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Trial record **1 of 1** for: CSPP100A2413

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8-week Randomized, Open-label Study to Evaluate Food Effect on Efficacy and Safety of Oral Aliskiren 300 mg in Patients With Hypertension

This study has been completed.

Sponsor:
Novartis Pharmaceuticals

Information provided by (Responsible Party):
Novartis (Novartis Pharmaceuticals)

ClinicalTrials.gov Identifier:
NCT01570686

First received: April 2, 2012
Last updated: January 15, 2014
Last verified: January 2014
History of Changes

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Results First Received: November 10, 2013

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Parallel Assignment; Masking: Open Label; Primary Purpose: Treatment
Condition:	Hypertension
Intervention:	Drug: Aliskiren

Participant Flow

Hide Participant Flow

Recruitment Details

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

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment
A total of 691 patients enrolled in the study with 590 patients randomized. 1 patient was mis-randomized and did not receive study medication, therefore 589 patients actually received study medication.

Reporting Groups

	Description
Aliskiren: Fed	Aliskiren 300 mg once daily, taken 30 minutes after start of light breakfast
Aliskiren: Fasting	Aliskiren 300 mg once daily taken after after an overnight fast

Participant Flow: Overall Study

	Aliskiren: Fed	**Aliskiren: Fasting**
STARTED	**296**	**294**
Safety and Full Analysis Set (FAS)	**295** [1]	**294**

COMPLETED	**274**	**278**
NOT COMPLETED	**22**	**16**
Abnormal test procedure result(s)	**1**	**1**
Administrative problems	**0**	**1**
Adverse Event	**8**	**6**
Lost to Follow-up	**4**	**3**
Protocol Deviation	**3**	**0**
Withdrawal by Subject	**4**	**4**
Unsatisfactory therapeutic effect	**2**	**1**

[1] One patient was mis-randomized and never received study drug. Hence not included in Safety or FAS.

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.
All Randomized patients (including one mis-randomized patient in Aliskiren:Fed arm).

Reporting Groups

	Description
Aliskiren: Fed	Aliskiren 300 mg once daily, taken 30 minutes after start of light breakfast
Aliskiren: Fasting	Aliskiren 300 mg once daily taken after after an overnight fast
Total	Total of all reporting groups

Baseline Measures

	Aliskiren: Fed	**Aliskiren: Fasting**	**Total**
Number of Participants [units: participants]	**296**	**294**	**590**
Age [units: Years] Mean (Standard Deviation)	**55.7 (10.44)**	**56.1 (11.03)**	**55.9 (10.73)**
Gender [units: Participants]			
Female	**152**	**126**	**278**
Male	**144**	**168**	**312**

Outcome Measures

Hide All Outcome Measures

1. Primary: Change From Baseline (Visit 3) to End of Study (Week 8) in Mean 24 Hour Ambulatory Systolic Blood Pressure (maSBP) [Time Frame: Baseline, week 8]

Measure Type	Primary
Measure Title	Change From Baseline (Visit 3) to End of Study (Week 8) in Mean 24 Hour Ambulatory Systolic Blood Pressure (maSBP)

Measure Description	24 hour ambulatory blood pressure measurement (ABPM) were taken twice, at baseline and at the end of 8 weeks. An Ambulatory Blood Pressure Monitoring device (ABPM) was attached to the non-dominant arm. The mean change of 24 hours maSBP from baseline to week 8 was estimated using an Analysis of Covariance (ANCOVA) model by using treatment, region as factors, and baseline as covariate.
Time Frame	Baseline, week 8
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Full Analysis Set (FAS): consisted of all randomized patients. Mis-randomized patients were excluded from the FAS. Patients with ABPM measurements at both baseline and week 8 were included in this analysis.

