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Trial record **1 of 1** for: CSPV100A2301

Previous Study | Return to List | Next Study

A Safety and Tolerability Study of the Combination of Aliskiren/Valsartan in Patients With High Blood Pressure, Followed by Long-term Safety and Tolerability of Aliskiren, Valsartan and Hydrochlorothiazide.

This study has been completed.

Sponsor:
Novartis

Information provided by:
Novartis

ClinicalTrials.gov Identifier:
NCT00386607

First received: October 10, 2006
Last updated: January 14, 2014
Last verified: January 2014
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: Non-Randomized; Endpoint Classification: Safety Study; Intervention Model: Single Group Assignment; Masking: Open Label; Primary Purpose: Treatment
Condition:	Hypertension
Interventions:	Drug: Aliskiren Drug: Valsartan Drug: Hydrochlorothiazide (HCTZ)

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
Core Treatment	Oral pills of aliskiren 150 mg /valsartan 160 mg in combination for 2-weeks. The aliskiren 300 mg /valsartan 320 mg in combiniation for 52-weeks, optional addition of HCTZ 12.5 mg starting from Week 10 if the blood pressure was uncontrolled (msSBP ≥ 140 and/or msDBP ≥ 90 mmHg). The dose of HCTZ 12.5 mg could be increased to 25 mg if blood pressure remained uncontrolled.
Extension Treatment	For patients entering into extension, those previously treated with HCTZ (12.5 or 25 mg) in addition to aliskiren 300 mg/valsartan 320 mg were treated with aliskiren 300 mg/valsartan 320 mg/HCTZ 25 mg in the extension. Those patients who had not received HCTZ during the core study were treated with aliskiren 300 mg/valsartan 320 mg/HCTZ 12.5 mg.

	The HCTZ 12.5 mg dose could be increased to HCTZ 25 mg if the msSBP was ≥140 mmHg and/or the msDBP was ≥90 mmHg for 2 consecutive visits.

Participant Flow for 2 periods

Period 1: Core

	Core Treatment	Extension Treatment
STARTED	601	0
COMPLETED	486	0
NOT COMPLETED	115	0
Adverse Event	40	0
Abnormal laboratory value(s)	3	0
Unsatisfactory therapeutic effect	23	0
Condition no longer requires study drug	4	0
Patient withdrew consent	15	0
Lost to Follow-up	23	0
Administrative problems	1	0
Protocol Deviation	6	0

Period 2: Extension

	Core Treatment	Extension Treatment
STARTED	0	162
COMPLETED	0	145
NOT COMPLETED	0	17
Adverse Event	0	6
Abnormal laboratory value(s)	0	1
Administrative problems	0	1
Lost to Follow-up	0	3
Patient withdrew consent	0	5
Unsatisfactory therapeutic effect	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
Core Treatment	Oral pills of aliskiren 150 mg /valsartan 160 mg in combination for 2-weeks. The aliskiren 300 mg /valsartan 320 mg in combiniation for 52-weeks, optional addition of HCTZ 12.5 mg starting from Week 10 if the blood pressure was uncontrolled (msSBP ≥ 140 and/or msDBP ≥ 90 mmHg). The dose of HCTZ 12.5 mg could be increased to 25 mg if blood pressure remained uncontrolled.

Baseline Measures

	Core Treatment
Number of Participants [units: participants]	**601**
Age [units: years] Mean (Standard Deviation)	**55.0 (11.20)**
Gender [units: participants]	
Female	**271**
Male	**330**

Outcome Measures

Hide All Outcome Measures

1. Primary: Overall Percentage of Patients With Adverse Events [Time Frame: Month 12]

Measure Type	Primary
Measure Title	Overall Percentage of Patients With Adverse Events
Measure Description	No text entered.
Time Frame	Month 12
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.
Treated population: All patients who received at least one dose of Aliskiren/Valsartan

Reporting Groups

	Description
Core Treatment- Aliskiren/Valsartan & Aliskiren/Valsartan/HCTZ	Oral pills of aliskiren 150 mg /valsartan 160 mg in combination for 2-weeks. The aliskiren 300 mg /valsartan 320 mg in combiniation for 52-weeks, optional addition of HCTZ 12.5 mg starting from Week 10 if the blood pressure was uncontrolled (msSBP ≥ 140 and/or msDBP ≥ 90 mmHg). The dose of HCTZ 12.5 mg could be increased to 25 mg if blood pressure remained uncontrolled.

