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Trial record **1 of 1** for: CSPP100A2238

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Effects of Aliskiren and Amlodipine on the Renin-Angiotensin System (RAS) and Lipid/Carbohydrate Metabolism in Obese Patients With Hypertension

This study has been terminated.

(Early termination resulted from interim analysis of the ALTITUDE trial)

Sponsor:
Novartis

Information provided by (Responsible Party):
Novartis

ClinicalTrials.gov Identifier:
NCT00498433

First received: July 8, 2007
Last updated: September 9, 2014
Last verified: September 2014
History of Changes

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Results First Received: March 21, 2013

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Pharmacokinetics/Dynamics Study; Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Investigator); Primary Purpose: Treatment
Conditions:	Hypertension Abdominal Obesity
Interventions:	Drug: Aliskiren Drug: Amlodipine Drug: Placebo of Aliskiren Drug: Placebo of amlodipine

Participant Flow

Hide Participant Flow

Recruitment Details

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

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment
Total 46 patients entered into the study; 10 patients in part 1 received study drug. 36 patients enrolled into part 2 and and 16 patients received study drug.

Reporting Groups

	Description
Placebo	Part 1, Period 1: After a 1-2 weeks initial washout period, all eligible patients underwent a two week placebo run-in phase. Part 2, Period 1: After confirming study eligibility based on inclusion and exclusion criteria, patients underwent a two week single-blind placebo run-in phase.

Aliskiren	Part 1 , Period 2: All eligible patients received 4 week treatment of 300 mg aliskiren o.d.. Part 2, Double Blind Period: Eligible randomized patients received aliskiren 300 mg tablet o.d. and amlodipine placebo capsule o.d. for 12 weeks
Amlodipine	Part 1, Period 3: All patients received 5 mg amlodipine o.d.. The length of the amlodipine period varied from 4 to 7 weeks. Part 2, Double Blind Period: Eligible randomized patients received amlodipine 5 mg o.d. and aliskiren placebo o.d. for 12 weeks

Participant Flow for 5 periods

Period 1: Part 1, Period 1:Placebo Run-in(2 Weeks)

	Placebo	Aliskiren	Amlodipine
STARTED	10	0	0
COMPLETED	10	0	0
NOT COMPLETED	0	0	0

Period 2: Part 1, Period 2: Aliskiren (4 Weeks)

	Placebo	Aliskiren	Amlodipine
STARTED	0	10	0
COMPLETED	0	10	0
NOT COMPLETED	0	0	0

Period 3: Part 1, Period 3: Amlodipine (4-8 Weeks)

	Placebo	Aliskiren	Amlodipine
STARTED	0	0	10
COMPLETED	0	0	10
NOT COMPLETED	0	0	0

Period 4: Part 2: Placebo Run-in (2 Weeks)

	Placebo	Aliskiren	Amlodipine
STARTED	36	0 [1]	0 [1]
COMPLETED	16	0	0
NOT COMPLETED	20	0	0
Adverse Event	2	0	0
Abnormal laboratory value	2	0	0
Abnormal test procedure	15	0	0
Administrative problems	1	0	0

[1] For part 2, this arm belongs to randomized, double blind period.

Period 5: Part 2: Double Blind (12 Weeks)

	Placebo	Aliskiren	Amlodipine
STARTED	0	8	8
COMPLETED	0	8	8
NOT COMPLETED	0	0	0

Baseline Characteristics

Hide Baseline Characteristics

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Part 1 : Baseline measures are on all patients. Part 2: Randomized population of double-blind period used for Baseline/Demographic measurements.

Reporting Groups

	Description
Part 1: Placebo/Aliskiren/Amlodipine	Part 1, Period 1: After a 1-2 weeks initial washout period, all eligible patients underwent a two week placebo run-in phase. Part 1 , Period 2: All eligible patients received 4 week treatment of 300 mg aliskiren o.d.. Part 1, Period 3: All patients received 5 mg amlodipine o.d.. The length of the amlodipine period varied from 4 to 7 weeks.
Part 2, Double Blind Period: Aliskiren	Eligible randomized patients received aliskiren 300 mg tablet o.d. and amlodipine placebo capsule o.d. for 12 weeks
Part 2, Double Blind: Amlodipine	Eligible randomized patients received amlodipine 5 mg o.d. and aliskiren placebo o.d. for 12 weeks
Total	Total of all reporting groups

Baseline Measures

	Part 1: Placebo/Aliskiren/Amlodipine	**Part 2, Double Blind Period: Aliskiren**	**Part 2, Double Blind: Amlodipine**	**Total**
Number of Participants [units: participants]	**10**	**8**	**8**	**26**
Age [units: years] Mean (Standard Deviation)				
Part 1, Open Label	**46 (7.5)**	**NA [1]**	**NA [1]**	**46 (7.5)**
Part 2, Double blind	**NA [2]**	**46.0 (10.92)**	**49.4 (10.53)**	**47.7 (10.17)**
Gender [units: participants]				
Female	**2**	**2**	**2**	**6**
Male	**8**	**6**	**6**	**20**

[1] This arm is used for part 2, double blind period
[2] This arm is used for part 1, open label .

Outcome Measures

Hide All Outcome Measures

1. Primary: Part 1: Aliskiren Concentrations From Interstitial Fluid (Microdialysis)at the End of Aliskiren Treatment Period [Time Frame: Day 42]

Measure Type	Primary
Measure Title	Part 1: Aliskiren Concentrations From Interstitial Fluid (Microdialysis)at the End of Aliskiren Treatment Period

Measure Description	Interstitial fluid was obtained from subcutaneous adipose and skeletal muscle tissues by microdialysis using the zero-flow method. Interstitial fluid was collected for measurements of drug concentrations on the last day of the aliskiren treatment periods (Day 42).
Time Frame	Day 42
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 received at least one dose of study drug and had at least one post-baseline assessment of pharmacokinetics (PK)/ pharmacodynamics (PD) data were included in the data analysis.

Reporting Groups

	Description
Part 1: Placebo/Aliskiren/Amlodipine	Part 1, Period 1: After a 1-2 weeks initial washout period, all eligible patients underwent a two week placebo run-in phase. Part 1 , Period 2: All eligible patients received 4 week treatment of 300 mg aliskiren o.d.. Part 1, Period 3: All patients received 5 mg amlodipine o.d.. The length of the amlodipine period varied from 4 to 7 weeks.

