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Trial record **1 of 1** for: CSPP100A2347

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Efficacy and Safety of Aliskiren and Valsartan Versus Placebo in Patients Stabilized Following an Acute Coronary Syndrome

This study has been completed.

Sponsor:
Novartis

Collaborator:
The TIMI Study Group

Information provided by:
Novartis

ClinicalTrials.gov Identifier:
NCT00409578

First received: December 7, 2006
Last updated: April 15, 2011
Last verified: April 2011
History of Changes

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

Results First Received: January 11, 2011

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Investigator, Outcomes Assessor); Primary Purpose: Treatment
Conditions:	Post Acute Coronary Syndrome Myocardial Ischemia
Interventions:	Drug: Placebo Drug: Aliskiren 300 mg Drug: Valsartan 320 mg Drug: Aliskiren/valsartan 300/320 mg

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	Placebo tablets and capsules
Aliskiren 300 mg	Following 1 week of treatment with 75 mg of aliskiren (tablets), patients in this arm were titrated up to 150 mg of aliskiren; 1 week later they were titrated up to 300 mg aliskiren for the remainder of the study.

Valsartan 320 mg	Following 1 week of treatment with 80 mg of valsartan (capsules), patients in this arm were titrated up to 160 mg of valsartan; 1 week later they were titrated up to 320 mg valsartan for the remainder of the study.
Aliskiren/Valsartan 300/320 mg	Following 1 week of treatment with 80 mg of valsartan (capsules), patients in this arm were titrated up to 160 mg of valsartan; 1 week later they were titrated up to 320 mg valsartan for the remainder of the study. Beginning with Week 4, in addition to 320 mg valsartan, patients were treated with 75 mg of aliskiren (tablets); 1 week later patients were titrated up to 150 mg of aliskiren and 1 week later they were titrated up to 300 mg aliskiren for the remainder of the study.

Participant Flow: Overall Study

	Placebo	Aliskiren 300 mg	Valsartan 320 mg	Aliskiren/Valsartan 300/320 mg
STARTED	**280**	**271**	**269**	**281**
COMPLETED	**228**	**201**	**215**	**214**
NOT COMPLETED	**52**	**70**	**54**	**67**
Adverse Event	**27**	**37**	**25**	**33**
Abnormal laboratory value(s)	**2**	**2**	**2**	**4**
Lack of Efficacy	**0**	**0**	**0**	**2**
Subject no longer requires study drug	**0**	**0**	**0**	**1**
Withdrawal by Subject	**8**	**15**	**16**	**17**
Lost to Follow-up	**2**	**0**	**2**	**2**
Administrative problems	**8**	**9**	**2**	**4**
Death	**2**	**4**	**4**	**2**
Protocol Violation	**3**	**2**	**3**	**1**
Missing	**0**	**1**	**0**	**1**

Baseline Characteristics

Hide Baseline Characteristics

Population Description

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

Reporting Groups

	Description
Placebo	Placebo tablets and capsules
Aliskiren 300 mg	Following 1 week of treatment with 75 mg of aliskiren (tablets), patients in this arm were titrated up to 150 mg of aliskiren; 1 week later they were titrated up to 300 mg aliskiren for the remainder of the study.
Valsartan 320 mg	Following 1 week of treatment with 80 mg of valsartan (capsules), patients in this arm were titrated up to 160 mg of valsartan; 1 week later they were titrated up to 320 mg valsartan for the remainder of the study.
Aliskiren/Valsartan 300/320 mg	Following 1 week of treatment with 80 mg of valsartan (capsules), patients in this arm were titrated up to 160 mg of valsartan; 1 week later they were titrated up to 320 mg valsartan for the remainder of the study. Beginning with Week 4, in addition to 320 mg valsartan, patients were treated with 75 mg of aliskiren (tablets); 1 week later patients were titrated up to 150 mg of aliskiren and 1 week later they were titrated up to 300 mg aliskiren for the remainder of the study.
Total	Total of all reporting groups

Baseline Measures

	Placebo	Aliskiren 300 mg	Valsartan 320 mg	Aliskiren/Valsartan 300/320 mg	Total
Number of Participants [units: participants]	**280**	**271**	**269**	**281**	**1101**
Age [units: years] Mean (Standard Deviation)	**63 (11.8)**	**63 (11.7)**	**64 (11.6)**	**63 (11.1)**	**63 (11.6)**
Gender [units: participants]					
Female	**103**	**86**	**72**	**87**	**348**
Male	**177**	**185**	**197**	**194**	**753**

