Measure Title	Change in HOMA-IR From Baseline to End of Study
Measure Description	Homeostasis model assessment-insulin resistance (HOMA-IR) was defined as (fasting insulin [µU/mL] x fasting glucose [mmol/L]) / 22.5.
Time Frame	Baseline to Week 12
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Intent-to-treat (ITT) population. All patients that received at least 1 dose of study drug and had baseline and at least 1 post-baseline assessment of the variable.

Reporting Groups

	Description
Aliskiren / Ramipril / Amlodipine	6 weeks treatment with aliskiren 150 mg tablets, ramipril 5 mg capsules, and amlodipine 5-10 mg tablets followed by an additional 6 weeks treatment with aliskiren 300 mg tablets, ramipril 10 mg capsules, and amlodipine 5-10 mg tablets. Patients received amlodipine 5 mg (or 10 mg if they were receiving 10 mg prior to study start). Each dose was to be taken orally with water once daily at approximately 8:00 A.M. with or without food, except on the morning of an office/clinic visit, when the study drug was to be taken at the site after the visit procedures had been completed.
Aliskiren /Amlodipine	6 weeks treatment with aliskiren 150 mg tablets, ramipril 5 mg placebo capsules, and amlodipine 5-10 mg tablets followed by an additional 6 weeks treatment with aliskiren 300 mg tablets, ramipril 10 mg placebo capsules, and amlodipine 5-10 mg tablets. Patients received amlodipine 5 mg (or 10 mg if they were receiving 10 mg prior to study start). Each dose was to be taken orally with water once daily at approximately 8:00 A.M. with or without food, except on the morning of an office/clinic visit, when the study drug was to be taken at the site after the visit procedures had been completed.
Ramipril / Amlodipine	6 weeks treatment with aliskiren 150 mg placebo tablets, ramipril 5 mg capsules, and amlodipine 5-10 mg tablets followed by an additional 6 weeks treatment with aliskiren 300 mg placebo tablets, ramipril 10 mg capsules, and amlodipine 5-10 mg tablets. Patients received amlodipine 5 mg (or 10 mg if they were receiving 10 mg prior to study start). Each dose was to be taken orally with water once daily at approximately 8:00 A.M. with or without food, except on the morning of an office/clinic visit, when the study drug was to be taken at the site after the visit procedures had been completed.

Measured Values

	Aliskiren / Ramipril / Amlodipine	**Aliskiren /Amlodipine**	**Ramipril / Amlodipine**
Number of Participants Analyzed [units: participants]	**45**	**44**	**45**
Change in HOMA-IR From Baseline to End of Study **[units: mmol/L]** **Mean (Standard Deviation)**	**0.98 (2.292)**	**0.87 (5.883)**	**0.60 (6.186)**

No statistical analysis provided for Change in HOMA-IR From Baseline to End of Study

7. Secondary: Change in HOMA-β From Baseline to End of Study [Time Frame: Baseline to Week 12]

Measure Type	Secondary
Measure Title	Change in HOMA-β From Baseline to End of Study
Measure Description	Homeostasis model assessment-β (HOMA-β) was defined as fasting insulin (µU/mL) x 20 / (fasting glucose (mmol/L) - 3.5).
Time Frame	Baseline to Week 12

Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Intent-to-treat (ITT) population. All patients that received at least 1 dose of study drug and had baseline and at least 1 post-baseline assessment of the variable.