Measured Values

	Part 1: Placebo/Aliskiren/Amlodipine
Number of Participants Analyzed [units: participants]	**10**
Part 1: Aliskiren Concentrations From Interstitial Fluid (Microdialysis)at the End of Aliskiren Treatment Period [units: ng/mL] Mean (Standard Deviation)	
Adipose tissue	**2.38 (2.11)**
Skeletal muscle	**7.05 (4.24)**

No statistical analysis provided for Part 1: Aliskiren Concentrations From Interstitial Fluid (Microdialysis)at the End of Aliskiren Treatment Period

2. Primary: Part 1: Amlodipine Concentrations From Interstitial Fluid (Microdialysis) at the End of Amlodipine Treatment Period [Time Frame: Day 98]

Measure Type	Primary
Measure Title	Part 1: Amlodipine Concentrations From Interstitial Fluid (Microdialysis) at the End of Amlodipine Treatment Period
Measure Description	Interstitial fluid was obtained from subcutaneous adipose and skeletal muscle tissues by microdialysis using the zero-flow method. Interstitial fluid was collected for measurements of drug concentration on the last day of the amlodipine treatment periods (Day 98).
Time Frame	Day 98
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.
Zero flow concentrations from microdialysates could not be derived by linear regression because of missing data due to inadequate sample volumes.

Reporting Groups

	Description
Part 1: Placebo/Aliskiren/Amlodipine	Part 1, Period 1: After a 1-2 weeks initial washout period, all eligible patients underwent a two week placebo run-in phase. Part 1 , Period 2: All eligible patients received 4 week treatment of 300 mg aliskiren o.d.. Part 1, Period 3: All patients received 5 mg amlodipine o.d.. The length of the amlodipine period varied from 4 to 7 weeks.

Measured Values

	Part 1: Placebo/Aliskiren/Amlodipine
Number of Participants Analyzed [units: participants]	**0**
Part 1: Amlodipine Concentrations From Interstitial Fluid (Microdialysis) at the End of Amlodipine Treatment Period	

No statistical analysis provided for Part 1: Amlodipine Concentrations From Interstitial Fluid (Microdialysis) at the End of Amlodipine Treatment Period

3. Primary: Part 1: Angiotensin II Levels in Interstitial Fluid of Fat and Skeletal Muscle (Microdialysis) During Aliskiren Treatment Period [Time Frame: Day 42]

Measure Type	Primary
Measure Title	Part 1: Angiotensin II Levels in Interstitial Fluid of Fat and Skeletal Muscle (Microdialysis) During Aliskiren Treatment Period
Measure Description	Interstitial fluid was obtained from subcutaneous adipose and skeletal muscle tissues by microdialysis using the zero-flow method to determine Ang II concentration.
Time Frame	Day 42
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.
Due to technical limitations, zero flow concentrations could not be derived for Ang II.

Reporting Groups

	Description
Part 1: Placebo/Aliskiren/Amlodipine	Part 1, Period 1: After a 1-2 weeks initial washout period, all eligible patients underwent a two week placebo run-in phase. Part 1 , Period 2: All eligible patients received 4 week treatment of 300 mg aliskiren o.d.. Part 1, Period 3: All patients received 5 mg amlodipine o.d.. The length of the amlodipine period varied from 4 to 7 weeks.

Measured Values

	Part 1: Placebo/Aliskiren/Amlodipine
Number of Participants Analyzed [units: participants]	**0**

Part 1: Angiotensin II Levels in Interstitial Fluid of Fat and Skeletal Muscle (Microdialysis) During Aliskiren Treatment Period	

No statistical analysis provided for Part 1: Angiotensin II Levels in Interstitial Fluid of Fat and Skeletal Muscle (Microdialysis) During Aliskiren Treatment Period

4. Primary: Part 1: Angiotensin II Levels in Interstitial Fluid of Fat and Skeletal Muscle (Microdialysis) During Amlodipine Treatment Period [Time Frame: Day 98]

Measure Type	Primary
Measure Title	Part 1: Angiotensin II Levels in Interstitial Fluid of Fat and Skeletal Muscle (Microdialysis) During Amlodipine Treatment Period
Measure Description	Interstitial fluid was obtained from subcutaneous adipose and skeletal muscle tissues by microdialysis using the zero-flow method to determine Ang II concentration.
Time Frame	Day 98
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.
Due to technical limitations, zero flow concentrations could not be derived for Ang II.

Reporting Groups

	Description
Part 1: Placebo/Aliskiren/Amlodipine	Part 1, Period 1: After a 1-2 weeks initial washout period, all eligible patients underwent a two week placebo run-in phase. Part 1 , Period 2: All eligible patients received 4 week treatment of 300 mg aliskiren o.d.. Part 1, Period 3: All patients received 5 mg amlodipine o.d.. The length of the amlodipine period varied from 4 to 7 weeks.

Measured Values

	Part 1: Placebo/Aliskiren/Amlodipine
Number of Participants Analyzed [units: participants]	**0**
Part 1: Angiotensin II Levels in Interstitial Fluid of Fat and Skeletal Muscle (Microdialysis) During Amlodipine Treatment Period	

No statistical analysis provided for Part 1: Angiotensin II Levels in Interstitial Fluid of Fat and Skeletal Muscle (Microdialysis) During Amlodipine Treatment Period

5. Primary: Part 1: Aliskiren Concentrations From Tissue at the End of Aliskiren Treatment Period [Time Frame: Day 42]

Measure Type	Primary
Measure Title	Part 1: Aliskiren Concentrations From Tissue at the End of Aliskiren Treatment Period
Measure Description	Biopsies were taken from abdominal adipose and skeletal muscle tissue to determine aliskiren concentration. Tissue biopsy samples for drug concentrations analyses were taken on the last day of the aliskiren treatment periods (Day 42).
Time Frame	Day 42

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 received at least one dose of study drug and had at least one post-baseline assessment of pharmacokinetics data were included in the data analysis.