Measured Values

	Core Treatment- Aliskiren/Valsartan & Aliskiren/Valsartan/HCTZ
Number of Participants Analyzed [units: participants]	**601**
Overall Percentage of Patients With Adverse Events [units: percentage of patients]	**76.2**

No statistical analysis provided for Overall Percentage of Patients With Adverse Events

2. Primary: Overall Percentage of Patients With Adverse Events [Time Frame: Month 18]

Measure Type	Primary
Measure Title	Overall Percentage of Patients With Adverse Events
Measure Description	adverse event data obtained from both the core study and the 6 month extension study.
Time Frame	Month 18
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.
No text entered.

Reporting Groups

	Description
Core and Extension Treatment - Aliskiren/Valsartan/HCTZ	All patients receiving aliskiren / valsartan / HCTZ during either core or extension study.

Measured Values

	Core and Extension Treatment - Aliskiren/Valsartan/HCTZ
Number of Participants Analyzed [units: participants]	**310**
Overall Percentage of Patients With Adverse Events [units: percentage of patients]	**61.6**

No statistical analysis provided for Overall Percentage of Patients With Adverse Events

3. Secondary: Change From Baseline in Mean Sitting Diastolic Blood Pressure. [Time Frame: Baseline and Weeks 2, 4, 6, 10, 14, 18, 28, 41, and 54]

Measure Type	Secondary
Measure Title	Change From Baseline in Mean Sitting Diastolic Blood Pressure.
Measure Description	No text entered.
Time Frame	Baseline and Weeks 2, 4, 6, 10, 14, 18, 28, 41, and 54
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.
Treated population

Reporting Groups

	Description
Core Treatment	Oral pills of aliskiren 150 mg /valsartan 160 mg in combination for 2-weeks. The aliskiren 300 mg /valsartan 320 mg in combiniation for 52-weeks, optional addition of HCTZ 12.5 mg starting from Week 10 if the blood pressure was uncontrolled (msSBP ≥ 140 and/or msDBP ≥ 90 mmHg). The dose of HCTZ 12.5 mg could be increased to 25 mg if blood pressure remained uncontrolled.

Measured Values

	Core Treatment

Number of Participants Analyzed [units: participants]	**601**
Change From Baseline in Mean Sitting Diastolic Blood Pressure. [units: mmHg] Mean (Standard Deviation)	
Week 2 (Visit 5)	**-7.9 (7.14)**
Week 4 (Visit 6)	**-10.8 (7.83)**
Week 6 (Visit 7)	**-11.8 (8.09)**
Week 10 (Visit 8)	**-12.5 (8.26)**
Week 14 (Visit 9)	**-13.7 (7.87)**
Week 18 (Visit 10)	**-15.0 (8.00)**
Week 28 (Visit 11)	**-15.2 (7.24)**
Week 41 (Visit 12)	**-15.2 (7.60)**
Week 54 (Visit 13)	**-14.2 (7.96)**
Endpoint (value at week 54 or LOCF)	**-13.4 (8.75)**

No statistical analysis provided for Change From Baseline in Mean Sitting Diastolic Blood Pressure.