Reporting Groups

	Description
Aliskiren / Ramipril / Amlodipine	6 weeks treatment with aliskiren 150 mg tablets, ramipril 5 mg capsules, and amlodipine 5-10 mg tablets followed by an additional 6 weeks treatment with aliskiren 300 mg tablets, ramipril 10 mg capsules, and amlodipine 5-10 mg tablets. Patients received amlodipine 5 mg (or 10 mg if they were receiving 10 mg prior to study start). Each dose was to be taken orally with water once daily at approximately 8:00 A.M. with or without food, except on the morning of an office/clinic visit, when the study drug was to be taken at the site after the visit procedures had been completed.
Aliskiren /Amlodipine	6 weeks treatment with aliskiren 150 mg tablets, ramipril 5 mg placebo capsules, and amlodipine 5-10 mg tablets followed by an additional 6 weeks treatment with aliskiren 300 mg tablets, ramipril 10 mg placebo capsules, and amlodipine 5-10 mg tablets. Patients received amlodipine 5 mg (or 10 mg if they were receiving 10 mg prior to study start). Each dose was to be taken orally with water once daily at approximately 8:00 A.M. with or without food, except on the morning of an office/clinic visit, when the study drug was to be taken at the site after the visit procedures had been completed.
Ramipril / Amlodipine	6 weeks treatment with aliskiren 150 mg placebo tablets, ramipril 5 mg capsules, and amlodipine 5-10 mg tablets followed by an additional 6 weeks treatment with aliskiren 300 mg placebo tablets, ramipril 10 mg capsules, and amlodipine 5-10 mg tablets. Patients received amlodipine 5 mg (or 10 mg if they were receiving 10 mg prior to study start). Each dose was to be taken orally with water once daily at approximately 8:00 A.M. with or without food, except on the morning of an office/clinic visit, when the study drug was to be taken at the site after the visit procedures had been completed.

Measured Values

	Aliskiren / Ramipril / Amlodipine	**Aliskiren /Amlodipine**	**Ramipril / Amlodipine**
Number of Participants Analyzed [units: participants]	**45**	**44**	**45**
Change in HOMA-β From Baseline to End of Study [units: mmol/L] Mean (Standard Deviation)	**2.71 (152.108)**	**0.87 (5.883)**	**0.60 (6.186)**

No statistical analysis provided for Change in HOMA-β From Baseline to End of Study

8. Secondary: Change in HbA1c (Glycated Hemoglobin) From Baseline to End of Study - Aliskiren/Ramipril/Amlodipine vs Ramipril/Amlodipine [Time Frame: Baseline to Week 12]

Measure Type	Secondary
Measure Title	Change in HbA1c (Glycated Hemoglobin) From Baseline to End of Study - Aliskiren/Ramipril/Amlodipine vs Ramipril/Amlodipine
Measure Description	No text entered.
Time Frame	Baseline to Week 12
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Intent-to-treat (ITT) population. All patients that received at least 1 dose of study drug and had baseline and at least 1 post-baseline assessment of the variable.

Reporting Groups

	Description
Aliskiren / Ramipril / Amlodipine	6 weeks treatment with aliskiren 150 mg tablets, ramipril 5 mg capsules, and amlodipine 5-10 mg tablets followed by an additional 6 weeks treatment with aliskiren 300 mg tablets, ramipril 10 mg capsules, and amlodipine 5-10 mg tablets. Patients received amlodipine 5 mg (or 10 mg if they were receiving 10 mg prior to study start). Each dose was to be taken orally with water once daily at approximately 8:00 A.M. with or without food, except on the morning of an office/clinic visit, when the study drug was to be taken at the site after the visit procedures had been completed.
Ramipril / Amlodipine	6 weeks treatment with aliskiren 150 mg placebo tablets, ramipril 5 mg capsules, and amlodipine 5-10 mg tablets followed by an additional 6 weeks treatment with aliskiren 300 mg placebo tablets, ramipril 10 mg capsules, and amlodipine 5-10 mg tablets. Patients received amlodipine 5 mg (or 10 mg if they were receiving 10 mg prior to study start). Each dose was to be taken orally with water once daily at approximately 8:00 A.M. with or without food, except on the morning of an office/clinic visit, when the study drug was to be taken at the site after the visit procedures had been completed.