Reporting Groups

	Description
Part 1: Placebo/Aliskiren/Amlodipine	Part 1, Period 1: After a 1-2 weeks initial washout period, all eligible patients underwent a two week placebo run-in phase. Part 1 , Period 2: All eligible patients received 4 week treatment of 300 mg aliskiren o.d.. Part 1, Period 3: All patients received 5 mg amlodipine o.d.. The length of the amlodipine period varied from 4 to 7 weeks.

Measured Values

	Part 1: Placebo/Aliskiren/Amlodipine
Number of Participants Analyzed [units: participants]	**9**
Part 1: Aliskiren Concentrations From Tissue at the End of Aliskiren Treatment Period [units: ng/g] Mean (Standard Deviation)	
Adipose tissue (n=6)	**29.05 (16.71)**
Skeletal muscle (n=9)	**107.32 (68.64)**

No statistical analysis provided for Part 1: Aliskiren Concentrations From Tissue at the End of Aliskiren Treatment Period

6. Primary: Part 1: Angiotensin II Levels From Tissue During Aliskiren Treatment Period [Time Frame: Day 42]

Measure Type	Primary
Measure Title	Part 1: Angiotensin II Levels From Tissue During Aliskiren Treatment Period
Measure Description	Biopsies were taken from abdominal adipose and skeletal muscle tissue to determine Ang II concentration.
Time Frame	Day 42
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.
More than 50% of the biopsy samples over all time points were either below lower limit of quantification (LLOQ) or not received.

Reporting Groups

	Description
Part 1: Placebo/Aliskiren/Amlodipine	Part 1, Period 1: After a 1-2 weeks initial washout period, all eligible patients underwent a two week placebo run-in phase. Part 1 , Period 2: All eligible patients received 4 week treatment of 300 mg aliskiren o.d.. Part 1, Period 3: All patients received 5 mg amlodipine o.d.. The length of the amlodipine period varied from 4 to 7 weeks.

Measured Values

	Part 1: Placebo/Aliskiren/Amlodipine
Number of Participants Analyzed [units: participants]	**0**
Part 1: Angiotensin II Levels From Tissue During Aliskiren Treatment Period	

No statistical analysis provided for Part 1: Angiotensin II Levels From Tissue During Aliskiren Treatment Period

7. Primary: Part 1: Renin Activity and Concentrations From Adipose and Skeletal Tissues During Aliskiren Treatment Period [Time Frame: Day 42]

Measure Type	Primary
Measure Title	Part 1: Renin Activity and Concentrations From Adipose and Skeletal Tissues During Aliskiren Treatment Period
Measure Description	No text entered.
Time Frame	Day 42
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.
Renin activity and concentration from adipose tissue and skeletal muscles were all below lower limitation of quantification (LLOQ) at all time points.

Reporting Groups

	Description
Part 1: Placebo/Aliskiren/Amlodipine	Part 1, Period 1: After a 1-2 weeks initial washout period, all eligible patients underwent a two week placebo run-in phase. Part 1 , Period 2: All eligible patients received 4 week treatment of 300 mg aliskiren o.d.. Part 1, Period 3: All patients received 5 mg amlodipine o.d.. The length of the amlodipine period varied from 4 to 7 weeks.

Measured Values

	Part 1: Placebo/Aliskiren/Amlodipine
Number of Participants Analyzed [units: participants]	**0**
Part 1: Renin Activity and Concentrations From Adipose and Skeletal Tissues During Aliskiren Treatment Period	

No statistical analysis provided for Part 1: Renin Activity and Concentrations From Adipose and Skeletal Tissues During Aliskiren Treatment Period

8. Primary: Part 1: Aliskiren Concentrations From Plasma at the End of Aliskiren Treatment Period [Time Frame: Day 42]

Measure Type	Primary
Measure Title	Part 1: Aliskiren Concentrations From Plasma at the End of Aliskiren Treatment Period
Measure Description	Plasma samples were obtained for measurement of aliskiren or amlodipine concentrations. All blood samples were

	taken by an indwelling cannula inserted in a forearm vein or direct venipuncture. The plasma samples for drug concentrations analyses were taken on the last day of the aliskiren treatment periods (Day 42).
Time Frame	Day 42
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 received at least one dose of study drug and had at least one post-baseline assessment of pharmacokinetics data were included in the data analysis.

Reporting Groups

	Description
Part 1: Placebo/Aliskiren/Amlodipine	Part 1, Period 1: After a 1-2 weeks initial washout period, all eligible patients underwent a two week placebo run-in phase. Part 1 , Period 2: All eligible patients received 4 week treatment of 300 mg aliskiren o.d.. Part 1, Period 3: All patients received 5 mg amlodipine o.d.. The length of the amlodipine period varied from 4 to 7 weeks.

Measured Values

	Part 1: Placebo/Aliskiren/Amlodipine
Number of Participants Analyzed [units: participants]	**10**
Part 1: Aliskiren Concentrations From Plasma at the End of Aliskiren Treatment Period [units: ng/mL] Mean (Standard Deviation)	**8.38 (4.41)**

No statistical analysis provided for Part 1: Aliskiren Concentrations From Plasma at the End of Aliskiren Treatment Period

9. Primary: Part 1: Amlodipine Concentrations From Plasma at the End of Amlodipine Treatment Period [Time Frame: Day 98]

Measure Type	Primary
Measure Title	Part 1: Amlodipine Concentrations From Plasma at the End of Amlodipine Treatment Period
Measure Description	Plasma samples were obtained for measurement of aliskiren or amlodipine concentrations. All blood samples were taken by an indwelling cannula inserted in a forearm vein or direct venipuncture. The plasma samples for drug concentrations analyses were taken on the last day of the amlodipine treatment periods (Day 98).
Time Frame	Day 98
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 received at least one dose of study drug and had at least one post-baseline assessment of pharmacokinetics data were included in the data analysis.

Reporting Groups

	Description
Part 1: Placebo/Aliskiren/Amlodipine	Part 1, Period 1: After a 1-2 weeks initial washout period, all eligible patients underwent a two week placebo run-in phase.

	Part 1 , Period 2: All eligible patients received 4 week treatment of 300 mg aliskiren o.d.. Part 1, Period 3: All patients received 5 mg amlodipine o.d.. The length of the amlodipine period varied from 4 to 7 weeks.

