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Trial record **1 of 1** for: CSPP100A2340

Previous Study | Return to List | Next Study

Safety and Efficacy of Aliskiren in Post Myocardial Infarction Patients (ASPIRE)

This study has been completed.

Sponsor:
Novartis

Information provided by (Responsible Party):
Novartis

ClinicalTrials.gov Identifier:
NCT00414609

First received: December 19, 2006
Last updated: July 5, 2012
Last verified: July 2012
History of Changes

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

Results First Received: December 20, 2010

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Investigator); Primary Purpose: Treatment
Condition:	Myocardial Infarction
Interventions:	Drug: Aliskiren Drug: placebo

Participant Flow

Hide Participant Flow

Recruitment Details

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

Pre-Assignment Details

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

Reporting Groups

	Description
Placebo_Core	Placebo for 36 weeks once daily in the morning
Aliskiren_Core	Aliskiren ascending doses: 75 mg tablet for 1st week, 150 mg for 2nd week, 300 mg for the next 34 weeks orally once daily in the morning.
Aliskiren_Extension	Patients from both the arms of the core study who completed core study and signed informed consent form were included in this arm of extension study. Patients received 150 mg aliskiren tablet orally once a day for two weeks. Patients were then up-titrated to 300 mg aliskiren orally once a day at the discretion of the principal investigator based on their clinical condition for the duration of the study.

Participant Flow for 2 periods

Period 1: Core Study

	Placebo_Core	Aliskiren_Core	Aliskiren_Extension
STARTED	397	423	0
Received Study Drug	397	422	0
Echocardiogram Evaluable Set	330	343	0
COMPLETED	363	378	0
NOT COMPLETED	34	45	0
Adverse Event	9	11	0
Abnormal laboratory values	0	1	0
Abnormal test procedure results	1	1	0
Protocol deviation	0	1	0
Patient withdrew consent	10	11	0
Lost to Follow-up	7	4	0
Administrative problems	0	2	0
Death	7	14	0

Period 2: Extension Study

	Placebo_Core	Aliskiren_Core	Aliskiren_Extension
STARTED	0	0	422 [1]
Echocardiogram (ECHO) Analysis Set	0	0	400
COMPLETED	0	0	365
NOT COMPLETED	0	0	57
Adverse Event	0	0	14
Unsatisfactory therapeutic effect	0	0	2
Withdrawal by Subject	0	0	13
Lost to Follow-up	0	0	10
Administrative problems	0	0	1
Death	0	0	17

[1] Patients of both core arms who completed core study and signed informed consent form for extension.

Baseline Characteristics

Hide Baseline Characteristics

Population Description

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

Reporting Groups

	Description
Placebo	Placebo for 36 weeks once daily in the morning

Aliskiren	Aliskiren ascending doses: 75 mg tablet for 1st week, 150 mg for 2nd week, 300 mg for the next 34 weeks orally once daily in the morning.
Total	Total of all reporting groups

Baseline Measures

	Placebo	Aliskiren	Total
Number of Participants [units: participants]	**397**	**423**	**820**
Age [1] [units: years] Mean (Standard Deviation)	**59.4 (11.67)**	**60.7 (11.63)**	**60.0 (11.66)**
Age, Customized [units: Participants]			
< 65 years	**261**	**254**	**515**
≥ 65 years and < 75 years	**93**	**114**	**207**
≥ 75 years	**43**	**55**	**98**
Gender [units: participants]			
Female	**61**	**80**	**141**
Male	**336**	**343**	**679**

[1] Demographics were measured for core randomized population

Outcome Measures

Hide All Outcome Measures

1. Primary: Core Study: Change From Baseline in Left Ventricular End Systolic Volume (LVESV) as Measured by Echocardiography at End of Study. [Time Frame: Baseline and final visit (after 26 to 36 weeks of treatment)]

Measure Type	Primary
Measure Title	Core Study: Change From Baseline in Left Ventricular End Systolic Volume (LVESV) as Measured by Echocardiography at End of Study.
Measure Description	Change from baseline to end of study in left ventricular end systolic volume (LVESV) as measured by echocardiography. LVESV is a measurement of the volume of blood in the heart's left ventricular chamber at the end of the heart's contraction. This measurement was made by the echocardiography lab. LVESV values between 22 to 58 mL for men and 19-49 mL for women are considered normal. Baseline LVESV was a covariate.
Time Frame	Baseline and final visit (after 26 to 36 weeks of treatment)
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.
Echocardiogram evaluable set (patients who had acceptable echocardiogram measurements both at baseline and at post-baseline after receiving at least 26 weeks of treatment)

Reporting Groups

	Description
Placebo_Core	Placebo for 36 weeks once daily in the morning
Aliskiren_Core	Aliskiren ascending doses: 75 mg tablet for 1st week, 150 mg for 2nd week, 300 mg for the next 34 weeks orally once daily

	in the morning.

Measured Values

	Placebo_Core	Aliskiren_Core
Number of Participants Analyzed [units: participants]	**329**	**343**
Core Study: Change From Baseline in Left Ventricular End Systolic Volume (LVESV) as Measured by Echocardiography at End of Study. [units: mL] Least Squares Mean (Standard Error)	**-3.14 (1.01)**	**-4.13 (0.97)**

No statistical analysis provided for Core Study: Change From Baseline in Left Ventricular End Systolic Volume (LVESV) as Measured by Echocardiography at End of Study.

2. Primary: Extension Study: Percentage of Participants With Deaths, Serious Adverse Events (SAEs), Discontinuation for Adverse Events (AEs) and Discontinuations for Abnormal Lab Values [Time Frame: Extension study (24 weeks)]

Measure Type	Primary
Measure Title	Extension Study: Percentage of Participants With Deaths, Serious Adverse Events (SAEs), Discontinuation for Adverse Events (AEs) and Discontinuations for Abnormal Lab Values
Measure Description	AEs are defined as any unfavorable and unintended diagnosis, symptom, sign (including an abnormal laboratory finding), syndrome or disease which either occurs during study, having been absent at baseline, or, if present at baseline, appears to worsen. Serious adverse events are any untoward medical occurrences that result in death, are life threatening, require (or prolong) hospitalization, cause persistent or significant disability/incapacity, result in congenital anomalies or birth defects, or are other conditions which in judgment of investigators represent significant hazards.
Time Frame	Extension study (24 weeks)
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Extension Population (considered as Safety population) consisting of all enrolled patients who received at least one dose of study medication in the extension study.

Reporting Groups

	Description
Aliskiren_Extension	Patients from both the arms of the core study who completed core study and signed informed consent form were included in this arm of extension study. Patients received 150 mg aliskiren tablet orally once a day for two weeks. Patients were then up-titrated to 300 mg aliskiren orally once a day at the discretion of the principal investigator based on their clinical condition for the duration of the study.

Measured Values

	Aliskiren_Extension
Number of Participants Analyzed [units: participants]	**422**
Extension Study: Percentage of Participants With Deaths, Serious Adverse Events (SAEs), Discontinuation for Adverse	

Events (AEs) and Discontinuations for Abnormal Lab Values [units: Percentage of participants]	
Deaths	4.0
SAEs	29.9
AE discontinuations	7.1
Drug-related AE discontinuations	2.4
SAE discontinuations	5.2
Discontinuations for abnormal lab values	0

No statistical analysis provided for Extension Study: Percentage of Participants With Deaths, Serious Adverse Events (SAEs), Discontinuation for Adverse Events (AEs) and Discontinuations for Abnormal Lab Values

3. Secondary: Core Study: Time to First Occurrence for the Composite Endpoints of Echocardiogram and Adjudicated Outcomes [Time Frame: LVEF was measured at baseline and at final visit (after 26 to 36 weeks of treatment). Other endpoint components were assessed from randomization until the end of the study (week 36).]