Outcome Measures

Hide All Outcome Measures

1. Primary: Change From Baseline in N-terminal proB-type Natriuretic Peptide (NT-proBNP) at Week 8 [Time Frame: Baseline to Week 8]

Measure Type	Primary
Measure Title	Change From Baseline in N-terminal proB-type Natriuretic Peptide (NT-proBNP) at Week 8
Measure Description	Blood samples for the measurement of NT-proBNP were collected, processed, and shipped to the TIMI Biomarker Core Laboratory, Boston MA for storage and analysis. The change from baseline to Week 8 was expressed as the geometric mean of the ratio: Week 8/Baseline.
Time Frame	Baseline to 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: All patients who were correctly randomized. Missing baseline values were not imputed. The last post-baseline biomarker measurement collected was used for analysis. In the aliskiren treated group, 4 patients never received study drug but were included in the full analysis set but were not included in any efficacy analyses.

Reporting Groups

	Description
Placebo	Placebo tablets and capsules
Aliskiren 300 mg	Following 1 week of treatment with 75 mg of aliskiren (tablets), patients in this arm were titrated up to 150 mg of aliskiren; 1 week later they were titrated up to 300 mg aliskiren for the remainder of the study.
Valsartan 320 mg	Following 1 week of treatment with 80 mg of valsartan (capsules), patients in this arm were titrated up to 160 mg of valsartan; 1 week later they were titrated up to 320 mg valsartan for the remainder of the study.
Aliskiren/Valsartan 300/320 mg	Following 1 week of treatment with 80 mg of valsartan (capsules), patients in this arm were titrated up to 160 mg of valsartan; 1 week later they were titrated up to 320 mg valsartan for the remainder of the study. Beginning with Week 4, in addition to 320 mg valsartan, patients were treated with 75 mg of aliskiren (tablets); 1 week later patients were titrated up to 150 mg of aliskiren and 1 week later they were titrated up to 300 mg aliskiren for the remainder of the study.

Measured Values

	Placebo	Aliskiren 300 mg	Valsartan 320 mg	Aliskiren/Valsartan 300/320 mg
Number of Participants Analyzed [units: participants]	**259**	**235**	**246**	**256**

Change From Baseline in N-terminal proB-type Natriuretic Peptide (NT-proBNP) at Week 8 [units: pg/mL] Geometric Mean (95% Confidence Interval)	**0.582 (0.502 to 0.676)**	**0.563 (0.483 to 0.656)**	**0.614 (0.526 to 0.716)**	**0.635 (0.548 to 0.737)**

No statistical analysis provided for Change From Baseline in N-terminal proB-type Natriuretic Peptide (NT-proBNP) at Week 8

2. Secondary: Change From Baseline in B-type Natriuretic Peptide (BNP) at Week 8 [Time Frame: Baseline to Week 8]

Measure Type	Secondary
Measure Title	Change From Baseline in B-type Natriuretic Peptide (BNP) at Week 8
Measure Description	Blood samples for the measurement of BNP were collected, processed, and shipped to the TIMI Biomarker Core Laboratory, Boston MA for storage and analysis. The change from baseline to Week 8 was expressed as the geometric mean of the ratio: Week 8/Baseline.
Time Frame	Baseline to 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: All patients who were correctly randomized. Missing baseline values were not imputed. The last post-baseline biomarker measurement collected was used for analysis. In the aliskiren treated group, 4 patients never received study drug but were included in the full analysis set but were not included in any efficacy analyses.

Reporting Groups

	Description
Placebo	Placebo tablets and capsules
Aliskiren 300 mg	Following 1 week of treatment with 75 mg of aliskiren (tablets), patients in this arm were titrated up to 150 mg of aliskiren; 1 week later they were titrated up to 300 mg aliskiren for the remainder of the study.
Valsartan 320 mg	Following 1 week of treatment with 80 mg of valsartan (capsules), patients in this arm were titrated up to 160 mg of valsartan; 1 week later they were titrated up to 320 mg valsartan for the remainder of the study.
Aliskiren/Valsartan 300/320 mg	Following 1 week of treatment with 80 mg of valsartan (capsules), patients in this arm were titrated up to 160 mg of valsartan; 1 week later they were titrated up to 320 mg valsartan for the remainder of the study. Beginning with Week 4, in addition to 320 mg valsartan, patients were treated with 75 mg of aliskiren (tablets); 1 week later patients were titrated up to 150 mg of aliskiren and 1 week later they were titrated up to 300 mg aliskiren for the remainder of the study.