Measured Values

	Part 1: Placebo/Aliskiren/Amlodipine
Number of Participants Analyzed [units: participants]	**10**
Part 1: Amlodipine Concentrations From Plasma at the End of Amlodipine Treatment Period [units: ng/mL] Mean (Standard Deviation)	**7.78 (3.61)**

No statistical analysis provided for Part 1: Amlodipine Concentrations From Plasma at the End of Amlodipine Treatment Period

10. Primary: Part 1: Angiotensin II Levels in Plasma During Aliskiren Treatment Period [Time Frame: Day 42]

Measure Type	Primary
Measure Title	Part 1: Angiotensin II Levels in Plasma During Aliskiren Treatment Period
Measure Description	Interstitial fluid was obtained from subcutaneous adipose and skeletal muscle tissues by microdialysis using the zero-flow method to determine Ang II concentration.
Time Frame	Day 42
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 received at least one dose of study drug and had at least one post-baseline assessment of pharmacodynamic data were included in the data analysis.

Reporting Groups

	Description
Part 1: Placebo/Aliskiren/Amlodipine	Part 1, Period 1: After a 1-2 weeks initial washout period, all eligible patients underwent a two week placebo run-in phase. Part 1 , Period 2: All eligible patients received 4 week treatment of 300 mg aliskiren o.d.. Part 1, Period 3: All patients received 5 mg amlodipine o.d.. The length of the amlodipine period varied from 4 to 7 weeks.

Measured Values

	Part 1: Placebo/Aliskiren/Amlodipine
Number of Participants Analyzed [units: participants]	**10**
Part 1: Angiotensin II Levels in Plasma During Aliskiren Treatment Period [units: fmol/mL] Geometric Mean (95% Confidence Interval)	**0.534 (0.223 to 1.28)**

No statistical analysis provided for Part 1: Angiotensin II Levels in Plasma During Aliskiren Treatment Period

11. Primary: Part 1: Angiotensin II Levels in Plasma During Amlodipine Treatment Period [Time Frame: Day 98]

Measure Type	Primary
Measure Title	Part 1: Angiotensin II Levels in Plasma During Amlodipine Treatment Period
Measure Description	Interstitial fluid was obtained from subcutaneous adipose and skeletal muscle tissues by microdialysis using the zero-flow method to determine Ang II concentration.
Time Frame	Day 98
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 received at least one dose of study drug and had at least one post-baseline assessment of pharmacodynamic data were included in the data analysis.

Reporting Groups

	Description
Part 1: Placebo/Aliskiren/Amlodipine	Part 1, Period 1: After a 1-2 weeks initial washout period, all eligible patients underwent a two week placebo run-in phase. Part 1 , Period 2: All eligible patients received 4 week treatment of 300 mg aliskiren o.d.. Part 1, Period 3: All patients received 5 mg amlodipine o.d.. The length of the amlodipine period varied from 4 to 7 weeks.

Measured Values

	Part 1: Placebo/Aliskiren/Amlodipine
Number of Participants Analyzed [units: participants]	**10**
Part 1: Angiotensin II Levels in Plasma During Amlodipine Treatment Period [units: fmol/mL] Geometric Mean (95% Confidence Interval)	**2.20 (0.88 to 5.51)**

No statistical analysis provided for Part 1: Angiotensin II Levels in Plasma During Amlodipine Treatment Period

12. Primary: Part 1: Renin Concentrations From Plasma During Aliskiren Treatment Period [Time Frame: Day 42]

Measure Type	Primary
Measure Title	Part 1: Renin Concentrations From Plasma During Aliskiren Treatment Period
Measure Description	Renin concentrations from plasma were measured as: plasma renin concentration (PRC), prorenin concentration and total renin concentration (renin + prorenin concentration).
Time Frame	Day 42
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 received at least one dose of study drug and had at least one post-baseline assessment of pharmacodynamic data were included in the data analysis.

Reporting Groups

	Description
Part 1: Placebo/Aliskiren/Amlodipine	Part 1, Period 1: After a 1-2 weeks initial washout period, all eligible patients underwent a two week placebo run-in phase. Part 1 , Period 2: All eligible patients received 4 week treatment of 300 mg aliskiren o.d.. Part 1, Period 3: All patients received 5 mg amlodipine o.d.. The length of the amlodipine period varied from 4 to 7 weeks.

Measured Values

	Part 1: Placebo/Aliskiren/Amlodipine
Number of Participants Analyzed [units: participants]	**10**
Part 1: Renin Concentrations From Plasma During Aliskiren Treatment Period [units: pg/mL] Geometric Mean (95% Confidence Interval)	
Plasma Renin Concentration	**22.29 (8.98 to 55.32)**
Total Renin Concentration	**89.9 (52.4 to 154.2)**
Prorenin Concentration	**62.1 (40.2 to 96.0)**

No statistical analysis provided for Part 1: Renin Concentrations From Plasma During Aliskiren Treatment Period

13. Primary: Part 1: Renin Concentrations From Plasma During Amlodipine Treatment Period [Time Frame: Day 98]

Measure Type	Primary
Measure Title	Part 1: Renin Concentrations From Plasma During Amlodipine Treatment Period
Measure Description	Renin concentrations from plasma were measured as plasma renin concentration (PRC), prorenin concentration and total renin concentration (renin + prorenin concentration).
Time Frame	Day 98
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 received at least one dose of study drug and had at least one post-baseline assessment of pharmacodynamic data were included in the data analysis.

Reporting Groups

	Description
Part 1: Placebo/Aliskiren/Amlodipine	Part 1, Period 1: After a 1-2 weeks initial washout period, all eligible patients underwent a two week placebo run-in phase. Part 1 , Period 2: All eligible patients received 4 week treatment of 300 mg aliskiren o.d.. Part 1, Period 3: All patients received 5 mg amlodipine o.d.. The length of the amlodipine period varied from 4 to 7 weeks.