Reporting Groups

	Description
Aliskiren: Fed	Aliskiren 300 mg once daily, taken 30 minutes after start of light breakfast
Aliskiren: Fasting	Aliskiren 300 mg once daily taken after after an overnight fast

Measured Values

	Aliskiren: Fed	**Aliskiren: Fasting**
Number of Participants Analyzed [units: participants]	**263**	**266**
Change From Baseline (Visit 3) to End of Study (Week 8) in Mean 24 Hour Ambulatory Systolic Blood Pressure (maSBP) [units: mmHg] Least Squares Mean (Standard Error)	**-7.03 (0.50)**	**-7.79 (0.50)**

No statistical analysis provided for Change From Baseline (Visit 3) to End of Study (Week 8) in Mean 24 Hour Ambulatory Systolic Blood Pressure (maSBP)

2. Secondary: Change From Baseline (Visit 3) to End of Study (Week 8) in Mean 24 Hour Ambulatory Diastolic Blood Pressure (maDBP) [Time Frame: Baseline, week 8]

Measure Type	Secondary
Measure Title	Change From Baseline (Visit 3) to End of Study (Week 8) in Mean 24 Hour Ambulatory Diastolic Blood Pressure (maDBP)
Measure Description	24 hour ambulatory blood pressure measurement (ABPM) were taken twice, at baseline and at the end of 8 weeks. An Ambulatory Blood Pressure Monitoring device (ABPM) was attached to the non-dominant arm. The mean change of 24 hours maDBP from baseline to week 8 was estimated using an Analysis of Covariance (ANCOVA) model by using treatment, region as factors, and baseline as covariate.
Time Frame	Baseline, week 8
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Full Analysis Set (FAS): consisted of all randomized patients. Mis-randomized patients were excluded from the FAS. Patients with ABPM measurements at both baseline and week 8 were included in this analysis.

Reporting Groups

	Description
Aliskiren: Fed	Aliskiren 300 mg once daily, taken 30 minutes after start of light breakfast
Aliskiren: Fasting	Aliskiren 300 mg once daily taken after after an overnight fast

Measured Values

	Aliskiren: Fed	Aliskiren: Fasting
Number of Participants Analyzed [units: participants]	**263**	**266**
Change From Baseline (Visit 3) to End of Study (Week 8) in Mean 24 Hour Ambulatory Diastolic Blood Pressure (maDBP) [units: mmHg] Least Squares Mean (Standard Error)	**-4.01 (0.31)**	**-4.39 (0.31)**

No statistical analysis provided for Change From Baseline (Visit 3) to End of Study (Week 8) in Mean 24 Hour Ambulatory Diastolic Blood Pressure (maDBP)

3. Secondary: Percentage of Patients Achieving Blood Pressure Control [Time Frame: 8 weeks]

Measure Type	Secondary
Measure Title	Percentage of Patients Achieving Blood Pressure Control
Measure Description	Patients achieving blood pressure control were patients who, at week 8, had a mean sitting systolic blood pressure (msSBP)/ mean sitting diastolic blood pressure (msDBP) < 140/90 mmHg
Time Frame	8 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.
Full Analysis Set (FAS): consisted of all randomized patients. Mis-randomized patients were excluded from the FAS. Patients with mean sitting blood pressure measurement over 8 weeks were included in this analysis.

Reporting Groups

	Description
Aliskiren: Fed	Aliskiren 300 mg once daily, taken 30 minutes after start of light breakfast
Aliskiren: Fasting	Aliskiren 300 mg once daily taken after after an overnight fast

Measured Values

	Aliskiren: Fed	Aliskiren: Fasting
Number of Participants Analyzed [units: participants]	**293**	**294**
Percentage of Patients Achieving Blood Pressure Control [units: Percentage of patients]	**44.7**	**41.5**

No statistical analysis provided for Percentage of Patients Achieving Blood Pressure Control

4. Secondary: Change From Baseline (Visit 3) to End of Study (8 Weeks) in Mean Sitting Systolic Blood Pressure (msSBP) and Mean Sitting

Diastolic Blood Pressure (msDBP) [Time Frame: Baseline, Week 8]