Measure Type	Secondary
Measure Title	Core Study: Time to First Occurrence for the Composite Endpoints of Echocardiogram and Adjudicated Outcomes
Measure Description	Composite outcome 1 included: Cardiovascular (CV) Death, hospitalization for heart failure (HF), or absolute reduction in Left Ventricular Ejection Fraction (LVEF) greater than 6%. Composite outcome 2 included: CV Death, hospitalization for HF, recurrent Myocardial Infarction, Stroke, or Resuscitated Sudden Death. LVEF was measured at baseline and final visit. All other events were adjudicated by a blinded external committee. Each composite endpoint analysis was based on (a) the percent of patients with that endpoint and (b) days in study to 1st event (or last exposure if no event occurred).
Time Frame	LVEF was measured at baseline and at final visit (after 26 to 36 weeks of treatment). Other endpoint components were assessed from randomization until the end of the study (week 36).
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Full Analysis Set (FAS) – All randomized patients who either (a) received study drug or (b) did not receive study drug but were not disqualified from randomization.

Reporting Groups

	Description
Placebo_Core	Placebo for 36 weeks once daily in the morning
Aliskiren_Core	Aliskiren ascending doses: 75 mg tablet for 1st week, 150 mg for 2nd week, 300 mg for the next 34 weeks orally once daily in the morning.

Measured Values

	Placebo_Core	Aliskiren_Core
Number of Participants Analyzed [units: participants]	**397**	**423**
Core Study: Time to First Occurrence for the Composite Endpoints of Echocardiogram and Adjudicated Outcomes [units: Percentage of participants]		
Composite Outcome 1	**6.0**	**6.9**

Composite Outcome 2	**8.6**	**9.2**

No statistical analysis provided for Core Study: Time to First Occurrence for the Composite Endpoints of Echocardiogram and Adjudicated Outcomes

4. Secondary: Core Study: Change From Baseline in Left Ventricular End Diastolic Volume (LVEDV) [Time Frame: Baseline and final visit (after 26 to 36 weeks of treatment)]

Measure Type	Secondary
Measure Title	Core Study: Change From Baseline in Left Ventricular End Diastolic Volume (LVEDV)
Measure Description	Change from baseline to end of study in left ventricular end diastolic volume (LVEDV) as measured by echocardiography. (LVEDV) is a measurement of the volume of blood in the heart's left ventricular chamber at the beginning of the chamber's filling with blood. This measurement was made by the echocardiography lab. LVEDV values between 67 to 155 mL for men and 56 to 104 mL for women are considered normal. Baseline LVEDV was a covariate.
Time Frame	Baseline and final visit (after 26 to 36 weeks of treatment)
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.
Echocardiogram evaluable set: Patients who had acceptable echocardiogram measurements both at baseline and at post-baseline after receiving at least 26 weeks of treatment.

Reporting Groups

	Description
Placebo_Core	Placebo for 36 weeks once daily in the morning
Aliskiren_Core	Aliskiren ascending doses: 75 mg tablet for 1st week, 150 mg for 2nd week, 300 mg for the next 34 weeks orally once daily in the morning.

Measured Values

	Placebo_Core	**Aliskiren_Core**
Number of Participants Analyzed [units: participants]	**329**	**343**
Core Study: Change From Baseline in Left Ventricular End Diastolic Volume (LVEDV) [units: mL] Least Squares Mean (Standard Error)	**-1.37 (1.19)**	**-3.08 (1.15)**

No statistical analysis provided for Core Study: Change From Baseline in Left Ventricular End Diastolic Volume (LVEDV)

5. Secondary: Core Study: Change From Baseline in Left Ventricular Ejection Fraction (LVEF) [Time Frame: Baseline and final visit (after 26 to 36 weeks of treatment)]

Measure Type	Secondary
Measure Title	Core Study: Change From Baseline in Left Ventricular Ejection Fraction (LVEF)
Measure Description	Change from baseline to end of study in left ventricular ejection fraction (LVEF) (%) as measured by echocardiography. LVEF is the fraction of blood (in percent) pumped out of the heart's left ventricular chamber with each heart beat, and is a measure of cardiac output for the heart. This measurement was made by the echocardiography lab. Ejection fraction percentages > 55% are considered normal. Baseline LVEF was a covariate.

Time Frame	Baseline and final visit (after 26 to 36 weeks of treatment)
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.
Echocardiogram evaluable set: Patients who had acceptable echocardiogram measurements both at baseline and at post-baseline after receiving at least 26 weeks of treatment.

Reporting Groups

	Description
Placebo_Core	Placebo for 36 weeks once daily in the morning
Aliskiren_Core	Aliskiren ascending doses: 75 mg tablet for 1st week, 150 mg for 2nd week, 300 mg for the next 34 weeks orally once daily in the morning.

Measured Values

	Placebo_Core	**Aliskiren_Core**
Number of Participants Analyzed [units: participants]	**329**	**343**
Core Study: Change From Baseline in Left Ventricular Ejection Fraction (LVEF) [units: percent of blood pumped from LV chamber] Least Squares Mean (Standard Error)	**2.12 (0.27)**	**2.24 (0.26)**

No statistical analysis provided for Core Study: Change From Baseline in Left Ventricular Ejection Fraction (LVEF)

6. Secondary: Core Study: Change From Baseline to End of Study in Infarction Segment Length (ISL) as Measured by Echocardiography [Time Frame: Baseline and final visit (after 26 to 36 weeks of treatment)]

Measure Type	Secondary
Measure Title	Core Study: Change From Baseline to End of Study in Infarction Segment Length (ISL) as Measured by Echocardiography
Measure Description	Change from baseline to end of study in infarction segment length (ISL) (%) as measured by echocardiography. This is the length of the myocardial infarction segment as a percentage of the total cavity perimeter length as calculated by the echocardiography lab. Baseline ISL was a covariate.
Time Frame	Baseline and final visit (after 26 to 36 weeks of treatment)
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.
Echocardiogram evaluable set: Patients who had acceptable echocardiogram measurements both at baseline and at post-baseline after receiving at least 26 weeks of treatment.

Reporting Groups

	Description
Placebo_Core	Placebo for 36 weeks once daily in the morning
Aliskiren_Core	Aliskiren ascending doses: 75 mg tablet for 1st week, 150 mg for 2nd week, 300 mg for the next 34 weeks orally once daily in the morning.

Measured Values

	Placebo_Core	Aliskiren_Core
Number of Participants Analyzed [units: participants]	**330**	**343**
Core Study: Change From Baseline to End of Study in Infarction Segment Length (ISL) as Measured by Echocardiography [units: percent of total cavity perimeter length] Least Squares Mean (Standard Error)	**-4.30 (0.53)**	**-5.04 (0.51)**

No statistical analysis provided for Core Study: Change From Baseline to End of Study in Infarction Segment Length (ISL) as Measured by Echocardiography

7. Secondary: Core Study: Change From Baseline to End of Study in Wall Motion Score (WMS) as Measured by Echocardiography [Time Frame: Baseline and final visit (after 26 to 36 weeks of treatment)]

Measure Type	Secondary
Measure Title	Core Study: Change From Baseline to End of Study in Wall Motion Score (WMS) as Measured by Echocardiography
Measure Description	Change from baseline to end of study in Wall Motion Score (WMS) as measured by echocardiography. WMS was obtained by examining multiple segments of the left ventricle and assigning each segment a score based on myocardial thickening: 1 for normal, 2 for hypokinetic; 3 for akinetic; and 4 for dyskinetic. The WMS was obtained as the average score for the segments visualized and was calculated by the echocardiography lab. Possible values range from 1 to 5. Higher scores are considered worse. Baseline WMS was a covariate.
Time Frame	Baseline and final visit (after 26 to 36 weeks of treatment)
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.
Echocardiogram evaluable set: Patients who had acceptable echocardiogram measurements both at baseline and at post-baseline after receiving at least 26 weeks of treatment.

Reporting Groups

	Description
Placebo_Core	Placebo for 36 weeks once daily in the morning
Aliskiren_Core	Aliskiren ascending doses: 75 mg tablet for 1st week, 150 mg for 2nd week, 300 mg for the next 34 weeks orally once daily in the morning.