Measured Values

	Part 1: Placebo/Aliskiren/Amlodipine
Number of Participants Analyzed	

[units: participants]	**10**
Part 1: Renin Concentrations From Plasma During Amlodipine Treatment Period [units: pg/mL] Geometric Mean (95% Confidence Interval)	
Plasma Renin Concentration	**7.36 (4.24 to 12.80)**
Total Renin Concentration	**66.3 (49.8 to 88.2)**
Prorenin Concentration	**57.9 (44.1 to 76.1)**

No statistical analysis provided for Part 1: Renin Concentrations From Plasma During Amlodipine Treatment Period

14. Primary: Part 1: Renin Activity From Plasma During Aliskiren Treatment Period [Time Frame: Day 42]

Measure Type	Primary
Measure Title	Part 1: Renin Activity From Plasma During Aliskiren Treatment Period
Measure Description	Plasma Renin activity (PRC) was measured by a trapping PRA (tPRA) assay.
Time Frame	Day 42
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 received at least one dose of study drug and had at least one post-baseline assessment of pharmacodynamic data were included in the data analysis.

Reporting Groups

	Description
Part 1: Placebo/Aliskiren/Amlodipine	Part 1, Period 1: After a 1-2 weeks initial washout period, all eligible patients underwent a two week placebo run-in phase. Part 1 , Period 2: All eligible patients received 4 week treatment of 300 mg aliskiren o.d.. Part 1, Period 3: All patients received 5 mg amlodipine o.d.. The length of the amlodipine period varied from 4 to 7 weeks.

Measured Values

	Part 1: Placebo/Aliskiren/Amlodipine
Number of Participants Analyzed [units: participants]	**10**
Part 1: Renin Activity From Plasma During Aliskiren Treatment Period [units: ng/nl/h] Geometric Mean (95% Confidence Interval)	**0.145 (0.055 to 0.386)**

No statistical analysis provided for Part 1: Renin Activity From Plasma During Aliskiren Treatment Period

15. Primary: Part 1: Renin Activity From Plasma During Amlodipine Treatment Period [Time Frame: Day 98]

Measure Type	Primary

Measure Title	Part 1: Renin Activity From Plasma During Amlodipine Treatment Period
Measure Description	Plasma renin activity (PRC) was measured by a trapping PRA (tPRA) assay.
Time Frame	Day 98
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 received at least one dose of study drug and had at least one post-baseline assessment of pharmacodynamic data were included in the data analysis.

Reporting Groups

	Description
Part 1: Placebo/Aliskiren/Amlodipine	Part 1, Period 1: After a 1-2 weeks initial washout period, all eligible patients underwent a two week placebo run-in phase. Part 1 , Period 2: All eligible patients received 4 week treatment of 300 mg aliskiren o.d.. Part 1, Period 3: All patients received 5 mg amlodipine o.d.. The length of the amlodipine period varied from 4 to 7 weeks.

Measured Values

	Part 1: Placebo/Aliskiren/Amlodipine
Number of Participants Analyzed [units: participants]	**10**
Part 1: Renin Activity From Plasma During Amlodipine Treatment Period [units: ng/nl/h] Geometric Mean (95% Confidence Interval)	**0.670 (0.269 to 1.672)**

No statistical analysis provided for Part 1: Renin Activity From Plasma During Amlodipine Treatment Period

16. Primary: Part 2: Change From Baseline in Angiotensin II Levels in Interstitial Fluid of Fat and Skeletal Muscle (Microdialysis) During Double Blind Treatment Period [Time Frame: Placebo Baseline (Day 14), Active Treatment (Day 98)]

Measure Type	Primary
Measure Title	Part 2: Change From Baseline in Angiotensin II Levels in Interstitial Fluid of Fat and Skeletal Muscle (Microdialysis) During Double Blind Treatment Period
Measure Description	Interstitial fluid was obtained from subcutaneous adipose and skeletal muscle tissues by microdialysis using the zero-flow method to determine Ang II concentration.
Time Frame	Placebo Baseline (Day 14), Active Treatment (Day 98)
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.
Total 40 completed subjects needed to have a power of 80% in detecting a significant difference between treatment groups. Due to early termination, the study was limited by a small sample size; hence, the planned analysis was not done.

Reporting Groups

	Description
Aliskiren	Part 2, Double Blind Period: Eligible randomized patients received aliskiren 300 mg tablet o.d. and amlodipine placebo capsule

	o.d. for 12 weeks
Amlodipine	Part 2, Double Blind Period: Eligible randomized patients received amlodipine 5 mg o.d. and aliskiren placebo o.d. for 12 weeks

Measured Values

	Aliskiren	Amlodipine
Number of Participants Analyzed [units: participants]	**0**	**0**
Part 2: Change From Baseline in Angiotensin II Levels in Interstitial Fluid of Fat and Skeletal Muscle (Microdialysis) During Double Blind Treatment Period		

No statistical analysis provided for Part 2: Change From Baseline in Angiotensin II Levels in Interstitial Fluid of Fat and Skeletal Muscle (Microdialysis) During Double Blind Treatment Period

17. Primary: Part 2: Change From Baseline in Plasma Angiotensin II Levels During Double Blind Treatment Period [Time Frame: Placebo Baseline (Day 14), Active Treatment (Day 98)]

Measure Type	Primary
Measure Title	Part 2: Change From Baseline in Plasma Angiotensin II Levels During Double Blind Treatment Period
Measure Description	Plasma Ang II was measured prior to and 1 hour after the Insulin modified-frequently sampled intravenous glucose tolerance test (IM-FSIGT) during placebo treatment (Days 14) and active treatment(Day 98).
Time Frame	Placebo Baseline (Day 14), Active Treatment (Day 98)
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.
Total 40 completed subjects needed to have a power of 80% in detecting a significant difference between treatment groups. Due to early termination, the study was limited by a small sample size; hence, the planned analysis was not done.

Reporting Groups

	Description
Aliskiren	Part 2, Double Blind Period: Eligible randomized patients received aliskiren 300 mg tablet o.d. and amlodipine placebo capsule o.d. for 12 weeks
Amlodipine	Part 2, Double Blind Period: Eligible randomized patients received amlodipine 5 mg o.d. and aliskiren placebo o.d. for 12 weeks

Measured Values

	Aliskiren	Amlodipine
Number of Participants Analyzed [units: participants]	**0**	**0**
Part 2: Change From Baseline in Plasma Angiotensin II Levels During Double Blind Treatment Period		

No statistical analysis provided for Part 2: Change From Baseline in Plasma Angiotensin II Levels During Double Blind Treatment Period

18. Primary: Part 2: Plasma Renin Activity (PRA) Concentration During Double Blind Treatment Period [Time Frame: Day 98]

Measure Type	Primary

Measure Title	Part 2: Plasma Renin Activity (PRA) Concentration During Double Blind Treatment Period
Measure Description	No text entered.
Time Frame	Day 98
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.
Total 40 completed subjects needed to have a power of 80% in detecting a significant difference between treatment groups. Due to early termination, the study was limited by a small sample size; hence, the planned analysis was not done.