Measure Type	Secondary
Measure Title	Change From Baseline (Visit 3) to End of Study (8 Weeks) in Mean Sitting Systolic Blood Pressure (msSBP) and Mean Sitting Diastolic Blood Pressure (msDBP)
Measure Description	Sitting blood pressure (BP) was measured at trough (approximately 24 hours ± 3 hours post dose) and recorded at all study visits. At the first study visit, the BP was checked in both arms and the arm with higher systolic BP (SBP) was used for all subsequent readings throughout the study. At each study visit, after the patient had been sitting for five minutes, systolic and diastolic blood pressures (msSBP and msDBP) were measured four times using a standard mercury sphygmomanometer and appropriate size cuff. The repeat sitting measurements were made at 2 minute intervals and the mean of all four sitting blood pressure measurements was used as the average sitting office blood pressure for that visit. The analysis of covariance (ANCOVA) model used treatment, region as factors, and baseline as covariate.
Time Frame	Baseline, Week 8
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Full Analysis Set (FAS): consisted of all randomized patients. Mis-randomized patients were excluded from the FAS. Patients with official mean sitting blood pressure measurements both at baseline and week 8 were icluded in this analysis.

Reporting Groups

	Description
Aliskiren: Fed	Aliskiren 300 mg once daily, taken 30 minutes after start of light breakfast
Aliskiren: Fasting	Aliskiren 300 mg once daily taken after after an overnight fast

Measured Values

	Aliskiren: Fed	**Aliskiren: Fasting**
Number of Participants Analyzed [units: participants]	**293**	**294**
Change From Baseline (Visit 3) to End of Study (8 Weeks) in Mean Sitting Systolic Blood Pressure (msSBP) and Mean Sitting Diastolic Blood Pressure (msDBP) [units: mmHg] Least Squares Mean (Standard Error)		
Mean sitting SBP (msSBP)	**-13.65 (0.85)**	**-13.98 (0.85)**
Mean sitting DBP (msDBP)	**-8.97 (0.50)**	**-8.56 (0.50)**

No statistical analysis provided for Change From Baseline (Visit 3) to End of Study (8 Weeks) in Mean Sitting Systolic Blood Pressure (msSBP) and Mean Sitting Diastolic Blood Pressure (msDBP)

5. Secondary: Percentage of Patients Achieving a Successful Response in Systolic Blood Pressure Reduction [Time Frame: Baseline, Week 8]

Measure Type	Secondary
Measure Title	Percentage of Patients Achieving a Successful Response in Systolic Blood Pressure Reduction
Measure Description	Successful response in systolic blood pressure reduction at end of 8-week treatment was defined as msSBP <140

	mmHg or a reduction in msSBP ≥ 20 mmHg from baseline.
Time Frame	Baseline, Week 8
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Full Analysis Set (FAS): consisted of all randomized patients. Mis-randomized patients were excluded from the FAS. Patients with mean sitting SBP measurement at baseline and over 8 weeks were included in this analysis.

Reporting Groups

	Description
Aliskiren: Fed	Aliskiren 300 mg once daily, taken 30 minutes after start of light breakfast
Aliskiren: Fasting	Aliskiren 300 mg once daily taken after after an overnight fast

Measured Values

	Aliskiren: Fed	**Aliskiren: Fasting**
Number of Participants Analyzed [units: participants]	**293**	**294**
Percentage of Patients Achieving a Successful Response in Systolic Blood Pressure Reduction [units: Percentage of patients]	**54.9**	**55.8**

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

6. Secondary: Pharmacokinetic (PK) of Aliskiren: The Observed Maximum Plasma Concentration (Cmax) Following Drug Administration in Fasted vs. Fed [Time Frame: Week 4 (0, 0.5, 1, 1.5, 2, 4, 6 and 24 hrs post-dose) and week 8 (0, 0.5, 1, 1.5, 2, 4, 6 and 24 hrs post-dose)]

Measure Type	Secondary
Measure Title	Pharmacokinetic (PK) of Aliskiren: The Observed Maximum Plasma Concentration (Cmax) Following Drug Administration in Fasted vs. Fed
Measure Description	Blood samples were collected at Week 4 and Week 8 in a subset of patients (approximately 15% of each treatment group) for PK analysis.
Time Frame	Week 4 (0, 0.5, 1, 1.5, 2, 4, 6 and 24 hrs post-dose) and week 8 (0, 0.5, 1, 1.5, 2, 4, 6 and 24 hrs post-dose)
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.
Pharmacokinetics set included all patients who had evaluable aliskiren concentration data with no protocol deviations that presumably affect PK results were included in the pharmacokinetic evaluations