Measured Values

	Placebo_Core	Aliskiren_Core
Number of Participants Analyzed [units: participants]	**327**	**340**
Core Study: Change From Baseline to End of Study in Wall Motion Score (WMS) as Measured by Echocardiography [units: Scores on a scale] Least Squares Mean (Standard Error)	**-0.08 (0.01)**	**-0.10 (0.01)**

No statistical analysis provided for Core Study: Change From Baseline to End of Study in Wall Motion Score (WMS) as Measured by Echocardiography

8. Secondary: Extension Study: Change From Baseline in Left Ventricular End Systolic Volume (LVESV) at Month 12 [Time Frame: Baseline(extension study), Month 12 (extension study)]

Measure Type	Secondary
Measure Title	Extension Study: Change From Baseline in Left Ventricular End Systolic Volume (LVESV) at Month 12
Measure Description	Change from baseline to Month 12 in left ventricular end systolic volume (LVESV) as measured by echocardiography. LVESV is a measurement of the volume of blood in the heart's left ventricular chamber at the end of the heart's contraction. This measurement was made by the echocardiography lab. LVESV values between 22 to 58 mL for men and 19-49 mL for women are considered normal.
Time Frame	Baseline(extension study), Month 12 (extension study)
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.
Echocardiogram Analysis Set consisting of all patients in the extension population who had acceptable ECHO measurements at extension baseline and Month 12.

Reporting Groups

	Description
Aliskiren_Extension	Patients from both the arms of the core study who completed core study and signed informed consent form were included in this arm of extension study. Patients received 150 mg aliskiren tablet orally once a day for two weeks. Patients were then up-titrated to 300 mg aliskiren orally once a day at the discretion of the principal investigator based on their clinical condition for the duration of the study.

Measured Values

	Aliskiren_Extension
Number of Participants Analyzed [units: participants]	**302**
Extension Study: Change From Baseline in Left Ventricular End Systolic Volume (LVESV) at Month 12 [units: Milliliter (mL)] Mean (Standard Deviation)	**-6.2 (14.32)**

No statistical analysis provided for Extension Study: Change From Baseline in Left Ventricular End Systolic Volume (LVESV) at Month 12

9. Secondary: Extension Study: Change From Baseline in Left Ventricular End Diastolic Volume (LVEDV) at Month 12 [Time Frame: Baseline (extension study), Month 12 (extension study)]

Measure Type	Secondary
Measure Title	Extension Study: Change From Baseline in Left Ventricular End Diastolic Volume (LVEDV) at Month 12
Measure Description	Change from baseline to Month 12 in left ventricular end diastolic volume (LVEDV) as measured by echocardiography. LVEDV is a measurement of the volume of blood in the heart's left ventricular chamber at the beginning of the chamber's filling with blood. This measurement was made by the echocardiography lab. LVEDV values between 67 to 155 mL for men and 56 to 104 mL for women are considered normal.
Time Frame	Baseline (extension study), Month 12 (extension study)
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.
Echocardiogram Analysis Set consisting of all patients in the extension population who had acceptable ECHO measurements at extension baseline and Month 12.

Reporting Groups

	Description
Aliskiren_Extension	150 mg aliskiren tablet orally once a day for two weeks. Patients were then up-titrated to 300 mg aliskiren orally once a day at the discretion of the principal investigator based on their clinical condition for the duration of the study.

Measured Values

	Aliskiren_Extension
Number of Participants Analyzed [units: participants]	**302**
Extension Study: Change From Baseline in Left Ventricular End Diastolic Volume (LVEDV) at Month 12 [units: Milliliter (mL)] Mean (Standard Deviation)	**6.0 (18.34)**

No statistical analysis provided for Extension Study: Change From Baseline in Left Ventricular End Diastolic Volume (LVEDV) at Month 12

10. Secondary: Extension Study: Change From Baseline in Left Ventricular Ejection Fraction (LVEF) at Month 12 [Time Frame: Baseline(extension study), Month 12 (extension study)]

Measure Type	Secondary
Measure Title	Extension Study: Change From Baseline in Left Ventricular Ejection Fraction (LVEF) at Month 12
Measure Description	Change from baseline to Month 12 in left ventricular ejection fraction (LVEF) (%) as measured by echocardiography. LVEF is the fraction of blood (in percent) pumped out of the heart's left ventricular chamber with each heart beat, and is a measure of cardiac output for the heart. This measurement was made by the echocardiography lab. Ejection fraction percentages > 55% are considered normal.
Time Frame	Baseline(extension study), Month 12 (extension study)
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.
Echocardiogram Analysis Set consisting of all patients in the extension population who had acceptable ECHO measurements at extension baseline and Month 12.

Reporting Groups

	Description
Aliskiren_Extension	Patients from both the arms of the core study who completed core study and signed informed consent form were included in this arm of extension study. Patients received 150 mg aliskiren tablet orally once a day for two weeks. Patients were then up-titrated to 300 mg aliskiren orally once a day at the discretion of the principal investigator based on their clinical condition for the duration of the study.

Measured Values

	Aliskiren_Extension

Number of Participants Analyzed [units: participants]	**302**
Extension Study: Change From Baseline in Left Ventricular Ejection Fraction (LVEF) at Month 12 [units: percent of blood pumped from LV chamber] Mean (Standard Deviation)	**7.4 (6.46)**

No statistical analysis provided for Extension Study: Change From Baseline in Left Ventricular Ejection Fraction (LVEF) at Month 12

11. Secondary: Extension Study: Percentage of Participants With Orthostatic Blood Pressure Change [Time Frame: Baseline (Day 0 Extension study), Week 2, Months 1, 3, 6, 9,16, 20, 24]

Measure Type	Secondary
Measure Title	Extension Study: Percentage of Participants With Orthostatic Blood Pressure Change
Measure Description	Orthostatic blood pressure change is defined as a decrease of at least 20 mmHg in systolic blood pressure or a decrease of at least 10 mmHg in diastolic blood pressure when a patient moves from a sitting position to a standing position. A patient could show orthostatic blood pressure change at more than one visit. End of study is Month 24 or early discontinuation.
Time Frame	Baseline (Day 0 Extension study), Week 2, Months 1, 3, 6, 9,16, 20, 24
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.
Extension population (considered as Safety population) consisted of all enrolled patients who received at least one dose of study medication in the extension study. "n" in each of the categories is the number of participants with data available at the given time-point.

Reporting Groups

	Description
Aliskiren_Extension	Patients from both the arms of the core study who completed core study and signed informed consent form were included in this arm of extension study. Patients received 150 mg aliskiren tablet orally once a day for two weeks. Patients were then up-titrated to 300 mg aliskiren orally once a day at the discretion of the principal investigator based on their clinical condition for the duration of the study.

Measured Values

	Aliskiren_Extension
Number of Participants Analyzed [units: participants]	**422**
Extension Study: Percentage of Participants With Orthostatic Blood Pressure Change [units: Percentage of Participants]	
Baseline (n=420)	**2.4**
Week 2 (n=416)	**4.6**
Month 1 (n=418)	**4.1**
Month 3 (n=410)	**4.6**
Month 6 (n=400)	**3.3**
Month 9 (n=397)	**4.3**
Month 12 (n=385)	**3.6**
Month 16 (n=383)	**5.0**

Month 20 (n=350)	**4.3**
Month 24 (n=360)	**3.6**
End of Study (n=422)	**3.8**
Any post-baseline visit (n=422)	**23.5**

No statistical analysis provided for Extension Study: Percentage of Participants With Orthostatic Blood Pressure Change

12. Secondary: Extension Study: Percentage of Participants With Specified Criteria in Selected Labs by Laboratory Parameter [Time Frame: 24 Months]

Measure Type	Secondary
Measure Title	Extension Study: Percentage of Participants With Specified Criteria in Selected Labs by Laboratory Parameter
Measure Description	Fasting blood samples were collected throughout the study and were analyzed at a central laboratory. Percentage of participants with the following clinically significant laboratory values are reported: Potassium <3.5 mmol/L; Low value (Normal reference range: 3.5- 5.3) Potassium >5.5 mmol/L and Potassium >6.0 mmol/L; High values (Normal reference range: 3.5-5.3) Creatinine >176.8 µmol/L; High value (Normal reference range= Male: 62- 106 and Female 44- 80) Blood Urea Nitrogen (BUN) >14.28; High value (Normal reference range: 2.1- 8.9)
Time Frame	24 Months
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.
Extension population (considered as Safety population) consisted of all enrolled patients who received at least one dose of study medication in the extension study. "n" in each of the categories is the number of participants with data available at the given time-point.