4. Secondary: Change From Baseline in Mean Sitting Systolic Blood Pressure. [Time Frame: Baseline and Weeks 2, 4, 6, 10, 14, 18, 28, 41 and 54]

Measure Type	Secondary
Measure Title	Change From Baseline in Mean Sitting Systolic Blood Pressure.
Measure Description	No text entered.
Time Frame	Baseline and Weeks 2, 4, 6, 10, 14, 18, 28, 41 and 54
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.
Treated population

Reporting Groups

	Description
Core Treatment	Oral pills of aliskiren 150 mg /valsartan 160 mg in combination for 2-weeks. The aliskiren 300 mg /valsartan 320 mg in combiniation for 52-weeks, optional addition of HCTZ 12.5 mg starting from Week 10 if the blood pressure was uncontrolled (msSBP ≥ 140 and/or msDBP ≥ 90 mmHg). The dose of HCTZ 12.5 mg could be increased to 25 mg if blood pressure remained uncontrolled.

Measured Values

	Core Treatment
Number of Participants Analyzed [units: participants]	**601**
Change From Baseline in Mean Sitting Systolic Blood Pressure. [units: mmHg] Mean (Standard Deviation)	
Week 2 (Visit 5)	**-11.0 (12.42)**

Week 4 (Visit 6)	**-15.0 (14.03)**
Week 6 (Visit 7)	**-17.6 (14.10)**
Week 10 (Visit 8)	**-18.4 (14.37)**
Week 14 (Visit 9)	**-20.7 (13.42)**
Week 18 (Visit 10)	**-22.6 (14.01)**
Week 28 (Visit 11)	**-24.3 (13.70)**
Week 41 (Visit 12)	**-24.3 (13.27)**
Week 54 (Visit 13)	**-22.3 (14.51)**
Endpoint (value at week 54 or LOCF)	**-20.5 (16.40)**

No statistical analysis provided for Change From Baseline in Mean Sitting Systolic Blood Pressure.

5. Secondary: Percentage of Patients Achieving Blood Pressure Control Target of < 140/90 mmHg [Time Frame: .Weeks 2, 4, 6, 10, 14, 18, 28, 41, and 54]

Measure Type	Secondary
Measure Title	Percentage of Patients Achieving Blood Pressure Control Target of < 140/90 mmHg
Measure Description	No text entered.
Time Frame	.Weeks 2, 4, 6, 10, 14, 18, 28, 41, and 54
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.
Treated population

Reporting Groups

	Description
Core Treatment	Oral pills of aliskiren 150 mg /valsartan 160 mg in combination for 2-weeks. The aliskiren 300 mg /valsartan 320 mg in combiniation for 52-weeks, optional addition of HCTZ 12.5 mg starting from Week 10 if the blood pressure was uncontrolled (msSBP ≥ 140 and/or msDBP ≥ 90 mmHg). The dose of HCTZ 12.5 mg could be increased to 25 mg if blood pressure remained uncontrolled.

Measured Values

	Core Treatment
Number of Participants Analyzed [units: participants]	**601**
Percentage of Patients Achieving Blood Pressure Control Target of < 140/90 mmHg [units: Percentage of patients]	
Week 2 (Visit 5)	**32.8**
Week 4 (Visit 6)	**45.9**
Week 6 (Visit 7)	**52.4**
Week 10 (Visit 8)	**60.8**
Week 14 (Visit 9)	**68.7**
Week 18 (Visit 10)	**76.4**
Week 28 (Visit 11)	**77.9**

Week 41 (Visit 12)	**78.2**
Week 54 (Visit 13)	**71.7**
Endpoint (value at week 54 or LOCF)	**66.9**

No statistical analysis provided for Percentage of Patients Achieving Blood Pressure Control Target of < 140/90 mmHg

6. Secondary: Change From Baseline in Mean Sitting Diastolic Blood Pressure [Time Frame: Baseline and Month 18]

Measure Type	Secondary
Measure Title	Change From Baseline in Mean Sitting Diastolic Blood Pressure
Measure Description	No text entered.
Time Frame	Baseline and Month 18
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.
Treated population

Reporting Groups

	Description
Extension Treatment	All patients receiving aliskiren / valsartan / HCTZ in extension study.