Measured Values

	Placebo	**Aliskiren 300 mg**	**Valsartan 320 mg**	**Aliskiren/Valsartan 300/320 mg**
Number of Participants Analyzed [units: participants]	**252**	**229**	**237**	**252**
Change From Baseline in B-type Natriuretic Peptide (BNP) at Week 8 [units: pg/mL] Geometric Mean (95% Confidence Interval)	**0.642 (0.535 to 0.770)**	**0.597 (0.495 to 0.720)**	**0.670 (0.554 to 0.810)**	**0.682 (0.568 to 0.818)**

No statistical analysis provided for Change From Baseline in B-type Natriuretic Peptide (BNP) at Week 8

3. Secondary: Percentage of Patients With a Cardiac Event [Time Frame: Baseline to Week 8]

Measure Type	Secondary
Measure Title	Percentage of Patients With a Cardiac Event
Measure Description	A cardiac event was defined as at least one of the following events: Cardiovascular death, recurrent myocardial infarction (MI), or hospitalization for congestive heart failure (CHF), all to be confirmed by adjudication.
Time Frame	Baseline to 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: All patients who were correctly randomized. Missing baseline values were not imputed. The last post-baseline biomarker measurement collected was used for analysis. In the aliskiren treated group, 4 patients never received study drug but were included in the full analysis set but were not included in any efficacy analyses.

Reporting Groups

	Description
Placebo	Placebo tablets and capsules
Aliskiren 300 mg	Following 1 week of treatment with 75 mg of aliskiren (tablets), patients in this arm were titrated up to 150 mg of aliskiren; 1 week later they were titrated up to 300 mg aliskiren for the remainder of the study.
Valsartan 320 mg	Following 1 week of treatment with 80 mg of valsartan (capsules), patients in this arm were titrated up to 160 mg of valsartan; 1 week later they were titrated up to 320 mg valsartan for the remainder of the study.
Aliskiren/Valsartan 300/320 mg	Following 1 week of treatment with 80 mg of valsartan (capsules), patients in this arm were titrated up to 160 mg of valsartan; 1 week later they were titrated up to 320 mg valsartan for the remainder of the study. Beginning with Week 4, in addition to 320 mg valsartan, patients were treated with 75 mg of aliskiren (tablets); 1 week later patients were titrated up to 150 mg of aliskiren and 1 week later they were titrated up to 300 mg aliskiren for the remainder of the study.

Measured Values

	Placebo	**Aliskiren 300 mg**	**Valsartan 320 mg**	**Aliskiren/Valsartan 300/320 mg**
Number of Participants Analyzed [units: participants]	**278**	**268**	**268**	**278**
Percentage of Patients With a Cardiac Event [units: Percentage of patients]	**2.9**	**4.9**	**4.9**	**4.0**

No statistical analysis provided for Percentage of Patients With a Cardiac Event

4. Secondary: Percentage of Patients With a Composite Clinical-biochemical Event [Time Frame: Baseline to Week 8]

Measure Type	Secondary
Measure Title	Percentage of Patients With a Composite Clinical-biochemical Event
Measure Description	A composite clinical-biochemical event was defined as at least one of the following events: cardiovascular death confirmed by adjudication, recurrent MI confirmed by adjudication, hospitalization for CHF confirmed by adjudication, and/or NT-proBNP => 200 pg/mL.
Time Frame	Baseline to 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: All patients who were correctly randomized. Missing baseline values were not imputed. The last post-baseline biomarker measurement collected was used for analysis. In the aliskiren treated group, 4 patients never received study drug but were included in the full analysis set but were not included in any efficacy analyses.