Reporting Groups

	Description
Aliskiren_Extension	Patients from both the arms of the core study who completed core study and signed informed consent form were included in this arm of extension study. Patients received 150 mg aliskiren tablet orally once a day for two weeks. Patients were then up-titrated to 300 mg aliskiren orally once a day at the discretion of the principal investigator based on their clinical condition for the duration of the study.

Measured Values

	Aliskiren_Extension
Number of Participants Analyzed [units: participants]	**422**
Extension Study: Percentage of Participants With Specified Criteria in Selected Labs by Laboratory Parameter [units: Percentage of participants]	
Potassium <3.5 mmol/L (n=409)	**1.5**
Potassium >5.5 mmol/L (n=409)	**11.2**
Potassium ≥6.0 mmol/L (n=409)	**4.6**
Creatinine >176.8 µmol/L (n=412)	**4.4**
BUN >14.28 mmol/L (n=412)	**8.7**

No statistical analysis provided for Extension Study: Percentage of Participants With Specified Criteria in Selected Labs by Laboratory Parameter

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	No text entered.
Additional Description	Core Safety population: All patients that received at least one dose of study drug. Extension Safety Population: All enrolled patients who received at least one dose of study medication in the extension study. Extension study enrolled patients from both the arms of core who complete core study and signed an informed consent form.

Reporting Groups

	Description
Placebo_core	Placebo for 36 weeks once daily in the morning
Aliskiren_core	Aliskiren ascending doses: 75 mg tablet for 1st week, 150 mg for 2nd week, 300 mg for the next 34 weeks orally once daily in the morning.
Aliskiren_extension	Patients from both the arms of the core study who completed core study and signed informed consent form were included in this arm of extension study. Patients received 150 mg aliskiren tablet orally once a day for two weeks. Patients were then up-titrated to 300 mg aliskiren orally once a day at the discretion of the principal investigator based on their clinical condition for the duration of the study.

Serious Adverse Events

	Placebo_core	Aliskiren_core	Aliskiren_extension
Total, serious adverse events			
# participants affected / at risk	**92/397 (23.17%)**	**107/422 (25.36%)**	**126/422 (29.86%)**
Blood and lymphatic system disorders			
Anaemia † 1			
# participants affected / at risk	**0/397 (0.00%)**	**4/422 (0.95%)**	**0/422 (0.00%)**
Haemorrhagic anaemia † 1			
# participants affected / at risk	**0/397 (0.00%)**	**0/422 (0.00%)**	**1/422 (0.24%)**
Cardiac disorders			
Acute coronary syndrome † 1			
# participants affected / at risk	**2/397 (0.50%)**	**3/422 (0.71%)**	**3/422 (0.71%)**
Acute myocardial infarction † 1			
# participants affected / at risk	**4/397 (1.01%)**	**6/422 (1.42%)**	**6/422 (1.42%)**
Angina pectoris † 1			
# participants affected / at risk	**15/397 (3.78%)**	**13/422 (3.08%)**	**15/422 (3.55%)**
Angina unstable † 1			
# participants affected / at risk	**8/397 (2.02%)**	**9/422 (2.13%)**	**4/422 (0.95%)**
Arrhythmia † 1			
# participants affected / at risk	**2/397 (0.50%)**	**0/422 (0.00%)**	**0/422 (0.00%)**
Arteriospasm coronary † 1			
# participants affected / at risk	**0/397 (0.00%)**	**0/422 (0.00%)**	**1/422 (0.24%)**

Atrial fibrillation † 1			
# participants affected / at risk	**1/397 (0.25%)**	**4/422 (0.95%)**	**3/422 (0.71%)**
Atrioventricular block complete † 1			
# participants affected / at risk	**1/397 (0.25%)**	**0/422 (0.00%)**	**0/422 (0.00%)**
Bradycardia † 1			
# participants affected / at risk	**1/397 (0.25%)**	**2/422 (0.47%)**	**0/422 (0.00%)**
Cardiac arrest † 1			
# participants affected / at risk	**2/397 (0.50%)**	**2/422 (0.47%)**	**2/422 (0.47%)**
Cardiac failure † 1			
# participants affected / at risk	**14/397 (3.53%)**	**18/422 (4.27%)**	**9/422 (2.13%)**
Cardiac failure acute † 1			
# participants affected / at risk	**2/397 (0.50%)**	**0/422 (0.00%)**	**0/422 (0.00%)**
Cardiac failure chronic † 1			
# participants affected / at risk	**1/397 (0.25%)**	**0/422 (0.00%)**	**5/422 (1.18%)**
Cardiac failure congestive † 1			
# participants affected / at risk	**4/397 (1.01%)**	**3/422 (0.71%)**	**1/422 (0.24%)**
Cardio-respiratory arrest † 1			
# participants affected / at risk	**1/397 (0.25%)**	**0/422 (0.00%)**	**1/422 (0.24%)**
Cardiopulmonary failure † 1			
# participants affected / at risk	**0/397 (0.00%)**	**0/422 (0.00%)**	**1/422 (0.24%)**
Coronary artery disease † 1			
# participants affected / at risk	**2/397 (0.50%)**	**0/422 (0.00%)**	**2/422 (0.47%)**
Coronary artery insufficiency † 1			
# participants affected / at risk	**0/397 (0.00%)**	**1/422 (0.24%)**	**0/422 (0.00%)**
Coronary artery stenosis † 1			
# participants affected / at risk	**4/397 (1.01%)**	**1/422 (0.24%)**	**2/422 (0.47%)**
Ischaemic cardiomyopathy † 1			
# participants affected / at risk	**0/397 (0.00%)**	**1/422 (0.24%)**	**1/422 (0.24%)**
Left ventricular failure † 1			
# participants affected / at risk	**0/397 (0.00%)**	**1/422 (0.24%)**	**0/422 (0.00%)**
Myocardial infarction † 1			
# participants affected / at risk	**5/397 (1.26%)**	**7/422 (1.66%)**	**6/422 (1.42%)**
Myocardial ischaemia † 1			
# participants affected / at risk	**2/397 (0.50%)**	**1/422 (0.24%)**	**2/422 (0.47%)**
Pericarditis † 1			
# participants affected / at risk	**1/397 (0.25%)**	**0/422 (0.00%)**	**0/422 (0.00%)**
Ventricular arrhythmia † 1			
# participants affected / at risk	**0/397 (0.00%)**	**1/422 (0.24%)**	**0/422 (0.00%)**
Ventricular extrasystoles † 1			
# participants affected / at risk	**1/397 (0.25%)**	**0/422 (0.00%)**	**0/422 (0.00%)**
Ventricular fibrillation † 1			
# participants affected / at risk	**1/397 (0.25%)**	**2/422 (0.47%)**	**0/422 (0.00%)**
Ventricular tachycardia † 1			
# participants affected / at risk	**2/397 (0.50%)**	**0/422 (0.00%)**	**1/422 (0.24%)**