Measured Values

	Aliskiren / Ramipril / Amlodipine	**Ramipril / Amlodipine**
Number of Participants Analyzed [units: participants]	**57**	**54**
Change in HbA1c (Glycated Hemoglobin) From Baseline to End of Study - Aliskiren/Ramipril/Amlodipine vs Ramipril/Amlodipine [units: mmol/mol] Least Squares Mean (Standard Error)	**0.1 (0.05)**	**0.1 (0.05)**

No statistical analysis provided for Change in HbA1c (Glycated Hemoglobin) From Baseline to End of Study - Aliskiren/Ramipril/Amlodipine vs Ramipril/Amlodipine

9. Secondary: Change in HbA1c (Glycated Hemoglobin) From Baseline to End of Study - Aliskiren/Amlodipine vs Ramipril/Amlodipine) [Time Frame: Baseline to Week 12]

Measure Type	Secondary
Measure Title	Change in HbA1c (Glycated Hemoglobin) From Baseline to End of Study - Aliskiren/Amlodipine vs Ramipril/Amlodipine)
Measure Description	No text entered.
Time Frame	Baseline to Week 12
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Intent-to-treat (ITT) population. All patients that received at least 1 dose of study drug and had baseline and at least 1 post-baseline assessment of the variable.

Reporting Groups

	Description
Aliskiren / Amlodipine	6 weeks treatment with aliskiren 150 mg tablets, ramipril 5 mg placebo capsules, and amlodipine 5-10 mg tablets

	followed by an additional 6 weeks treatment with aliskiren 300 mg tablets, ramipril 10 mg placebo capsules, and amlodipine 5-10 mg tablets. Patients received amlodipine 5 mg (or 10 mg if they were receiving 10 mg prior to study start). Each dose was to be taken orally with water once daily at approximately 8:00 A.M. with or without food, except on the morning of an office/clinic visit, when the study drug was to be taken at the site after the visit procedures had been completed.
Ramipril / Amlodipine	6 weeks treatment with aliskiren 150 mg placebo tablets, ramipril 5 mg capsules, and amlodipine 5-10 mg tablets followed by an additional 6 weeks treatment with aliskiren 300 mg placebo tablets, ramipril 10 mg capsules, and amlodipine 5-10 mg tablets. Patients received amlodipine 5 mg (or 10 mg if they were receiving 10 mg prior to study start). Each dose was to be taken orally with water once daily at approximately 8:00 A.M. with or without food, except on the morning of an office/clinic visit, when the study drug was to be taken at the site after the visit procedures had been completed.

Measured Values

	Aliskiren / Amlodipine	**Ramipril / Amlodipine**
Number of Participants Analyzed [units: participants]	**58**	**54**
Change in HbA1c (Glycated Hemoglobin) From Baseline to End of Study - Aliskiren/Amlodipine vs Ramipril/Amlodipine) [units: mmol/mol] Least Squares Mean (Standard Error)	**0.1 (0.06)**	**0.1 (0.06)**

No statistical analysis provided for Change in HbA1c (Glycated Hemoglobin) From Baseline to End of Study - Aliskiren/Amlodipine vs Ramipril/Amlodipine)

10. Secondary: Percentage of Patients Who Developed Diabetes at End of Study [Time Frame: Week 12]

Measure Type	Secondary
Measure Title	Percentage of Patients Who Developed Diabetes at End of Study
Measure Description	A patient had diabetes if fasting plasma glucose > 7 mmol/L.
Time Frame	Week 12
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Intent-to-treat (ITT) population: All patients that received at least 1 dose of study drug and had baseline and at least 1 post-baseline assessment of the primary efficacy variable.

Reporting Groups

	Description
Aliskiren / Ramipril / Amlodipine	6 weeks treatment with aliskiren 150 mg tablets, ramipril 5 mg capsules, and amlodipine 5-10 mg tablets followed by an additional 6 weeks treatment with aliskiren 300 mg tablets, ramipril 10 mg capsules, and amlodipine 5-10 mg tablets. Patients received amlodipine 5 mg (or 10 mg if they were receiving 10 mg prior to study start). Each dose was to be taken orally with water once daily at approximately 8:00 A.M. with or without food, except on the morning of an office/clinic visit, when the study drug was to be taken at the site after the visit procedures had been completed.
Aliskiren /Amlodipine	6 weeks treatment with aliskiren 150 mg tablets, ramipril 5 mg placebo capsules, and amlodipine 5-10 mg tablets followed by an additional 6 weeks treatment with aliskiren 300 mg tablets, ramipril 10 mg placebo capsules, and amlodipine 5-10 mg tablets. Patients received amlodipine 5 mg (or 10 mg if they were receiving 10 mg prior to study start). Each dose was to be taken orally with water once daily at approximately 8:00 A.M. with or without food, except on the morning of an office/clinic visit, when the study drug was to be taken at the site after the visit procedures had been completed.