Reporting Groups

	Description
Placebo	Placebo tablets and capsules
Aliskiren 300 mg	Following 1 week of treatment with 75 mg of aliskiren (tablets), patients in this arm were titrated up to 150 mg of aliskiren; 1 week later they were titrated up to 300 mg aliskiren for the remainder of the study.
Valsartan 320 mg	Following 1 week of treatment with 80 mg of valsartan (capsules), patients in this arm were titrated up to 160 mg of valsartan; 1 week later they were titrated up to 320 mg valsartan for the remainder of the study.
Aliskiren/Valsartan 300/320 mg	Following 1 week of treatment with 80 mg of valsartan (capsules), patients in this arm were titrated up to 160 mg of valsartan; 1 week later they were titrated up to 320 mg valsartan for the remainder of the study. Beginning with Week 4, in addition to 320 mg valsartan, patients were treated with 75 mg of aliskiren (tablets); 1 week later patients were titrated up to 150 mg of aliskiren and 1 week later they were titrated up to 300 mg aliskiren for the remainder of the study.

Measured Values

	Placebo	**Aliskiren 300 mg**	**Valsartan 320 mg**	**Aliskiren/Valsartan 300/320 mg**
Number of Participants Analyzed [units: participants]	**278**	**268**	**268**	**278**
Percentage of Patients With a Composite Clinical-biochemical Event [units: Percentage of patients]	**79.5**	**73.5**	**77.2**	**75.2**

No statistical analysis provided for Percentage of Patients With a Composite Clinical-biochemical Event

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	No text entered.
Additional Description	Safety set: All patients that received at least 1 dose of study drug. Missing values were not imputed. In the aliskiren group, 4 patients were excluded because they never received study drug. One patient who never received study drug was included in the safety set because he had a date for the end of study treatment on the study completion page.

Reporting Groups

	Description
Placebo	Placebo tablets and capsules
Aliskiren 300 mg	Following 1 week of treatment with 75 mg of aliskiren (tablets), patients in this arm were titrated up to 150 mg of aliskiren; 1 week later they were titrated up to 300 mg aliskiren for the remainder of the study.
Valsartan 320 mg	Following 1 week of treatment with 80 mg of valsartan (capsules), patients in this arm were titrated up to 160 mg of valsartan; 1 week later they were titrated up to 320 mg valsartan for the remainder of the study.
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Serious Adverse Events

	Placebo	Aliskiren 300 mg	Valsartan 320 mg	Aliskiren/Valsartan 300/320 mg
Total, serious adverse events				
# participants affected / at risk	**26/278 (9.35%)**	**39/264 (14.77%)**	**33/268 (12.31%)**	**46/279 (16.49%)**
Blood and lymphatic system disorders				
Anaemia † 1				
# participants affected / at risk	**0/278 (0.00%)**	**1/264 (0.38%)**	**0/268 (0.00%)**	**0/279 (0.00%)**
Idiopathic thrombocytopenic purpura † 1				
# participants affected / at risk	**0/278 (0.00%)**	**0/264 (0.00%)**	**0/268 (0.00%)**	**1/279 (0.36%)**
Cardiac disorders				
Acute coronary syndrome † 1				
# participants affected / at risk	**0/278 (0.00%)**	**3/264 (1.14%)**	**1/268 (0.37%)**	**1/279 (0.36%)**
Acute myocardial infarction † 1				
# participants affected / at risk	**1/278 (0.36%)**	**4/264 (1.52%)**	**2/268 (0.75%)**	**0/279 (0.00%)**
Angina pectoris † 1				
# participants affected / at risk	**2/278 (0.72%)**	**5/264 (1.89%)**	**3/268 (1.12%)**	**6/279 (2.15%)**
Angina unstable † 1				
# participants affected / at risk	**1/278 (0.36%)**	**2/264 (0.76%)**	**1/268 (0.37%)**	**4/279 (1.43%)**
Atrial fibrillation † 1				
# participants affected / at risk	**2/278 (0.72%)**	**1/264 (0.38%)**	**0/268 (0.00%)**	**0/279 (0.00%)**
Atrioventricular block complete † 1				
# participants affected / at risk	**0/278 (0.00%)**	**0/264 (0.00%)**	**1/268 (0.37%)**	**0/279 (0.00%)**
Cardiac failure † 1				
# participants affected / at risk	**2/278 (0.72%)**	**1/264 (0.38%)**	**3/268 (1.12%)**	**2/279 (0.72%)**
Cardiac failure congestive † 1				
# participants affected / at risk	**0/278 (0.00%)**	**1/264 (0.38%)**	**1/268 (0.37%)**	**0/279 (0.00%)**
Coronary artery disease † 1				
# participants affected / at risk	**1/278 (0.36%)**	**2/264 (0.76%)**	**2/268 (0.75%)**	**0/279 (0.00%)**
Coronary artery occlusion † 1				
# participants affected / at risk	**1/278 (0.36%)**	**0/264 (0.00%)**	**0/268 (0.00%)**	**0/279 (0.00%)**
Coronary artery stenosis † 1				
# participants affected / at risk	**0/278 (0.00%)**	**0/264 (0.00%)**	**0/268 (0.00%)**	**1/279 (0.36%)**
Dressler's syndrome † 1				