Reporting Groups

	Description
Aliskiren: Fed	Aliskiren 300 mg once daily, taken 30 minutes after start of light breakfast
Aliskiren: Fasting	Aliskiren 300 mg once daily taken after after an overnight fast

Measured Values

	Aliskiren: Fed	Aliskiren: Fasting
Number of Participants Analyzed [units: participants]	**46**	**53**
Pharmacokinetic (PK) of Aliskiren: The Observed Maximum Plasma Concentration (Cmax) Following Drug Administration in Fasted vs. Fed [units: ng/mL] Mean (Standard Deviation)		
Week 4 (Day 28) (N= 46, 52)	**108 (153)**	**273 (276)**
Week 8 (Day 56) (N= 42, 53)	**102 (139)**	**252 (220)**

No statistical analysis provided for Pharmacokinetic (PK) of Aliskiren: The Observed Maximum Plasma Concentration (Cmax) Following Drug Administration in Fasted vs. Fed

7. Secondary: Pharmacokinetic of Aliskiren: The Area Under the Plasma Concentration-time Curve From Time Zero to the End of the Dosing Interval Tau (AUCtau) in Fasted vs. Fed [Time Frame: Week 4 (0, 0.5, 1, 1.5, 2, 4, 6 and 24 hrs post-dose) and week 8 (0, 0.5, 1, 1.5, 2, 4, 6 and 24 hrs post-dose)]

Measure Type	Secondary
Measure Title	Pharmacokinetic of Aliskiren: The Area Under the Plasma Concentration-time Curve From Time Zero to the End of the Dosing Interval Tau (AUCtau) in Fasted vs. Fed
Measure Description	Blood samples were collected at Week 4 and Week 8 in a subset of patients (approximately 15% of each treatment group) for PK analysis.
Time Frame	Week 4 (0, 0.5, 1, 1.5, 2, 4, 6 and 24 hrs post-dose) and week 8 (0, 0.5, 1, 1.5, 2, 4, 6 and 24 hrs post-dose)
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.
Pharmacokinetics set included all patients who had evaluable aliskiren concentration data with no protocol deviations that presumably affect PK results were included in the pharmacokinetic evaluations.

Reporting Groups

	Description
Aliskiren: Fed	Aliskiren 300 mg once daily, taken 30 minutes after start of light breakfast
Aliskiren: Fasting	Aliskiren 300 mg once daily taken after after an overnight fast

Measured Values

	Aliskiren: Fed	Aliskiren: Fasting
Number of Participants Analyzed [units: participants]	**46**	**53**
Pharmacokinetic of Aliskiren: The Area Under the Plasma Concentration-time Curve From Time Zero to the End of the Dosing Interval Tau (AUCtau) in Fasted vs. Fed [units: ng*h/mL] Mean (Standard Deviation)		
Week 4 (Day 28) (N= 44, 50)	**872 (603)**	**1580 (1120)**
Week 8 (Day 56) (N= 40, 51)	**1100 (1620)**	**1540 (1120)**

No statistical analysis provided for Pharmacokinetic of Aliskiren: The Area Under the Plasma Concentration-time Curve From Time Zero to the End of the Dosing Interval Tau (AUCtau) in Fasted vs. Fed

8. Secondary: Pharmacokinetic of Aliskiren: Time to Reach the Maximum Concentration (Tmax) After Drug Administration in Fasted vs. Fed [Time Frame: Week 4 (0, 0.5, 1, 1.5, 2, 4, 6 and 24 hrs post-dose) and week 8 (0, 0.5, 1, 1.5, 2, 4, 6 and 24 hrs post-dose)]

Measure Type	Secondary
Measure Title	Pharmacokinetic of Aliskiren: Time to Reach the Maximum Concentration (Tmax) After Drug Administration in Fasted vs. Fed
Measure Description	Blood samples were collected at Week 4 and Week 8 in a subset of patients (approximately 15% of each treatment group) for PK analysis.
Time Frame	Week 4 (0, 0.5, 1, 1.5, 2, 4, 6 and 24 hrs post-dose) and week 8 (0, 0.5, 1, 1.5, 2, 4, 6 and 24 hrs post-dose)
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.
Pharmacokinetics set included all patients who had evaluable aliskiren concentration data with no protocol deviations that presumably affect PK results were included in the pharmacokinetic evaluations.