Ear and labyrinth disorders			
Vertigo † 1			
# participants affected / at risk	**1/397 (0.25%)**	**0/422 (0.00%)**	**0/422 (0.00%)**
Eye disorders			
Cataract † 1			
# participants affected / at risk	**0/397 (0.00%)**	**1/422 (0.24%)**	**1/422 (0.24%)**
Gastrointestinal disorders			
Abdominal hernia † 1			
# participants affected / at risk	**0/397 (0.00%)**	**0/422 (0.00%)**	**1/422 (0.24%)**
Abdominal pain † 1			
# participants affected / at risk	**1/397 (0.25%)**	**1/422 (0.24%)**	**0/422 (0.00%)**
Abdominal pain upper † 1			
# participants affected / at risk	**0/397 (0.00%)**	**1/422 (0.24%)**	**0/422 (0.00%)**
Abdominal tenderness † 1			
# participants affected / at risk	**0/397 (0.00%)**	**0/422 (0.00%)**	**1/422 (0.24%)**
Chronic gastrointestinal bleeding † 1			
# participants affected / at risk	**0/397 (0.00%)**	**0/422 (0.00%)**	**1/422 (0.24%)**
Colitis † 1			
# participants affected / at risk	**1/397 (0.25%)**	**0/422 (0.00%)**	**0/422 (0.00%)**
Dental caries † 1			
# participants affected / at risk	**1/397 (0.25%)**	**0/422 (0.00%)**	**0/422 (0.00%)**
Diarrhoea † 1			
# participants affected / at risk	**1/397 (0.25%)**	**1/422 (0.24%)**	**0/422 (0.00%)**
Duodenal ulcer perforation † 1			
# participants affected / at risk	**0/397 (0.00%)**	**0/422 (0.00%)**	**1/422 (0.24%)**
Gastric haemorrhage † 1			
# participants affected / at risk	**0/397 (0.00%)**	**1/422 (0.24%)**	**0/422 (0.00%)**
Gastric ulcer † 1			
# participants affected / at risk	**0/397 (0.00%)**	**1/422 (0.24%)**	**0/422 (0.00%)**
Gastrointestinal obstruction † 1			
# participants affected / at risk	**0/397 (0.00%)**	**0/422 (0.00%)**	**1/422 (0.24%)**
Inguinal hernia, obstructive † 1			
# participants affected / at risk	**0/397 (0.00%)**	**0/422 (0.00%)**	**1/422 (0.24%)**
Mouth haemorrhage † 1			
# participants affected / at risk	**1/397 (0.25%)**	**0/422 (0.00%)**	**0/422 (0.00%)**
Nausea † 1			
# participants affected / at risk	**0/397 (0.00%)**	**1/422 (0.24%)**	**1/422 (0.24%)**
Pancreatitis † 1			
# participants affected / at risk	**1/397 (0.25%)**	**0/422 (0.00%)**	**0/422 (0.00%)**
Pancreatitis acute † 1			
# participants affected / at risk	**0/397 (0.00%)**	**1/422 (0.24%)**	**0/422 (0.00%)**
Peritonitis † 1			
# participants affected / at risk	**0/397 (0.00%)**	**0/422 (0.00%)**	**1/422 (0.24%)**
Rectal haemorrhage † 1			

# participants affected / at risk	0/397 (0.00%)	0/422 (0.00%)	1/422 (0.24%)
Upper gastrointestinal haemorrhage † 1			
# participants affected / at risk	0/397 (0.00%)	1/422 (0.24%)	0/422 (0.00%)
Vomiting † 1			
# participants affected / at risk	1/397 (0.25%)	0/422 (0.00%)	0/422 (0.00%)
General disorders			
Apparent death † 1			
# participants affected / at risk	2/397 (0.50%)	0/422 (0.00%)	0/422 (0.00%)
Asthenia † 1			
# participants affected / at risk	0/397 (0.00%)	1/422 (0.24%)	0/422 (0.00%)
Chest pain † 1			
# participants affected / at risk	0/397 (0.00%)	2/422 (0.47%)	1/422 (0.24%)
Death † 1			
# participants affected / at risk	0/397 (0.00%)	1/422 (0.24%)	0/422 (0.00%)
Device failure † 1			
# participants affected / at risk	0/397 (0.00%)	0/422 (0.00%)	1/422 (0.24%)
Generalised oedema † 1			
# participants affected / at risk	1/397 (0.25%)	0/422 (0.00%)	0/422 (0.00%)
Impaired healing † 1			
# participants affected / at risk	0/397 (0.00%)	1/422 (0.24%)	0/422 (0.00%)
Malaise † 1			
# participants affected / at risk	1/397 (0.25%)	0/422 (0.00%)	0/422 (0.00%)
Multi-organ failure † 1			
# participants affected / at risk	0/397 (0.00%)	0/422 (0.00%)	1/422 (0.24%)
Non-cardiac chest pain † 1			
# participants affected / at risk	6/397 (1.51%)	7/422 (1.66%)	7/422 (1.66%)
Oedema peripheral † 1			
# participants affected / at risk	0/397 (0.00%)	1/422 (0.24%)	0/422 (0.00%)
Pyrexia † 1			
# participants affected / at risk	2/397 (0.50%)	0/422 (0.00%)	1/422 (0.24%)
Sudden cardiac death † 1			
# participants affected / at risk	0/397 (0.00%)	2/422 (0.47%)	0/422 (0.00%)
Sudden death † 1			
# participants affected / at risk	1/397 (0.25%)	2/422 (0.47%)	4/422 (0.95%)
Thrombosis in device † 1			
# participants affected / at risk	0/397 (0.00%)	0/422 (0.00%)	2/422 (0.47%)
Vessel puncture site haematoma † 1			
# participants affected / at risk	1/397 (0.25%)	0/422 (0.00%)	0/422 (0.00%)
Hepatobiliary disorders			
Bile duct stone † 1			
# participants affected / at risk	1/397 (0.25%)	0/422 (0.00%)	0/422 (0.00%)
Cholangitis † 1			
# participants affected / at risk	0/397 (0.00%)	0/422 (0.00%)	1/422 (0.24%)
Cholecystitis acute † 1			

# participants affected / at risk	1/397 (0.25%)	0/422 (0.00%)	0/422 (0.00%)
Cholelithiasis † 1			
# participants affected / at risk	2/397 (0.50%)	1/422 (0.24%)	0/422 (0.00%)
Hepatic function abnormal † 1			
# participants affected / at risk	1/397 (0.25%)	0/422 (0.00%)	0/422 (0.00%)
Infections and infestations			
Appendicitis † 1			
# participants affected / at risk	0/397 (0.00%)	0/422 (0.00%)	1/422 (0.24%)
Bronchitis † 1			
# participants affected / at risk	0/397 (0.00%)	1/422 (0.24%)	0/422 (0.00%)
Cellulitis † 1			
# participants affected / at risk	2/397 (0.50%)	1/422 (0.24%)	0/422 (0.00%)
Enterococcal infection † 1			
# participants affected / at risk	1/397 (0.25%)	0/422 (0.00%)	0/422 (0.00%)
Febrile infection † 1			
# participants affected / at risk	0/397 (0.00%)	1/422 (0.24%)	0/422 (0.00%)
Gangrene † 1			
# participants affected / at risk	1/397 (0.25%)	1/422 (0.24%)	0/422 (0.00%)
Gastroenteritis † 1			
# participants affected / at risk	1/397 (0.25%)	1/422 (0.24%)	1/422 (0.24%)
Gastroenteritis norovirus † 1			
# participants affected / at risk	1/397 (0.25%)	0/422 (0.00%)	0/422 (0.00%)
Nasopharyngitis † 1			
# participants affected / at risk	0/397 (0.00%)	1/422 (0.24%)	0/422 (0.00%)
Peritoneal abscess † 1			
# participants affected / at risk	0/397 (0.00%)	0/422 (0.00%)	1/422 (0.24%)
Pneumonia † 1			
# participants affected / at risk	5/397 (1.26%)	7/422 (1.66%)	3/422 (0.71%)
Pyelonephritis † 1			
# participants affected / at risk	1/397 (0.25%)	0/422 (0.00%)	0/422 (0.00%)
Respiratory tract infection † 1			
# participants affected / at risk	1/397 (0.25%)	1/422 (0.24%)	0/422 (0.00%)
Scrotal abscess † 1			
# participants affected / at risk	1/397 (0.25%)	0/422 (0.00%)	0/422 (0.00%)
Sepsis † 1			
# participants affected / at risk	0/397 (0.00%)	2/422 (0.47%)	0/422 (0.00%)
Urinary tract infection † 1			
# participants affected / at risk	1/397 (0.25%)	0/422 (0.00%)	2/422 (0.47%)
Injury, poisoning and procedural complications			
Accidental overdose † 1			
# participants affected / at risk	0/397 (0.00%)	1/422 (0.24%)	0/422 (0.00%)
Ankle fracture † 1			
# participants affected / at risk	0/397 (0.00%)	0/422 (0.00%)	1/422 (0.24%)
Coronary artery restenosis † 1			