# participants affected / at risk	**1/278 (0.36%)**	**1/264 (0.38%)**	**0/268 (0.00%)**	**0/279 (0.00%)**
Myocardial infarction † 1				
# participants affected / at risk	**1/278 (0.36%)**	**2/264 (0.76%)**	**0/268 (0.00%)**	**5/279 (1.79%)**
Myocardial ischaemia † 1				
# participants affected / at risk	**0/278 (0.00%)**	**1/264 (0.38%)**	**1/268 (0.37%)**	**4/279 (1.43%)**
Palpitations † 1				
# participants affected / at risk	**0/278 (0.00%)**	**0/264 (0.00%)**	**0/268 (0.00%)**	**1/279 (0.36%)**
Pericarditis † 1				
# participants affected / at risk	**0/278 (0.00%)**	**0/264 (0.00%)**	**1/268 (0.37%)**	**0/279 (0.00%)**
Postinfarction angina † 1				
# participants affected / at risk	**1/278 (0.36%)**	**0/264 (0.00%)**	**0/268 (0.00%)**	**1/279 (0.36%)**
Tachyarrhythmia † 1				
# participants affected / at risk	**0/278 (0.00%)**	**0/264 (0.00%)**	**1/268 (0.37%)**	**0/279 (0.00%)**
Ventricular fibrillation † 1				
# participants affected / at risk	**1/278 (0.36%)**	**0/264 (0.00%)**	**0/268 (0.00%)**	**0/279 (0.00%)**
Ear and labyrinth disorders				
Vertigo † 1				
# participants affected / at risk	**0/278 (0.00%)**	**0/264 (0.00%)**	**0/268 (0.00%)**	**1/279 (0.36%)**
Vertigo positional † 1				
# participants affected / at risk	**0/278 (0.00%)**	**0/264 (0.00%)**	**0/268 (0.00%)**	**1/279 (0.36%)**
Gastrointestinal disorders				
Diarrhoea † 1				
# participants affected / at risk	**0/278 (0.00%)**	**0/264 (0.00%)**	**2/268 (0.75%)**	**0/279 (0.00%)**
Gastritis erosive † 1				
# participants affected / at risk	**0/278 (0.00%)**	**0/264 (0.00%)**	**0/268 (0.00%)**	**1/279 (0.36%)**
Impaired gastric emptying † 1				
# participants affected / at risk	**0/278 (0.00%)**	**0/264 (0.00%)**	**1/268 (0.37%)**	**0/279 (0.00%)**
Inguinal hernia † 1				
# participants affected / at risk	**1/278 (0.36%)**	**0/264 (0.00%)**	**0/268 (0.00%)**	**0/279 (0.00%)**
Peptic ulcer † 1				
# participants affected / at risk	**0/278 (0.00%)**	**0/264 (0.00%)**	**1/268 (0.37%)**	**0/279 (0.00%)**
General disorders				
Asthenia † 1				
# participants affected / at risk	**0/278 (0.00%)**	**1/264 (0.38%)**	**0/268 (0.00%)**	**0/279 (0.00%)**