Measured Values

	Extension Treatment
Number of Participants Analyzed [units: participants]	**179**
Change From Baseline in Mean Sitting Diastolic Blood Pressure [units: mmHg] Mean (Standard Deviation)	**-18.3 (8.52)**

No statistical analysis provided for Change From Baseline in Mean Sitting Diastolic Blood Pressure

7. Secondary: Change From Baseline in Mean Sitting Systolic Blood Pressure [Time Frame: Baseline and Month 18]

Measure Type	Secondary
Measure Title	Change From Baseline in Mean Sitting Systolic Blood Pressure
Measure Description	No text entered.
Time Frame	Baseline and Month 18
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.
Treated population

Reporting Groups

	Description
Extension Treatment	All patients receiving aliskiren / valsartan / HCTZ in extension study.

Measured Values

	Extension Treatment
Number of Participants Analyzed [units: participants]	**179**
Change From Baseline in Mean Sitting Systolic Blood Pressure [units: mmHg] Mean (Standard Deviation)	**-28.8 (14.80)**

No statistical analysis provided for Change From Baseline in Mean Sitting Systolic Blood Pressure

8. Secondary: Percentage of Patients Achieving Blood Pressure Control Target of < 140/90 mmHg in Extension Treatment [Time Frame: Month 18]

Measure Type	Secondary
Measure Title	Percentage of Patients Achieving Blood Pressure Control Target of < 140/90 mmHg in Extension Treatment
Measure Description	No text entered.
Time Frame	Month 18
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.
Treated population

Reporting Groups

	Description
Extension Treatment	All patients receiving aliskiren / valsartan / HCTZ in extension study.

Measured Values

	Extension Treatment
Number of Participants Analyzed [units: participants]	**179**
Percentage of Patients Achieving Blood Pressure Control Target of < 140/90 mmHg in Extension Treatment [units: Percentage of patients]	**86.6**

No statistical analysis provided for Percentage of Patients Achieving Blood Pressure Control Target of < 140/90 mmHg in Extension Treatment

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	18 months
Additional Description	All patients who received at least one dose of study medication.

Reporting Groups

	Description
Core Period: Aliskiren 150 mg / Valsartan 160 mg Alone	Core Period: Aliskiren 150 mg /Valsartan 160 mg alone
Core Period: Aliskiren 300 mg / Valsartan 320 mg Alone	Core Period: Aliskiren 300 mg /Valsartan 320 mg alone
Core Period: Aliskiren / Valsartan	Core Period: Aliskiren/Valsartan
Core and Extension: Aliskiren / Valsartan / HCTZ 12.5 mg	Core and Extension: Aliskiren / Valsartan / HCTZ 12.5 mg
Core and Extension: Aliskiren / Valsartan / HCTZ 25 mg	Core and Extension: Aliskiren/Valsartan/HCTZ 25 mg
Core and Extension: Total	Core and Extension: Total includes all study patients, treated with Aliskiren/Valsartan or Aliskiren//valsartan/HCTZ during core or extension.