# participants affected / at risk	0/397 (0.00%)	2/422 (0.47%)	0/422 (0.00%)
Face injury † 1			
# participants affected / at risk	0/397 (0.00%)	0/422 (0.00%)	1/422 (0.24%)
Fall † 1			
# participants affected / at risk	1/397 (0.25%)	1/422 (0.24%)	0/422 (0.00%)
Femoral neck fracture † 1			
# participants affected / at risk	1/397 (0.25%)	0/422 (0.00%)	0/422 (0.00%)
Graft thrombosis † 1			
# participants affected / at risk	0/397 (0.00%)	0/422 (0.00%)	1/422 (0.24%)
Hip fracture † 1			
# participants affected / at risk	0/397 (0.00%)	0/422 (0.00%)	1/422 (0.24%)
Implantable defibrillator malfunction † 1			
# participants affected / at risk	1/397 (0.25%)	0/422 (0.00%)	0/422 (0.00%)
In-stent coronary artery restenosis † 1			
# participants affected / at risk	2/397 (0.50%)	2/422 (0.47%)	2/422 (0.47%)
Joint sprain † 1			
# participants affected / at risk	0/397 (0.00%)	1/422 (0.24%)	0/422 (0.00%)
Laceration † 1			
# participants affected / at risk	0/397 (0.00%)	0/422 (0.00%)	1/422 (0.24%)
Lower limb fracture † 1			
# participants affected / at risk	0/397 (0.00%)	0/422 (0.00%)	1/422 (0.24%)
Medical device complication † 1			
# participants affected / at risk	0/397 (0.00%)	1/422 (0.24%)	0/422 (0.00%)
Post procedural haemorrhage † 1			
# participants affected / at risk	1/397 (0.25%)	0/422 (0.00%)	0/422 (0.00%)
Radius fracture † 1			
# participants affected / at risk	0/397 (0.00%)	0/422 (0.00%)	1/422 (0.24%)
Tendon rupture † 1			
# participants affected / at risk	0/397 (0.00%)	0/422 (0.00%)	1/422 (0.24%)
Thrombosis in device † 1			
# participants affected / at risk	0/397 (0.00%)	1/422 (0.24%)	0/422 (0.00%)
Tibia fracture † 1			
# participants affected / at risk	0/397 (0.00%)	1/422 (0.24%)	0/422 (0.00%)
Upper limb fracture † 1			
# participants affected / at risk	1/397 (0.25%)	1/422 (0.24%)	0/422 (0.00%)
Investigations			
Aspartate aminotransferase increased † 1			
# participants affected / at risk	0/397 (0.00%)	0/422 (0.00%)	1/422 (0.24%)
Blood creatinine increased † 1			
# participants affected / at risk	0/397 (0.00%)	0/422 (0.00%)	2/422 (0.47%)
Blood potassium increased † 1			
# participants affected / at risk	0/397 (0.00%)	0/422 (0.00%)	1/422 (0.24%)
Blood pressure decreased † 1			
# participants affected / at risk	0/397 (0.00%)	1/422 (0.24%)	0/422 (0.00%)

Ejection fraction decreased † 1			
# participants affected / at risk	**2/397 (0.50%)**	**0/422 (0.00%)**	**0/422 (0.00%)**
Electrocardiogram QRS complex prolonged † 1			
# participants affected / at risk	**1/397 (0.25%)**	**0/422 (0.00%)**	**0/422 (0.00%)**
Renal function test abnormal † 1			
# participants affected / at risk	**0/397 (0.00%)**	**0/422 (0.00%)**	**1/422 (0.24%)**
Venous pressure jugular increased † 1			
# participants affected / at risk	**0/397 (0.00%)**	**1/422 (0.24%)**	**0/422 (0.00%)**
Weight decreased † 1			
# participants affected / at risk	**0/397 (0.00%)**	**1/422 (0.24%)**	**0/422 (0.00%)**
Metabolism and nutrition disorders			
Decreased appetite † 1			
# participants affected / at risk	**0/397 (0.00%)**	**1/422 (0.24%)**	**0/422 (0.00%)**
Dehydration † 1			
# participants affected / at risk	**0/397 (0.00%)**	**0/422 (0.00%)**	**1/422 (0.24%)**
Diabetes mellitus † 1			
# participants affected / at risk	**0/397 (0.00%)**	**0/422 (0.00%)**	**1/422 (0.24%)**
Electrolyte imbalance † 1			
# participants affected / at risk	**1/397 (0.25%)**	**0/422 (0.00%)**	**0/422 (0.00%)**
Hypoglycaemia † 1			
# participants affected / at risk	**2/397 (0.50%)**	**1/422 (0.24%)**	**2/422 (0.47%)**
Hypophagia † 1			
# participants affected / at risk	**1/397 (0.25%)**	**0/422 (0.00%)**	**0/422 (0.00%)**
Musculoskeletal and connective tissue disorders			
Arthralgia † 1			
# participants affected / at risk	**0/397 (0.00%)**	**1/422 (0.24%)**	**0/422 (0.00%)**
Back pain † 1			
# participants affected / at risk	**0/397 (0.00%)**	**0/422 (0.00%)**	**2/422 (0.47%)**
Fibromyalgia † 1			
# participants affected / at risk	**1/397 (0.25%)**	**0/422 (0.00%)**	**0/422 (0.00%)**
Gouty arthritis † 1			
# participants affected / at risk	**0/397 (0.00%)**	**0/422 (0.00%)**	**1/422 (0.24%)**
Intervertebral disc protrusion † 1			
# participants affected / at risk	**0/397 (0.00%)**	**0/422 (0.00%)**	**1/422 (0.24%)**
Muscular weakness † 1			
# participants affected / at risk	**0/397 (0.00%)**	**0/422 (0.00%)**	**1/422 (0.24%)**
Musculoskeletal chest pain † 1			
# participants affected / at risk	**1/397 (0.25%)**	**0/422 (0.00%)**	**2/422 (0.47%)**
Musculoskeletal pain † 1			
# participants affected / at risk	**1/397 (0.25%)**	**1/422 (0.24%)**	**1/422 (0.24%)**
Pain in extremity † 1			
# participants affected / at risk	**1/397 (0.25%)**	**0/422 (0.00%)**	**0/422 (0.00%)**
Rhabdomyolysis † 1			
# participants affected / at risk	**0/397 (0.00%)**	**0/422 (0.00%)**	**1/422 (0.24%)**

Rheumatoid arthritis † 1			
# participants affected / at risk	**0/397 (0.00%)**	**0/422 (0.00%)**	**1/422 (0.24%)**
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Basal cell carcinoma † 1			
# participants affected / at risk	**0/397 (0.00%)**	**1/422 (0.24%)**	**0/422 (0.00%)**
Benign neoplasm of skin † 1			
# participants affected / at risk	**0/397 (0.00%)**	**0/422 (0.00%)**	**1/422 (0.24%)**
Bile duct cancer † 1			
# participants affected / at risk	**1/397 (0.25%)**	**0/422 (0.00%)**	**0/422 (0.00%)**
Brain cancer metastatic † 1			
# participants affected / at risk	**1/397 (0.25%)**	**0/422 (0.00%)**	**0/422 (0.00%)**
Brain neoplasm malignant † 1			
# participants affected / at risk	**0/397 (0.00%)**	**0/422 (0.00%)**	**1/422 (0.24%)**
Bronchial carcinoma † 1			
# participants affected / at risk	**0/397 (0.00%)**	**1/422 (0.24%)**	**0/422 (0.00%)**
Carcinoid tumour of the pancreas † 1			
# participants affected / at risk	**0/397 (0.00%)**	**1/422 (0.24%)**	**0/422 (0.00%)**
Colon cancer † 1			
# participants affected / at risk	**0/397 (0.00%)**	**0/422 (0.00%)**	**1/422 (0.24%)**
Gastric cancer † 1			
# participants affected / at risk	**0/397 (0.00%)**	**1/422 (0.24%)**	**1/422 (0.24%)**
Leukaemia † 1			
# participants affected / at risk	**0/397 (0.00%)**	**0/422 (0.00%)**	**1/422 (0.24%)**
Lung neoplasm † 1			
# participants affected / at risk	**0/397 (0.00%)**	**0/422 (0.00%)**	**2/422 (0.47%)**
Lung neoplasm malignant † 1			
# participants affected / at risk	**0/397 (0.00%)**	**1/422 (0.24%)**	**1/422 (0.24%)**
Metastatic neoplasm † 1			
# participants affected / at risk	**0/397 (0.00%)**	**0/422 (0.00%)**	**1/422 (0.24%)**
Myeloproliferative disorder † 1			
# participants affected / at risk	**0/397 (0.00%)**	**0/422 (0.00%)**	**1/422 (0.24%)**
Ovarian cancer † 1			
# participants affected / at risk	**0/397 (0.00%)**	**0/422 (0.00%)**	**1/422 (0.24%)**
Plasmacytoma † 1			
# participants affected / at risk	**0/397 (0.00%)**	**0/422 (0.00%)**	**1/422 (0.24%)**
Renal cancer † 1			
# participants affected / at risk	**0/397 (0.00%)**	**1/422 (0.24%)**	**0/422 (0.00%)**
Small cell lung cancer stage unspecified † 1			
# participants affected / at risk	**0/397 (0.00%)**	**1/422 (0.24%)**	**0/422 (0.00%)**
Nervous system disorders			
Balance disorder † 1			
# participants affected / at risk	**0/397 (0.00%)**	**1/422 (0.24%)**	**0/422 (0.00%)**
Basilar artery occlusion † 1			