Reporting Groups

	Description
Aliskiren	Part 2, Double Blind Period: Eligible randomized patients of this arm received aliskiren 300 mg tablet o.d. and amlodipine placebo capsule o.d. for 12 weeks
Amlodipine	Part 2, Double Blind Period: Eligible randomized patients of this arm received amlodipine 5 mg o.d. and aliskiren placebo o.d. for 12 weeks

Measured Values

	Aliskiren	**Amlodipine**
Number of Participants Analyzed [units: participants]	**0**	**0**
Part 2: Plasma Renin Activity (PRA) Concentration During Double Blind Treatment Period		

No statistical analysis provided for Part 2: Plasma Renin Activity (PRA) Concentration During Double Blind Treatment Period

19. Primary: Part 2: Plasma Renin Concentration (PRC) Levels During Double Blind Treatment Period [Time Frame: Day 98]

Measure Type	Primary
Measure Title	Part 2: Plasma Renin Concentration (PRC) Levels During Double Blind Treatment Period
Measure Description	No text entered.
Time Frame	Day 98
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.
Total 40 completed subjects needed to have a power of 80% in detecting a significant difference between treatment groups. Due to early termination, the study was limited by a small sample size; hence, the planned analysis was not done.

Reporting Groups

	Description
Aliskiren	Part 2, Double Blind Period: Eligible randomized patients received aliskiren 300 mg tablet o.d. and amlodipine placebo capsule o.d. for 12 weeks
Amlodipine	Part 2, Double Blind Period: Eligible randomized patients received amlodipine 5 mg o.d. and aliskiren placebo o.d. for 12 weeks

Measured Values

	Aliskiren	Amlodipine
Number of Participants Analyzed [units: participants]	**0**	**0**
Part 2: Plasma Renin Concentration (PRC) Levels During Double Blind Treatment Period		

No statistical analysis provided for Part 2: Plasma Renin Concentration (PRC) Levels During Double Blind Treatment Period

20. Secondary: Part 2: Microdialysis Metabolic Analytes in Response to Insulin Modified Frequently Sampled Intravenous Glucose Test [IM-FSIGT]for Each Tissue (Adipose or Skeletal Muscle) [Time Frame: Day 14 and Day 98]

Measure Type	Secondary
Measure Title	Part 2: Microdialysis Metabolic Analytes in Response to Insulin Modified Frequently Sampled Intravenous Glucose Test [IM-FSIGT]for Each Tissue (Adipose or Skeletal Muscle)
Measure Description	No text entered.
Time Frame	Day 14 and Day 98
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.
Total 40 completed subjects needed to have a power of 80% in detecting a significant difference between treatment groups. Due to early termination, the study was limited by a small sample size; hence, the planned analysis was not done.

Reporting Groups

	Description
Aliskiren	Part 2, Double Blind Period: Eligible randomized patients received aliskiren 300 mg tablet o.d. and amlodipine placebo capsule o.d. for 12 weeks
Amlodipine	Part 2, Double Blind Period: Eligible randomized patients received amlodipine 5 mg o.d. and aliskiren placebo o.d. for 12 weeks

Measured Values

	Aliskiren	Amlodipine
Number of Participants Analyzed [units: participants]	**0**	**0**
Part 2: Microdialysis Metabolic Analytes in Response to Insulin Modified Frequently Sampled Intravenous Glucose Test [IM-FSIGT]for Each Tissue (Adipose or Skeletal Muscle)		

No statistical analysis provided for Part 2: Microdialysis Metabolic Analytes in Response to Insulin Modified Frequently Sampled Intravenous Glucose Test [IM-FSIGT]for Each Tissue (Adipose or Skeletal Muscle)

21. Secondary: Part 2: Change From Baseline in Official Blood Pressure [Time Frame: Placebo Baseline (Day 14), Active Treatment (Day 98)]

Measure Type	Secondary
Measure Title	Part 2: Change From Baseline in Official Blood Pressure
Measure Description	No text entered.
Time Frame	Placebo Baseline (Day 14), Active Treatment (Day 98)

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.
Total 40 completed subjects needed to have a power of 80% in detecting a significant difference between treatment groups. Due to early termination, the study was limited by a small sample size; hence, the planned analysis was not done.

Reporting Groups

	Description
Aliskiren	Part 2, Double Blind: Eligible randomized patients received aliskiren 300 mg tablet o.d. and amlodipine placebo capsule o.d. for 12 weeks
Amlodipine	Part 2, Double Blind: Eligible randomized patients received amlodipine 5 mg o.d. and aliskiren placebo o.d. for 12 weeks

Measured Values

	Aliskiren	**Amlodipine**
Number of Participants Analyzed [units: participants]	**0**	**0**
Part 2: Change From Baseline in Official Blood Pressure		

No statistical analysis provided for Part 2: Change From Baseline in Official Blood Pressure

22. Secondary: Part 2: Renin Activity and Concentration of Aliskiren and Amlodipine in Fat and Skeletal Muscle Interstitial Fluid [Time Frame: Placebo Baseline (Day 14), Active Treatment (Day 98)]

Measure Type	Secondary
Measure Title	Part 2: Renin Activity and Concentration of Aliskiren and Amlodipine in Fat and Skeletal Muscle Interstitial Fluid
Measure Description	No text entered.
Time Frame	Placebo Baseline (Day 14), Active Treatment (Day 98)
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.
Total 40 completed subjects needed to have a power of 80% in detecting a significant difference between treatment groups. Due to early termination, the study was limited by a small sample size; hence, the planned analysis was not done.