Ramipril / Amlodipine	6 weeks treatment with aliskiren 150 mg placebo tablets, ramipril 5 mg capsules, and amlodipine 5-10 mg tablets followed by an additional 6 weeks treatment with aliskiren 300 mg placebo tablets, ramipril 10 mg capsules, and amlodipine 5-10 mg tablets. Patients received amlodipine 5 mg (or 10 mg if they were receiving 10 mg prior to study start). Each dose was to be taken orally with water once daily at approximately 8:00 A.M. with or without food, except on the morning of an office/clinic visit, when the study drug was to be taken at the site after the visit procedures had been completed.

Measured Values

	Aliskiren / Ramipril / Amlodipine	Aliskiren /Amlodipine	Ramipril / Amlodipine
Number of Participants Analyzed [units: participants]	**61**	**60**	**57**
Percentage of Patients Who Developed Diabetes at End of Study [units: Percentage of patients]	**1.9**	**4.1**	**2.1**

No statistical analysis provided for Percentage of Patients Who Developed Diabetes at End of Study

Serious Adverse Events

Hide Serious Adverse Events

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

Reporting Groups

	Description
Aliskiren / Ramipril / Amlodipine	6 weeks treatment with aliskiren 150 mg tablets, ramipril 5 mg capsules, and amlodipine 5-10 mg tablets followed by an additional 6 weeks treatment with aliskiren 300 mg tablets, ramipril 10 mg capsules, and amlodipine 5-10 mg tablets. Patients received amlodipine 5 mg (or 10 mg if they were receiving 10 mg prior to study start). Each dose was to be taken orally with water once daily at approximately 8:00 A.M. with or without food, except on the morning of an office/clinic visit, when the study drug was to be taken at the site after the visit procedures had been completed.
Aliskiren /Amlodipine	6 weeks treatment with aliskiren 150 mg tablets, ramipril 5 mg placebo capsules, and amlodipine 5-10 mg tablets followed by an additional 6 weeks treatment with aliskiren 300 mg tablets, ramipril 10 mg placebo capsules, and amlodipine 5-10 mg tablets. Patients received amlodipine 5 mg (or 10 mg if they were receiving 10 mg prior to study start). Each dose was to be taken orally with water once daily at approximately 8:00 A.M. with or without food, except on the morning of an office/clinic visit, when the study drug was to be taken at the site after the visit procedures had been completed.
Ramipril / Amlodipine	6 weeks treatment with aliskiren 150 mg placebo tablets, ramipril 5 mg capsules, and amlodipine 5-10 mg tablets followed by an additional 6 weeks treatment with aliskiren 300 mg placebo tablets, ramipril 10 mg capsules, and amlodipine 5-10 mg tablets. Patients received amlodipine 5 mg (or 10 mg if they were receiving 10 mg prior to study start). Each dose was to be taken orally with water once daily at approximately 8:00 A.M. with or without food, except on the morning of an office/clinic visit, when the study drug was to be taken at the site after the visit procedures had been completed.

Serious Adverse Events

	Aliskiren / Ramipril / Amlodipine	Aliskiren /Amlodipine	Ramipril / Amlodipine
Total, serious adverse events			
# participants affected / at risk	**3/61 (4.92%)**	**1/60 (1.67%)**	**3/57 (5.26%)**
Cardiac disorders			
Myocardial infarction † [1]			
# participants affected / at risk	**1/61 (1.64%)**	**0/60 (0.00%)**	**0/57 (0.00%)**

Immune system disorders			
Latex allergy † 1			
# participants affected / at risk	**0/61 (0.00%)**	**1/60 (1.67%)**	**0/57 (0.00%)**
Infections and infestations			
Eczema infected † 1			
# participants affected / at risk	**0/61 (0.00%)**	**1/60 (1.67%)**	**0/57 (0.00%)**
Investigations			
Glucose tolerance test abnormal † 1			
# participants affected / at risk	**0/61 (0.00%)**	**0/60 (0.00%)**	**1/57 (1.75%)**
Metabolism and nutrition disorders			
Diabetes mellitus † 1			
# participants affected / at risk	**2/61 (3.28%)**	**0/60 (0.00%)**	**2/57 (3.51%)**