Cardiac death † 1				
# participants affected / at risk	**0/278 (0.00%)**	**0/264 (0.00%)**	**1/268 (0.37%)**	**1/279 (0.36%)**
Chest pain † 1				
# participants affected / at risk	**0/278 (0.00%)**	**0/264 (0.00%)**	**0/268 (0.00%)**	**1/279 (0.36%)**
Malaise † 1				
# participants affected / at risk	**0/278 (0.00%)**	**1/264 (0.38%)**	**0/268 (0.00%)**	**0/279 (0.00%)**
Non-cardiac chest pain † 1				
# participants affected / at risk	**2/278 (0.72%)**	**7/264 (2.65%)**	**2/268 (0.75%)**	**3/279 (1.08%)**
Sudden cardiac death † 1				
# participants affected / at risk	**0/278 (0.00%)**	**2/264 (0.76%)**	**2/268 (0.75%)**	**0/279 (0.00%)**
Sudden death † 1				
# participants affected / at risk	**1/278 (0.36%)**	**1/264 (0.38%)**	**0/268 (0.00%)**	**0/279 (0.00%)**
Infections and infestations				
Bronchitis † 1				
# participants affected / at risk	**0/278 (0.00%)**	**0/264 (0.00%)**	**2/268 (0.75%)**	**1/279 (0.36%)**
Cellulitis † 1				
# participants affected / at risk	**0/278 (0.00%)**	**1/264 (0.38%)**	**0/268 (0.00%)**	**0/279 (0.00%)**
Clostridium difficile colitis † 1				
# participants affected / at risk	**0/278 (0.00%)**	**0/264 (0.00%)**	**1/268 (0.37%)**	**0/279 (0.00%)**
Diverticulitis † 1				
# participants affected / at risk	**0/278 (0.00%)**	**0/264 (0.00%)**	**0/268 (0.00%)**	**1/279 (0.36%)**
Erysipelas † 1				
# participants affected / at risk	**0/278 (0.00%)**	**0/264 (0.00%)**	**0/268 (0.00%)**	**1/279 (0.36%)**
Helicobacter gastritis † 1				
# participants affected / at risk	**1/278 (0.36%)**	**0/264 (0.00%)**	**0/268 (0.00%)**	**0/279 (0.00%)**
Influenza † 1				
# participants affected / at risk	**1/278 (0.36%)**	**0/264 (0.00%)**	**0/268 (0.00%)**	**0/279 (0.00%)**
Localised infection † 1				
# participants affected / at risk	**1/278 (0.36%)**	**0/264 (0.00%)**	**0/268 (0.00%)**	**0/279 (0.00%)**
Pneumonia † 1				
# participants affected / at risk	**1/278 (0.36%)**	**0/264 (0.00%)**	**3/268 (1.12%)**	**1/279 (0.36%)**
Postoperative wound infection † 1				
# participants affected / at risk	**0/278 (0.00%)**	**1/264 (0.38%)**	**1/268 (0.37%)**	**0/279 (0.00%)**
Sepsis † 1				

# participants affected / at risk	0/278 (0.00%)	1/264 (0.38%)	0/268 (0.00%)	0/279 (0.00%)
Septic shock † 1				
# participants affected / at risk	0/278 (0.00%)	0/264 (0.00%)	1/268 (0.37%)	0/279 (0.00%)
Viral infection † 1				
# participants affected / at risk	0/278 (0.00%)	1/264 (0.38%)	0/268 (0.00%)	0/279 (0.00%)
Injury, poisoning and procedural complications				
Arterial injury † 1				
# participants affected / at risk	0/278 (0.00%)	1/264 (0.38%)	0/268 (0.00%)	0/279 (0.00%)
Fall † 1				
# participants affected / at risk	0/278 (0.00%)	0/264 (0.00%)	0/268 (0.00%)	1/279 (0.36%)
Pelvic fracture † 1				
# participants affected / at risk	1/278 (0.36%)	0/264 (0.00%)	0/268 (0.00%)	0/279 (0.00%)
Subdural haematoma † 1				
# participants affected / at risk	1/278 (0.36%)	0/264 (0.00%)	0/268 (0.00%)	0/279 (0.00%)
Thrombosis in device † 1				
# participants affected / at risk	0/278 (0.00%)	2/264 (0.76%)	0/268 (0.00%)	0/279 (0.00%)
Tibia fracture † 1				
# participants affected / at risk	0/278 (0.00%)	0/264 (0.00%)	0/268 (0.00%)	1/279 (0.36%)
Vascular pseudoaneurysm † 1				
# participants affected / at risk	0/278 (0.00%)	1/264 (0.38%)	0/268 (0.00%)	0/279 (0.00%)
Investigations				
ECG signs of myocardial ischaemia † 1				
# participants affected / at risk	1/278 (0.36%)	0/264 (0.00%)	0/268 (0.00%)	0/279 (0.00%)
Heart rate decreased † 1				
# participants affected / at risk	1/278 (0.36%)	0/264 (0.00%)	0/268 (0.00%)	0/279 (0.00%)
Metabolism and nutrition disorders				
Gout † 1				
# participants affected / at risk	1/278 (0.36%)	0/264 (0.00%)	0/268 (0.00%)	1/279 (0.36%)
Hypoglycaemic unconsciousness † 1				
# participants affected / at risk	0/278 (0.00%)	0/264 (0.00%)	1/268 (0.37%)	0/279 (0.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
Colon cancer † 1				
# participants affected / at risk	0/278 (0.00%)	1/264 (0.38%)	0/268 (0.00%)	0/279 (0.00%)