Serious Adverse Events

	Core Period: Aliskiren 150 mg / Valsartan 160 mg Alone	Core Period: Aliskiren 300 mg / Valsartan 320 mg Alone	Core Period: Aliskiren / Valsartan	Core and Extension: Aliskiren / Valsartan / HCTZ 12.5 mg	Core and Extension: Aliskiren / Valsartan / HCTZ 25 mg	Core and Extension: Total
Total, serious adverse events						
# participants affected / at risk	**3/601 (0.50%)**	**14/585 (2.39%)**	**17/601 (2.83%)**	**3/306 (0.98%)**	**6/137 (4.38%)**	**26/601 (4.33%)**
Cardiac disorders						
Acute myocardial infarction † 1						
# participants affected / at risk	**1/601 (0.17%)**	**0/585 (0.00%)**	**1/601 (0.17%)**	**0/306 (0.00%)**	**0/137 (0.00%)**	**1/601 (0.17%)**
Angina pectoris † 1						
# participants affected / at risk	**1/601 (0.17%)**	**0/585 (0.00%)**	**1/601 (0.17%)**	**1/306 (0.33%)**	**0/137 (0.00%)**	**2/601 (0.33%)**
Cardiac failure † 1						
# participants affected / at risk	**0/601 (0.00%)**	**1/585 (0.17%)**	**1/601 (0.17%)**	**0/306 (0.00%)**	**0/137 (0.00%)**	**1/601 (0.17%)**
Myocardial infarction † 1						
# participants affected / at risk	**0/601 (0.00%)**	**1/585 (0.17%)**	**1/601 (0.17%)**	**0/306 (0.00%)**	**0/137 (0.00%)**	**1/601 (0.17%)**
Tachycardia † 1						
# participants affected / at risk	**0/601 (0.00%)**	**1/585 (0.17%)**	**1/601 (0.17%)**	**0/306 (0.00%)**	**0/137 (0.00%)**	**1/601 (0.17%)**
Ventricular hypokinesia † 1						
# participants affected / at risk	**0/601 (0.00%)**	**1/585 (0.17%)**	**1/601 (0.17%)**	**0/306 (0.00%)**	**0/137 (0.00%)**	**1/601 (0.17%)**
Eye disorders						
Retinal vascular thrombosis † 1						
# participants affected / at risk	**1/601 (0.17%)**	**0/585 (0.00%)**	**1/601 (0.17%)**	**0/306 (0.00%)**	**0/137 (0.00%)**	**1/601 (0.17%)**
Gastrointestinal disorders						

Ascites † 1						
# participants affected / at risk	**0/601 (0.00%)**	**1/585 (0.17%)**	**1/601 (0.17%)**	**0/306 (0.00%)**	**0/137 (0.00%)**	**1/601 (0.17%)**
General disorders						
Generalised oedema † 1						
# participants affected / at risk	**0/601 (0.00%)**	**1/585 (0.17%)**	**1/601 (0.17%)**	**0/306 (0.00%)**	**0/137 (0.00%)**	**1/601 (0.17%)**
Pain † 1						
# participants affected / at risk	**0/601 (0.00%)**	**0/585 (0.00%)**	**0/601 (0.00%)**	**0/306 (0.00%)**	**1/137 (0.73%)**	**1/601 (0.17%)**
Hepatobiliary disorders						
Gallbladder disorder † 1						
# participants affected / at risk	**0/601 (0.00%)**	**1/585 (0.17%)**	**1/601 (0.17%)**	**0/306 (0.00%)**	**0/137 (0.00%)**	**1/601 (0.17%)**
Infections and infestations						
Appendicitis † 1						
# participants affected / at risk	**0/601 (0.00%)**	**1/585 (0.17%)**	**1/601 (0.17%)**	**0/306 (0.00%)**	**0/137 (0.00%)**	**1/601 (0.17%)**
Clostridium difficile colitis † 1						
# participants affected / at risk	**0/601 (0.00%)**	**0/585 (0.00%)**	**0/601 (0.00%)**	**0/306 (0.00%)**	**1/137 (0.73%)**	**1/601 (0.17%)**
Hepatitis B † 1						
# participants affected / at risk	**0/601 (0.00%)**	**0/585 (0.00%)**	**0/601 (0.00%)**	**0/306 (0.00%)**	**1/137 (0.73%)**	**1/601 (0.17%)**
Peritoneal abscess † 1						
# participants affected / at risk	**0/601 (0.00%)**	**0/585 (0.00%)**	**0/601 (0.00%)**	**0/306 (0.00%)**	**1/137 (0.73%)**	**1/601 (0.17%)**
Injury, poisoning and procedural complications						
Accidental overdose † 1						
# participants affected / at risk	**0/601 (0.00%)**	**1/585 (0.17%)**	**1/601 (0.17%)**	**0/306 (0.00%)**	**0/137 (0.00%)**	**1/601 (0.17%)**
Post-traumatic pain † 1						
# participants affected / at risk	**0/601 (0.00%)**	**0/585 (0.00%)**	**0/601 (0.00%)**	**0/306 (0.00%)**	**1/137 (0.73%)**	**1/601 (0.17%)**
Subdural haematoma † 1						
# participants affected / at risk	**0/601 (0.00%)**	**1/585 (0.17%)**	**1/601 (0.17%)**	**0/306 (0.00%)**	**0/137 (0.00%)**	**1/601 (0.17%)**
Therapeutic agent toxicity † 1						
# participants affected / at risk	**0/601 (0.00%)**	**1/585 (0.17%)**	**1/601 (0.17%)**	**0/306 (0.00%)**	**0/137 (0.00%)**	**1/601 (0.17%)**