Reporting Groups

	Description
Aliskiren: Fed	Aliskiren 300 mg once daily, taken 30 minutes after start of light breakfast
Aliskiren: Fasting	Aliskiren 300 mg once daily taken after after an overnight fast

Measured Values

	Aliskiren: Fed	**Aliskiren: Fasting**
Number of Participants Analyzed [units: participants]	**46**	**53**
Pharmacokinetic of Aliskiren: Time to Reach the Maximum Concentration (Tmax) After Drug Administration in Fasted vs. Fed [units: Hour] Mean (Standard Deviation)		
Week 4 (Day 28) (N=46, 52)	**2.60 (1.68)**	**1.71 (1.45)**
Week 8 (Day 56) (N= 42, 53)	**3.33 (3.71)**	**1.72 (3.32)**

No statistical analysis provided for Pharmacokinetic of Aliskiren: Time to Reach the Maximum Concentration (Tmax) After Drug Administration in Fasted vs. Fed

9. Secondary: Change From Baseline to Week 8 in Plasma Renin Activity (PRA) [Time Frame: Baseline, Week 8]

Measure Type	Secondary
Measure Title	Change From Baseline to Week 8 in Plasma Renin Activity (PRA)
Measure Description	Biomarkers related to hypertension-related pathophysiology were evaluated in this study, such as plasma renin activity (PRA) . Blood samples were taken at Visit 3 (baseline) and Visit 6 (week 8).The difference between baseline and week 8 was calculated.

Time Frame	Baseline, Week 8
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Full Analysis Set (FAS): consisted of all randomized patients. Mis-randomized patients were excluded from the FAS. Patients with both baseline and week 8 measurement for PRA are included in this analysis.

Reporting Groups

	Description
Aliskiren: Fed	Aliskiren 300 mg once daily, taken 30 minutes after start of light breakfast
Aliskiren: Fasting	Aliskiren 300 mg once daily taken after after an overnight fast

Measured Values

	Aliskiren: Fed	**Aliskiren: Fasting**
Number of Participants Analyzed [units: participants]	**42**	**47**
Change From Baseline to Week 8 in Plasma Renin Activity (PRA) [units: ng/mL/hr] Mean (Standard Deviation)	**-0.519 (1.4016)**	**-1.962 (6.7419)**

No statistical analysis provided for Change From Baseline to Week 8 in Plasma Renin Activity (PRA)

10. Secondary: Change From Baseline to Week 8 in Plasma Renin Concentration (PRC) [Time Frame: Baseline, Week 8]

Measure Type	Secondary
Measure Title	Change From Baseline to Week 8 in Plasma Renin Concentration (PRC)
Measure Description	Biomarkers related to hypertension-related pathophysiology were evaluated in this study, such as plasma renin concentration (PRC). Blood samples were taken at Visit 3 (baseline) and Visit 6 (week 8). The difference between baseline and week 8 was calculated.
Time Frame	Baseline, Week 8
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Full Analysis Set (FAS): consisted of all randomized patients. Mis-randomized patients were excluded from the FAS. Patients with both baseline and week 8 measurement for PRC are included in this analysis.