Hepatic cancer metastatic † 1				
# participants affected / at risk	**0/278 (0.00%)**	**0/264 (0.00%)**	**1/268 (0.37%)**	**0/279 (0.00%)**
Nervous system disorders				
Cerebral haemorrhage † 1				
# participants affected / at risk	**0/278 (0.00%)**	**0/264 (0.00%)**	**0/268 (0.00%)**	**1/279 (0.36%)**
Cerebrovascular accident † 1				
# participants affected / at risk	**1/278 (0.36%)**	**0/264 (0.00%)**	**0/268 (0.00%)**	**0/279 (0.00%)**
Cervicobrachial syndrome † 1				
# participants affected / at risk	**0/278 (0.00%)**	**0/264 (0.00%)**	**0/268 (0.00%)**	**1/279 (0.36%)**
Convulsion † 1				
# participants affected / at risk	**0/278 (0.00%)**	**0/264 (0.00%)**	**0/268 (0.00%)**	**1/279 (0.36%)**
Presyncope † 1				
# participants affected / at risk	**0/278 (0.00%)**	**0/264 (0.00%)**	**0/268 (0.00%)**	**1/279 (0.36%)**
Syncope † 1				
# participants affected / at risk	**0/278 (0.00%)**	**0/264 (0.00%)**	**1/268 (0.37%)**	**2/279 (0.72%)**
Vertebrobasilar insufficiency † 1				
# participants affected / at risk	**0/278 (0.00%)**	**0/264 (0.00%)**	**0/268 (0.00%)**	**1/279 (0.36%)**
Psychiatric disorders				
Anxiety † 1				
# participants affected / at risk	**0/278 (0.00%)**	**1/264 (0.38%)**	**0/268 (0.00%)**	**0/279 (0.00%)**
Respiratory, thoracic and mediastinal disorders				
Asthma † 1				
# participants affected / at risk	**0/278 (0.00%)**	**0/264 (0.00%)**	**0/268 (0.00%)**	**1/279 (0.36%)**
Chronic obstructive pulmonary disease † 1				
# participants affected / at risk	**0/278 (0.00%)**	**1/264 (0.38%)**	**0/268 (0.00%)**	**0/279 (0.00%)**
Dyspnoea † 1				
# participants affected / at risk	**1/278 (0.36%)**	**1/264 (0.38%)**	**0/268 (0.00%)**	**0/279 (0.00%)**
Epistaxis † 1				
# participants affected / at risk	**0/278 (0.00%)**	**0/264 (0.00%)**	**0/268 (0.00%)**	**1/279 (0.36%)**
Pulmonary embolism † 1				
# participants affected / at risk	**0/278 (0.00%)**	**0/264 (0.00%)**	**1/268 (0.37%)**	**1/279 (0.36%)**
Pulmonary oedema † 1				
# participants affected / at risk	**1/278 (0.36%)**	**0/264 (0.00%)**	**2/268 (0.75%)**	**1/279 (0.36%)**
Vascular disorders				