Reporting Groups

	Description
Aliskiren	Part 2, Double Blind Period: Eligible randomized patients received aliskiren 300 mg tablet o.d. and amlodipine placebo capsule o.d. for 12 weeks
Amlodipine	Part 2, Double Blind Period: Eligible randomized patients received amlodipine 5 mg o.d. and aliskiren placebo o.d. for 12 weeks

Measured Values

	Aliskiren	**Amlodipine**
Number of Participants Analyzed [units: participants]	**0**	**0**

Part 2: Renin Activity and Concentration of Aliskiren and Amlodipine in Fat and Skeletal Muscle Interstitial Fluid		

No statistical analysis provided for Part 2: Renin Activity and Concentration of Aliskiren and Amlodipine in Fat and Skeletal Muscle Interstitial Fluid

23. Secondary: Part 2: Change From Baseline in Peripheral Insulin Sensitivity in Response to Insulin Modified Frequently Sampled Intravenous Glucose Test [IM-FSIGT]for Each Tissue (Adipose or Skeletal Muscle) [Time Frame: Placebo Baseline (Day 14), Active Treatment (Day 98)]

Measure Type	Secondary
Measure Title	Part 2: Change From Baseline in Peripheral Insulin Sensitivity in Response to Insulin Modified Frequently Sampled Intravenous Glucose Test [IM-FSIGT]for Each Tissue (Adipose or Skeletal Muscle)
Measure Description	No text entered.
Time Frame	Placebo Baseline (Day 14), Active Treatment (Day 98)
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.
Total 40 completed subjects needed to have a power of 80% in detecting a significant difference between treatment groups. Due to early termination, the study was limited by a small sample size; hence, the planned analysis was not done.

Reporting Groups

	Description
Aliskiren	Part 2, Double Blind Period: Eligible randomized patients received aliskiren 300 mg tablet o.d. and amlodipine placebo capsule o.d. for 12 weeks
Amlodipine	Part 2, Double Blind Period: Eligible randomized patients received amlodipine 5 mg o.d. and aliskiren placebo o.d. for 12 weeks

Measured Values

	Aliskiren	**Amlodipine**
Number of Participants Analyzed [units: participants]	**0**	**0**
Part 2: Change From Baseline in Peripheral Insulin Sensitivity in Response to Insulin Modified Frequently Sampled Intravenous Glucose Test [IM-FSIGT]for Each Tissue (Adipose or Skeletal Muscle)		

No statistical analysis provided for Part 2: Change From Baseline in Peripheral Insulin Sensitivity in Response to Insulin Modified Frequently Sampled Intravenous Glucose Test [IM-FSIGT]for Each Tissue (Adipose or Skeletal Muscle)

24. Secondary: Part 2: Change From Baseline in Mitochondrial Mass in Subcutaneous Fat and Skeletal Muscle (Tissue Biopsies) [Time Frame: Placebo Baseline (Day 14), Active Treatment (Day 98)]

Measure Type	Secondary
Measure Title	Part 2: Change From Baseline in Mitochondrial Mass in Subcutaneous Fat and Skeletal Muscle (Tissue Biopsies)
Measure Description	No text entered.
Time Frame	Placebo Baseline (Day 14), Active Treatment (Day 98)
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.
Total 40 completed subjects needed to have a power of 80% in detecting a significant difference between treatment groups. Due to early termination, the study was limited by a small sample size; hence, the planned analysis was not done.

Reporting Groups

	Description
Aliskiren	Part 2, Double Blind Period: Eligible randomized patients received aliskiren 300 mg tablet o.d. and amlodipine placebo capsule o.d. for 12 weeks
Amlodipine	Part 2, Double Blind Period: Eligible randomized patients received amlodipine 5 mg o.d. and aliskiren placebo o.d. for 12 weeks

Measured Values

	Aliskiren	**Amlodipine**
Number of Participants Analyzed [units: participants]	**0**	**0**
Part 2: Change From Baseline in Mitochondrial Mass in Subcutaneous Fat and Skeletal Muscle (Tissue Biopsies)		

No statistical analysis provided for Part 2: Change From Baseline in Mitochondrial Mass in Subcutaneous Fat and Skeletal Muscle (Tissue Biopsies)

25. Secondary: Part 2: Number of Participants With Reported Any Adverse Events, Serious Adverse Events and Death [Time Frame: 98 days]

Measure Type	Secondary
Measure Title	Part 2: Number of Participants With Reported Any Adverse Events, Serious Adverse Events and Death
Measure Description	No text entered.
Time Frame	98 days
Safety Issue	Yes

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 safety population consisted of all patients who received at least one dose of study drug with at least one post-baseline safety assessment. Patients were analyzed according to treatment received.

Reporting Groups

	Description
Placebo run-in	Part 2, Period 1, Placebo run-in phase: After confirming study eligibility based on inclusion and exclusion criteria, patients will undergo a two week single-blind placebo run-in phase.
Aliskiren	Part 2, Double Blind Period: Eligible randomized patients of this arm received aliskiren 300 mg tablet o.d. and amlodipine placebo capsule o.d. for 12 weeks
Amlodipine	Part 2, Double Blind: Eligible randomized patients of this arm received amlodipine 5 mg o.d. and aliskiren placebo o.d. for 12 weeks

Measured Values

	Placebo run-in	Aliskiren	Amlodipine
Number of Participants Analyzed [units: participants]	**36**	**8**	**8**
Part 2: Number of Participants With Reported Any Adverse Events, Serious Adverse Events and Death [units: Participants]			
Adverse event	**9**	**2**	**3**
Serious Adverse Event	**1**	**0**	**0**
Death	**0**	**0**	**0**

No statistical analysis provided for Part 2: Number of Participants With Reported Any Adverse Events, Serious Adverse Events and Death

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	No text entered.
Additional Description	The Safety Population consisted of all patients that received at least one dose of study drug with at least one post-baseline safety assessment. In Part 1 of the study, no events were reported in period 1 when patients received placebo.