Reporting Groups

	Description
Aliskiren: Fed	Aliskiren 300 mg once daily, taken 30 minutes after start of light breakfast
Aliskiren: Fasting	Aliskiren 300 mg once daily taken after after an overnight fast

Measured Values

	Aliskiren: Fed	**Aliskiren: Fasting**
Number of Participants Analyzed		

[units: participants]	**42**	**47**
Change From Baseline to Week 8 in Plasma Renin Concentration (PRC) [units: ng/L] Mean (Standard Deviation)	**37.881 (63.4412)**	**50.967 (81.8987)**

No statistical analysis provided for Change From Baseline to Week 8 in Plasma Renin Concentration (PRC)

11. Secondary: Number of Patients With Adverse Events, Serious Adverse Events and Death [Time Frame: 8 weeks]

Measure Type	Secondary
Measure Title	Number of Patients With Adverse Events, Serious Adverse Events and Death
Measure Description	No text entered.
Time Frame	8 weeks
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.
Safety Set (SAF): consisted of all patients who received at least one dose of randomized study medication.

Reporting Groups

	Description
Aliskiren: Fed	Aliskiren 300 mg once daily, taken 30 minutes after start of light breakfast
Aliskiren: Fasting	Aliskiren 300 mg once daily taken after after an overnight fast

Measured Values

	Aliskiren: Fed	**Aliskiren: Fasting**
Number of Participants Analyzed [units: participants]	**295**	**294**
Number of Patients With Adverse Events, Serious Adverse Events and Death [units: Patients]		
Any Adverse event	**73**	**90**
Serious Adverse events	**4**	**2**
Death	**0**	**0**

No statistical analysis provided for Number of Patients With Adverse Events, Serious Adverse Events and Death

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	No text entered.
Additional Description	Safety Set (SAF): consisted of all patients who received at least one dose of randomized study medication.

Reporting Groups

	Description

Aliskiren: Fed	Aliskiren 300 mg once daily, taken 30 minutes after start of light breakfast
Aliskiren 300 mg (Fasted)	Aliskiren 300 mg once daily taken after after an overnight fast

Serious Adverse Events

	Aliskiren: Fed	Aliskiren 300 mg (Fasted)
Total, serious adverse events		
# participants affected / at risk	**4/295 (1.36%)**	**2/294 (0.68%)**
Cardiac disorders		
Coronary artery stenosis † 1		
# participants affected / at risk	**0/295 (0.00%)**	**1/294 (0.34%)**
Gastrointestinal disorders		
Gastritis † 1		
# participants affected / at risk	**1/295 (0.34%)**	**0/294 (0.00%)**
Infections and infestations		
Staphylococcal infection † 1		
# participants affected / at risk	**1/295 (0.34%)**	**0/294 (0.00%)**
Injury, poisoning and procedural complications		
Overdose † 1		
# participants affected / at risk	**1/295 (0.34%)**	**0/294 (0.00%)**
Wrist fracture † 1		
# participants affected / at risk	**0/295 (0.00%)**	**1/294 (0.34%)**
Vascular disorders		
Hypertension † 1		
# participants affected / at risk	**1/295 (0.34%)**	**0/294 (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	Safety Set (SAF): consisted of all patients who received at least one dose of randomized study medication.

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
Aliskiren: Fed	Aliskiren 300 mg once daily, taken 30 minutes after start of light breakfast
Aliskiren 300 mg (Fasted)	Aliskiren 300 mg once daily taken after after an overnight fast

Other Adverse Events

	Aliskiren: Fed	Aliskiren 300 mg (Fasted)
Total, other (not including serious) adverse events		

# participants affected / at risk	**3/295 (1.02%)**	**16/294 (5.44%)**
Gastrointestinal disorders		
Diarrhoea † 1		
# participants affected / at risk	**3/295 (1.02%)**	**16/294 (5.44%)**

† 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
e-mail: trialandresults.registries@novartis.com

No publications provided

Responsible Party:	Novartis (Novartis Pharmaceuticals)
ClinicalTrials.gov Identifier:	NCT01570686 History of Changes
Other Study ID Numbers:	**CSPP100A2413** 2011-005297-36 (EudraCT Number)
Study First Received:	April 2, 2012
Results First Received:	November 10, 2013
Last Updated:	January 15, 2014
Health Authority:	United States: Food and Drug Administration Canada: Health Products and Food Branch Europe: European Medicines Agency

Taiwan: Department of Health