Aortic aneurysm † 1				
# participants affected / at risk	**0/278 (0.00%)**	**0/264 (0.00%)**	**1/268 (0.37%)**	**0/279 (0.00%)**
Arterial occlusive disease † 1				
# participants affected / at risk	**0/278 (0.00%)**	**1/264 (0.38%)**	**0/268 (0.00%)**	**0/279 (0.00%)**
Arterial stenosis † 1				
# participants affected / at risk	**0/278 (0.00%)**	**0/264 (0.00%)**	**0/268 (0.00%)**	**1/279 (0.36%)**
Deep vein thrombosis † 1				
# participants affected / at risk	**0/278 (0.00%)**	**1/264 (0.38%)**	**0/268 (0.00%)**	**0/279 (0.00%)**
Femoral artery aneurysm † 1				
# participants affected / at risk	**0/278 (0.00%)**	**1/264 (0.38%)**	**0/268 (0.00%)**	**1/279 (0.36%)**
Hypertension † 1				
# participants affected / at risk	**1/278 (0.36%)**	**0/264 (0.00%)**	**0/268 (0.00%)**	**0/279 (0.00%)**
Hypertensive emergency † 1				
# participants affected / at risk	**0/278 (0.00%)**	**1/264 (0.38%)**	**0/268 (0.00%)**	**0/279 (0.00%)**
Hypotension † 1				
# participants affected / at risk	**0/278 (0.00%)**	**3/264 (1.14%)**	**0/268 (0.00%)**	**2/279 (0.72%)**
Ischaemia † 1				
# participants affected / at risk	**0/278 (0.00%)**	**0/264 (0.00%)**	**1/268 (0.37%)**	**0/279 (0.00%)**
Orthostatic hypotension † 1				
# participants affected / at risk	**0/278 (0.00%)**	**0/264 (0.00%)**	**1/268 (0.37%)**	**0/279 (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: All patients that received at least 1 dose of study drug. Missing values were not imputed. In the aliskiren group, 4 patients were excluded because they never received study drug. One patient who never received study drug was included in the safety set because he had a date for the end of study treatment on the study completion page.

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
Placebo	Placebo tablets and capsules
Aliskiren 300 mg	Following 1 week of treatment with 75 mg of aliskiren (tablets), patients in this arm were titrated up to 150

	mg of aliskiren; 1 week later they were titrated up to 300 mg aliskiren for the remainder of the study.
Valsartan 320 mg	Following 1 week of treatment with 80 mg of valsartan (capsules), patients in this arm were titrated up to 160 mg of valsartan; 1 week later they were titrated up to 320 mg valsartan for the remainder of the study.
Aliskiren/Valsartan 300/320 mg	Following 1 week of treatment with 80 mg of valsartan (capsules), patients in this arm were titrated up to 160 mg of valsartan; 1 week later they were titrated up to 320 mg valsartan for the remainder of the study. Beginning with Week 4, in addition to 320 mg valsartan, patients were treated with 75 mg of aliskiren (tablets); 1 week later patients were titrated up to 150 mg of aliskiren and 1 week later they were titrated up to 300 mg aliskiren for the remainder of the study.

Other Adverse Events

	Placebo	Aliskiren 300 mg	Valsartan 320 mg	Aliskiren/Valsartan 300/320 mg
Total, other (not including serious) adverse events				
# participants affected / at risk	**64/278 (23.02%)**	**61/264 (23.11%)**	**51/268 (19.03%)**	**57/279 (20.43%)**
Cardiac disorders				
Angina pectoris † 1				
# participants affected / at risk	**13/278 (4.68%)**	**9/264 (3.41%)**	**14/268 (5.22%)**	**8/279 (2.87%)**
Metabolism and nutrition disorders				
Hyperkalaemia † 1				
# participants affected / at risk	**17/278 (6.12%)**	**16/264 (6.06%)**	**13/268 (4.85%)**	**13/279 (4.66%)**
Nervous system disorders				
Dizziness † 1				
# participants affected / at risk	**15/278 (5.40%)**	**23/264 (8.71%)**	**13/268 (4.85%)**	**19/279 (6.81%)**
Headache † 1				
# participants affected / at risk	**18/278 (6.47%)**	**10/264 (3.79%)**	**7/268 (2.61%)**	**10/279 (3.58%)**
Vascular disorders				
Orthostatic hypotension † 1				
# participants affected / at risk	**14/278 (5.04%)**	**16/264 (6.06%)**	**12/268 (4.48%)**	**13/279 (4.66%)**

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

Limitations and Caveats

Hide Limitations and Caveats

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

More Information

Hide More Information

Certain Agreements:

Principal Investigators are **NOT** employed by the organization sponsoring the study.
There **IS** an agreement between Principal Investigators and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.

The agreement is:

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

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

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

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

Results Point of Contact:

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

No publications provided

Responsible Party:	External Affairs, Novartis
ClinicalTrials.gov Identifier:	NCT00409578 History of Changes
Other Study ID Numbers:	**CSPP100A2347**
Study First Received:	December 7, 2006
Results First Received:	January 11, 2011
Last Updated:	April 15, 2011
Health Authority:	United States: Food and Drug Administration Germany: Federal Institute for Drugs and Medical Devices Belgium: The Federal Public Service (FPS) Health, Food Chain Safety and Environment