† 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 / Ramipril / Amlodipine	6 weeks treatment with aliskiren 150 mg tablets, ramipril 5 mg capsules, and amlodipine 5-10 mg tablets followed by an additional 6 weeks treatment with aliskiren 300 mg tablets, ramipril 10 mg capsules, and amlodipine 5-10 mg tablets. Patients received amlodipine 5 mg (or 10 mg if they were receiving 10 mg prior to study start). Each dose was to be taken orally with water once daily at approximately 8:00 A.M. with or without food, except on the morning of an office/clinic visit, when the study drug was to be taken at the site after the visit procedures had been completed.
Aliskiren /Amlodipine	6 weeks treatment with aliskiren 150 mg tablets, ramipril 5 mg placebo capsules, and amlodipine 5-10 mg tablets followed by an additional 6 weeks treatment with aliskiren 300 mg tablets, ramipril 10 mg placebo capsules, and amlodipine 5-10 mg tablets. Patients received amlodipine 5 mg (or 10 mg if they were receiving 10 mg prior to study start). Each dose was to be taken orally with water once daily at approximately 8:00 A.M. with or without food, except on the morning of an office/clinic visit, when the study drug was to be taken at the site after the visit procedures had been completed.
Ramipril / Amlodipine	6 weeks treatment with aliskiren 150 mg placebo tablets, ramipril 5 mg capsules, and amlodipine 5-10 mg tablets followed by an additional 6 weeks treatment with aliskiren 300 mg placebo tablets, ramipril 10 mg capsules, and amlodipine 5-10 mg tablets. Patients received amlodipine 5 mg (or 10 mg if they were receiving 10 mg prior to study start). Each dose was to be taken orally with water once daily at approximately 8:00 A.M. with or without food, except on the morning of an office/clinic visit, when the study drug was to be taken at the site after the visit procedures had been completed.

Other Adverse Events

	Aliskiren / Ramipril / Amlodipine	**Aliskiren /Amlodipine**	**Ramipril / Amlodipine**
Total, other (not including serious) adverse events			

# participants affected / at risk	**27/61 (44.26%)**	**24/60 (40.00%)**	**26/57 (45.61%)**
Gastrointestinal disorders			
Dyspepsia † 1			
# participants affected / at risk	**2/61 (3.28%)**	**3/60 (5.00%)**	**0/57 (0.00%)**
General disorders			
Oedema peripheral † 1			
# participants affected / at risk	**17/61 (27.87%)**	**14/60 (23.33%)**	**16/57 (28.07%)**
Infections and infestations			
Lower respiratory tract infection † 1			
# participants affected / at risk	**3/61 (4.92%)**	**0/60 (0.00%)**	**3/57 (5.26%)**
Urinary tract infection † 1			
# participants affected / at risk	**0/61 (0.00%)**	**1/60 (1.67%)**	**3/57 (5.26%)**
Musculoskeletal and connective tissue disorders			
Arthralgia † 1			
# participants affected / at risk	**2/61 (3.28%)**	**3/60 (5.00%)**	**2/57 (3.51%)**
Nervous system disorders			
Dizziness † 1			
# participants affected / at risk	**5/61 (8.20%)**	**2/60 (3.33%)**	**2/57 (3.51%)**
Headache † 1			
# participants affected / at risk	**2/61 (3.28%)**	**3/60 (5.00%)**	**2/57 (3.51%)**
Respiratory, thoracic and mediastinal disorders			
Cough † 1			
# participants affected / at risk	**4/61 (6.56%)**	**2/60 (3.33%)**	**1/57 (1.75%)**

† 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
ClinicalTrials.gov Identifier:	NCT00542269 History of Changes
Other Study ID Numbers:	**CSPP100AGB01**
Study First Received:	October 9, 2007
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