Reporting Groups

	Description
Part 1: Aliskiren	All eligible patients received 4 week treatment of 300 mg aliskiren o.d..
Part 1: Amlodipine	All patients received 5 mg amlodipine o.d.. The length of the amlodipine period varied from 4 to 7 weeks.
Part 2: Placebo run-in Period	After confirming study eligibility based on inclusion and exclusion criteria, patients will undergo a two week single-blind placebo run-in phase.
Part 2: Aliskiren	Eligible randomized patients of this arm received aliskiren 300 mg tablet o.d. and amlodipine placebo capsule o.d. for 12 weeks
Part 2: Amlodipine	Double Blind Period: Eligible randomized patients of this arm received amlodipine 5 mg o.d. and aliskiren placebo o.d. for 12 weeks

Serious Adverse Events

	Part 1: Aliskiren	Part 1: Amlodipine	Part 2: Placebo run-in Period	Part 2: Aliskiren	Part 2: Amlodipine
Total, serious adverse events					
# participants affected / at risk	**1/10 (10.00%)**	**0/10 (0.00%)**	**1/36 (2.78%)**	**0/8 (0.00%)**	**0/8 (0.00%)**
Musculoskeletal and connective tissue disorders					
MUSCLE HAEMORRHAGE † 1					
# participants affected / at risk	**1/10 (10.00%)**	**0/10 (0.00%)**	**0/36 (0.00%)**	**0/8 (0.00%)**	**0/8 (0.00%)**
Vascular disorders					
HYPERTENSIVE CRISIS † 1					
# participants affected / at risk	**0/10 (0.00%)**	**0/10 (0.00%)**	**1/36 (2.78%)**	**0/8 (0.00%)**	**0/8 (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	The Safety Population consisted of all patients that received at least one dose of study drug with at least one post-baseline safety assessment. In Part 1 of the study, no events were reported in period 1 when patients received placebo.

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
Part 1: Aliskiren	All eligible patients received 4 week treatment of 300 mg aliskiren o.d..
Part 1: Amlodipine	All patients received 5 mg amlodipine o.d.. The length of the amlodipine period varied from 4 to 7 weeks.
Part 2: Placebo run-in Period	After confirming study eligibility based on inclusion and exclusion criteria, patients will undergo a two week single-blind placebo run-in phase.
Part 2: Aliskiren	Eligible randomized patients of this arm received aliskiren 300 mg tablet o.d. and amlodipine placebo capsule o.d. for 12 weeks
Part 2: Amlodipine	Double Blind Period: Eligible randomized patients of this arm received amlodipine 5 mg o.d. and aliskiren placebo o.d. for 12 weeks

Other Adverse Events

	Part 1: Aliskiren	Part 1: Amlodipine	Part 2: Placebo run-in Period	Part 2: Aliskiren	Part 2: Amlodipine
Total, other (not including serious) adverse events					
# participants affected / at risk	**6/10 (60.00%)**	**3/10 (30.00%)**	**1/36 (2.78%)**	**2/8 (25.00%)**	**3/8 (37.50%)**
Gastrointestinal disorders					
DIARRHOEA † 1					
# participants affected / at risk	**0/10 (0.00%)**	**1/10 (10.00%)**	**0/36 (0.00%)**	**0/8 (0.00%)**	**1/8 (12.50%)**
DRY MOUTH † 1					
# participants affected / at risk	**0/10 (0.00%)**	**0/10 (0.00%)**	**0/36 (0.00%)**	**1/8 (12.50%)**	**0/8 (0.00%)**
General disorders					
IRRITABILITY † 1					
# participants affected / at risk	**0/10 (0.00%)**	**0/10 (0.00%)**	**0/36 (0.00%)**	**1/8 (12.50%)**	**0/8 (0.00%)**
Infections and infestations					
NASOPHARYNGITIS † 1					
# participants affected / at risk	**2/10 (20.00%)**	**2/10 (20.00%)**	**0/36 (0.00%)**	**0/8 (0.00%)**	**0/8 (0.00%)**
RHINITIS † 1					
# participants affected / at risk	**1/10 (10.00%)**	**0/10 (0.00%)**	**0/36 (0.00%)**	**0/8 (0.00%)**	**0/8 (0.00%)**
Injury, poisoning and procedural complications					

CONTUSION † 1					
# participants affected / at risk	0/10 (0.00%)	0/10 (0.00%)	0/36 (0.00%)	0/8 (0.00%)	1/8 (12.50%)
MUSCLE STRAIN † 1					
# participants affected / at risk	1/10 (10.00%)	0/10 (0.00%)	0/36 (0.00%)	0/8 (0.00%)	0/8 (0.00%)
POST PROCEDURAL HAEMATOMA † 1					
# participants affected / at risk	1/10 (10.00%)	0/10 (0.00%)	0/36 (0.00%)	0/8 (0.00%)	0/8 (0.00%)
Investigations					
WEIGHT INCREASED † 1					
# participants affected / at risk	0/10 (0.00%)	0/10 (0.00%)	0/36 (0.00%)	1/8 (12.50%)	0/8 (0.00%)
Nervous system disorders					
HEADACHE † 1					
# participants affected / at risk	1/10 (10.00%)	0/10 (0.00%)	1/36 (2.78%)	1/8 (12.50%)	0/8 (0.00%)
PARAESTHESIA † 1					
# participants affected / at risk	0/10 (0.00%)	0/10 (0.00%)	0/36 (0.00%)	1/8 (12.50%)	0/8 (0.00%)
Psychiatric disorders					
INSOMNIA † 1					
# participants affected / at risk	0/10 (0.00%)	0/10 (0.00%)	0/36 (0.00%)	1/8 (12.50%)	0/8 (0.00%)
Renal and urinary disorders					
DYSURIA † 1					
# participants affected / at risk	0/10 (0.00%)	0/10 (0.00%)	0/36 (0.00%)	0/8 (0.00%)	1/8 (12.50%)
Reproductive system and breast disorders					
ERECTILE DYSFUNCTION † 1					
# participants affected / at risk	0/10 (0.00%)	0/10 (0.00%)	0/36 (0.00%)	1/8 (12.50%)	0/8 (0.00%)
Respiratory, thoracic and mediastinal disorders					
COUGH † 1					
# participants affected / at risk	2/10 (20.00%)	1/10 (10.00%)	0/36 (0.00%)	0/8 (0.00%)	0/8 (0.00%)
Skin and subcutaneous tissue disorders					
PSORIASIS † 1					
# participants affected / at risk	0/10 (0.00%)	0/10 (0.00%)	0/36 (0.00%)	0/8 (0.00%)	1/8 (12.50%)

† 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 or disclosure of trial results in their entirety.

Results Point of Contact:

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

No publications provided

Responsible Party:	Novartis
ClinicalTrials.gov Identifier:	NCT00498433 History of Changes
Other Study ID Numbers:	**CSPP100A2238**
Study First Received:	July 8, 2007
Results First Received:	March 21, 2013
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