# participants affected / at risk	0/397 (0.00%)	0/422 (0.00%)	1/422 (0.24%)
Brain stem infarction † 1			
# participants affected / at risk	0/397 (0.00%)	0/422 (0.00%)	1/422 (0.24%)
Carotid artery stenosis † 1			
# participants affected / at risk	0/397 (0.00%)	0/422 (0.00%)	1/422 (0.24%)
Cerebral haemorrhage † 1			
# participants affected / at risk	0/397 (0.00%)	1/422 (0.24%)	0/422 (0.00%)
Cerebral infarction † 1			
# participants affected / at risk	0/397 (0.00%)	0/422 (0.00%)	1/422 (0.24%)
Cerebral ischaemia † 1			
# participants affected / at risk	0/397 (0.00%)	0/422 (0.00%)	2/422 (0.47%)
Cerebral microangiopathy † 1			
# participants affected / at risk	1/397 (0.25%)	0/422 (0.00%)	0/422 (0.00%)
Cerebrovascular accident † 1			
# participants affected / at risk	0/397 (0.00%)	5/422 (1.18%)	5/422 (1.18%)
Dizziness † 1			
# participants affected / at risk	1/397 (0.25%)	2/422 (0.47%)	1/422 (0.24%)
Encephalomalacia † 1			
# participants affected / at risk	0/397 (0.00%)	0/422 (0.00%)	1/422 (0.24%)
Hypoaesthesia † 1			
# participants affected / at risk	1/397 (0.25%)	0/422 (0.00%)	0/422 (0.00%)
Intercostal neuralgia † 1			
# participants affected / at risk	0/397 (0.00%)	1/422 (0.24%)	0/422 (0.00%)
Ischaemic stroke † 1			
# participants affected / at risk	1/397 (0.25%)	2/422 (0.47%)	0/422 (0.00%)
Loss of consciousness † 1			
# participants affected / at risk	0/397 (0.00%)	1/422 (0.24%)	0/422 (0.00%)
Parkinsonism † 1			
# participants affected / at risk	0/397 (0.00%)	1/422 (0.24%)	0/422 (0.00%)
Presyncope † 1			
# participants affected / at risk	0/397 (0.00%)	1/422 (0.24%)	0/422 (0.00%)
Sciatica † 1			
# participants affected / at risk	1/397 (0.25%)	1/422 (0.24%)	0/422 (0.00%)
Syncope † 1			
# participants affected / at risk	2/397 (0.50%)	2/422 (0.47%)	6/422 (1.42%)
Transient ischaemic attack † 1			
# participants affected / at risk	0/397 (0.00%)	1/422 (0.24%)	3/422 (0.71%)
Psychiatric disorders			
Anxiety † 1			
# participants affected / at risk	2/397 (0.50%)	0/422 (0.00%)	0/422 (0.00%)
Confusional state † 1			
# participants affected / at risk	0/397 (0.00%)	0/422 (0.00%)	1/422 (0.24%)
Depression † 1			
# participants affected / at risk	0/397 (0.00%)	2/422 (0.47%)	0/422 (0.00%)

Renal and urinary disorders			
Calculus urinary † 1			
# participants affected / at risk	**0/397 (0.00%)**	**1/422 (0.24%)**	**0/422 (0.00%)**
Haematuria † 1			
# participants affected / at risk	**0/397 (0.00%)**	**1/422 (0.24%)**	**1/422 (0.24%)**
Hydronephrosis † 1			
# participants affected / at risk	**0/397 (0.00%)**	**1/422 (0.24%)**	**0/422 (0.00%)**
Nephrolithiasis † 1			
# participants affected / at risk	**0/397 (0.00%)**	**1/422 (0.24%)**	**0/422 (0.00%)**
Nephropathy toxic † 1			
# participants affected / at risk	**0/397 (0.00%)**	**0/422 (0.00%)**	**1/422 (0.24%)**
Nephrotic syndrome † 1			
# participants affected / at risk	**0/397 (0.00%)**	**0/422 (0.00%)**	**1/422 (0.24%)**
Renal failure † 1			
# participants affected / at risk	**1/397 (0.25%)**	**2/422 (0.47%)**	**1/422 (0.24%)**
Renal failure acute † 1			
# participants affected / at risk	**1/397 (0.25%)**	**1/422 (0.24%)**	**1/422 (0.24%)**
Reproductive system and breast disorders			
Epididymitis † 1			
# participants affected / at risk	**1/397 (0.25%)**	**0/422 (0.00%)**	**0/422 (0.00%)**
Metrorrhagia † 1			
# participants affected / at risk	**0/397 (0.00%)**	**0/422 (0.00%)**	**1/422 (0.24%)**
Respiratory, thoracic and mediastinal disorders			
Acute pulmonary oedema † 1			
# participants affected / at risk	**4/397 (1.01%)**	**2/422 (0.47%)**	**1/422 (0.24%)**
Chronic obstructive pulmonary disease † 1			
# participants affected / at risk	**1/397 (0.25%)**	**1/422 (0.24%)**	**2/422 (0.47%)**
Cough † 1			
# participants affected / at risk	**1/397 (0.25%)**	**0/422 (0.00%)**	**0/422 (0.00%)**
Dyspnoea † 1			
# participants affected / at risk	**4/397 (1.01%)**	**4/422 (0.95%)**	**2/422 (0.47%)**
Dyspnoea exertional † 1			
# participants affected / at risk	**1/397 (0.25%)**	**0/422 (0.00%)**	**0/422 (0.00%)**
Haemoptysis † 1			
# participants affected / at risk	**1/397 (0.25%)**	**0/422 (0.00%)**	**0/422 (0.00%)**
Hydrothorax † 1			
# participants affected / at risk	**0/397 (0.00%)**	**1/422 (0.24%)**	**0/422 (0.00%)**
Hypercapnia † 1			
# participants affected / at risk	**1/397 (0.25%)**	**0/422 (0.00%)**	**0/422 (0.00%)**
Hyperventilation † 1			
# participants affected / at risk	**1/397 (0.25%)**	**0/422 (0.00%)**	**0/422 (0.00%)**
Pleural effusion † 1			
# participants affected / at risk	**0/397 (0.00%)**	**0/422 (0.00%)**	**1/422 (0.24%)**
Pneumonia aspiration † 1			

# participants affected / at risk	1/397 (0.25%)	0/422 (0.00%)	0/422 (0.00%)
Pneumothorax † 1			
# participants affected / at risk	0/397 (0.00%)	0/422 (0.00%)	1/422 (0.24%)
Pulmonary congestion † 1			
# participants affected / at risk	1/397 (0.25%)	0/422 (0.00%)	0/422 (0.00%)
Pulmonary embolism † 1			
# participants affected / at risk	0/397 (0.00%)	0/422 (0.00%)	2/422 (0.47%)
Pulmonary mass † 1			
# participants affected / at risk	1/397 (0.25%)	0/422 (0.00%)	0/422 (0.00%)
Pulmonary oedema † 1			
# participants affected / at risk	2/397 (0.50%)	4/422 (0.95%)	3/422 (0.71%)
Respiratory failure † 1			
# participants affected / at risk	1/397 (0.25%)	1/422 (0.24%)	1/422 (0.24%)
Wegener's granulomatosis † 1			
# participants affected / at risk	1/397 (0.25%)	0/422 (0.00%)	0/422 (0.00%)
Skin and subcutaneous tissue disorders			
Cold sweat † 1			
# participants affected / at risk	0/397 (0.00%)	0/422 (0.00%)	1/422 (0.24%)
Hyperhidrosis † 1			
# participants affected / at risk	1/397 (0.25%)	0/422 (0.00%)	0/422 (0.00%)
Psoriasis † 1			
# participants affected / at risk	0/397 (0.00%)	0/422 (0.00%)	1/422 (0.24%)
Surgical and medical procedures			
Hospitalisation † 1			
# participants affected / at risk	0/397 (0.00%)	0/422 (0.00%)	1/422 (0.24%)
Vascular disorders			
Angiopathy † 1			
# participants affected / at risk	1/397 (0.25%)	0/422 (0.00%)	0/422 (0.00%)
Aortic aneurysm † 1			
# participants affected / at risk	0/397 (0.00%)	0/422 (0.00%)	1/422 (0.24%)
Arteriovenous fistula † 1			
# participants affected / at risk	1/397 (0.25%)	0/422 (0.00%)	0/422 (0.00%)
Deep vein thrombosis † 1			
# participants affected / at risk	0/397 (0.00%)	1/422 (0.24%)	0/422 (0.00%)
Femoral artery occlusion † 1			
# participants affected / at risk	0/397 (0.00%)	0/422 (0.00%)	1/422 (0.24%)
Haematoma † 1			
# participants affected / at risk	1/397 (0.25%)	0/422 (0.00%)	0/422 (0.00%)
Hypertension † 1			
# participants affected / at risk	0/397 (0.00%)	1/422 (0.24%)	0/422 (0.00%)
Hypertensive crisis † 1			
# participants affected / at risk	1/397 (0.25%)	1/422 (0.24%)	0/422 (0.00%)
Hypotension † 1			
# participants affected / at risk	3/397 (0.76%)	1/422 (0.24%)	3/422 (0.71%)

Intermittent claudication † 1			
# participants affected / at risk	**1/397 (0.25%)**	**0/422 (0.00%)**	**1/422 (0.24%)**
Peripheral vascular disorder † 1			
# participants affected / at risk	**0/397 (0.00%)**	**0/422 (0.00%)**	**1/422 (0.24%)**

† 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	Core Safety population: All patients that received at least one dose of study drug. Extension Safety Population: All enrolled patients who received at least one dose of study medication in the extension study. Extension study enrolled patients from both the arms of core who complete core study and signed an informed consent form.

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
Placebo_core	Placebo for 36 weeks once daily in the morning
Aliskiren_core	Aliskiren ascending doses: 75 mg tablet for 1st week, 150 mg for 2nd week, 300 mg for the next 34 weeks orally once daily in the morning.
Aliskiren_extension	Patients from both the arms of the core study who completed core study and signed informed consent form were included in this arm of extension study. Patients received 150 mg aliskiren tablet orally once a day for two weeks. Patients were then up-titrated to 300 mg aliskiren orally once a day at the discretion of the principal investigator based on their clinical condition for the duration of the study.

Other Adverse Events

	Placebo_core	**Aliskiren_core**	**Aliskiren_extension**
Total, other (not including serious) adverse events			
# participants affected / at risk	**118/397 (29.72%)**	**161/422 (38.15%)**	**123/422 (29.15%)**
Cardiac disorders			
Angina pectoris † 1			
# participants affected / at risk	**23/397 (5.79%)**	**24/422 (5.69%)**	**19/422 (4.50%)**
Cardiac failure † 1			
# participants affected / at risk	**21/397 (5.29%)**	**30/422 (7.11%)**	**7/422 (1.66%)**
General disorders			
Non-cardiac chest pain † 1			
# participants affected / at risk	**15/397 (3.78%)**	**22/422 (5.21%)**	**19/422 (4.50%)**
Infections and infestations			
Nasopharyngitis † 1			

# participants affected / at risk	**24/397 (6.05%)**	**23/422 (5.45%)**	**28/422 (6.64%)**
Metabolism and nutrition disorders			
Hyperkalaemia † 1			
# participants affected / at risk	**5/397 (1.26%)**	**22/422 (5.21%)**	**12/422 (2.84%)**
Nervous system disorders			
Dizziness † 1			
# participants affected / at risk	**15/397 (3.78%)**	**27/422 (6.40%)**	**24/422 (5.69%)**
Respiratory, thoracic and mediastinal disorders			
Cough † 1			
# participants affected / at risk	**28/397 (7.05%)**	**27/422 (6.40%)**	**15/422 (3.55%)**
Vascular disorders			
Hypotension † 1			
# participants affected / at risk	**16/397 (4.03%)**	**36/422 (8.53%)**	**41/422 (9.72%)**

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

Limitations and Caveats

Hide Limitations and Caveats

Limitations of the study, such as early termination leading to small numbers of participants analyzed and technical problems with measurement leading to unreliable or uninterpretable data
No text entered.

More Information

Hide More Information

Certain Agreements:

Principal Investigators are **NOT** employed by the organization sponsoring the study.

There **IS** an agreement between Principal Investigators and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.

The agreement is:

☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **less than or equal to 60 days**. The sponsor cannot require changes to the communication and cannot extend the embargo.

☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **more than 60 days but less than or equal to 180 days**. The sponsor cannot require changes to the communication and cannot extend the embargo.

Other disclosure agreement that restricts the right of the PI to discuss or publish trial results after the trial is completed.

☑ **Restriction Description:** The terms and conditions of Novartis' agreements with its investigators may vary. However, Novartis does not prohibit any investigator from publishing. Any publications from a single-site are postponed until the publication of the pooled data (i.e., data from all sites) in the clinical trial.

Results Point of Contact:

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

No publications provided by Novartis

Publications automatically indexed to this study:

Solomon SD, Shin SH, Shah A, Skali H, Desai A, Kober L, Maggioni AP, Rouleau JL, Kelly RY, Hester A, McMurray JJ, Pfeffer MA; Aliskiren Study in Post-MI Patients to Reduce Remodeling (ASPIRE) Investigators. Effect of the direct renin inhibitor aliskiren on left ventricular remodelling following myocardial infarction with systolic dysfunction. Eur Heart J. 2011 May;32(10):1227-34. doi: 10.1093/eurheartj/ehq522. Epub 2011 Feb 10.

Responsible Party:	Novartis
ClinicalTrials.gov Identifier:	NCT00414609 History of Changes
Obsolete Identifiers:	NCT00699075
Other Study ID Numbers:	**CSPP100A2340**
Study First Received:	December 19, 2006
Results First Received:	December 20, 2010
Last Updated:	July 5, 2012
Health Authority:	United States: Food and Drug Administration Argentina: Administracion Nacional de Medicamentos, Alimentos y Tecnologia Medica Belgium: Ministry of Social Affairs, Public Health and the Environment Brazil: National Health Surveillance Agency Canada: Canadian Institutes of Health Research Colombia: INVIMA Instituto Nacional de Vigilancia de Medicamentos y Alimentos Czech Republic: State Institute for Drug Control Denmark: Danish Medicines Agency Germany: Federal Institute for Drugs and Medical Devices Hungary: National Institute of Pharmacy India: Ministry of Health Israel: Israeli Health Ministry Pharmaceutical Administration Italy: The Italian Medicines Agency South Korea: Korea Food and Drug Administration (KFDA) Netherlands: Medicines Evaluation Board (MEB) Norway: Norwegian Medicines Agency Peru: General Directorate of Pharmaceuticals, Devices, and Drugs Poland: Office for Registration of Medicinal Products, Medical Devices and Biocidal Products Russia: Pharmacological Committee, Ministry of Health Slovakia: State Institute for Drug Control Spain: Spanish Agency of Medicines Sweden: Medical Products Agency Turkey: Ministry of Health United Kingdom: Medicines and Healthcare Products Regulatory Agency Venezuela: Ministry of Health and Social Development