Thermal burn † 1						
# participants affected / at risk	**0/601 (0.00%)**	**0/585 (0.00%)**	**0/601 (0.00%)**	**0/306 (0.00%)**	**1/137 (0.73%)**	**1/601 (0.17%)**
Metabolism and nutrition disorders						
Hypoglycaemia † 1						
# participants affected / at risk	**0/601 (0.00%)**	**0/585 (0.00%)**	**0/601 (0.00%)**	**0/306 (0.00%)**	**1/137 (0.73%)**	**1/601 (0.17%)**
Hypokalaemia † 1						
# participants affected / at risk	**0/601 (0.00%)**	**0/585 (0.00%)**	**0/601 (0.00%)**	**0/306 (0.00%)**	**1/137 (0.73%)**	**1/601 (0.17%)**
Musculoskeletal and connective tissue disorders						
Arthralgia † 1						
# participants affected / at risk	**0/601 (0.00%)**	**1/585 (0.17%)**	**1/601 (0.17%)**	**0/306 (0.00%)**	**0/137 (0.00%)**	**1/601 (0.17%)**
Intervertebral disc protrusion † 1						
# participants affected / at risk	**0/601 (0.00%)**	**0/585 (0.00%)**	**0/601 (0.00%)**	**0/306 (0.00%)**	**1/137 (0.73%)**	**1/601 (0.17%)**
Osteoarthritis † 1						
# participants affected / at risk	**0/601 (0.00%)**	**1/585 (0.17%)**	**1/601 (0.17%)**	**0/306 (0.00%)**	**1/137 (0.73%)**	**2/601 (0.33%)**
Neoplasms benign, malignant and unspecified (incl cysts and polyps)						
Breast cancer † 1						
# participants affected / at risk	**0/601 (0.00%)**	**1/585 (0.17%)**	**1/601 (0.17%)**	**0/306 (0.00%)**	**0/137 (0.00%)**	**1/601 (0.17%)**
Malignant melanoma † 1						
# participants affected / at risk	**0/601 (0.00%)**	**0/585 (0.00%)**	**0/601 (0.00%)**	**1/306 (0.33%)**	**0/137 (0.00%)**	**1/601 (0.17%)**
Nervous system disorders						
Cerebral haemorrhage † 1						
# participants affected / at risk	**0/601 (0.00%)**	**1/585 (0.17%)**	**1/601 (0.17%)**	**0/306 (0.00%)**	**0/137 (0.00%)**	**1/601 (0.17%)**
Dizziness † 1						
# participants affected / at risk	**1/601 (0.17%)**	**0/585 (0.00%)**	**1/601 (0.17%)**	**0/306 (0.00%)**	**1/137 (0.73%)**	**2/601 (0.33%)**
Syncope † 1						
# participants affected / at risk	**0/601 (0.00%)**	**1/585 (0.17%)**	**1/601 (0.17%)**	**0/306 (0.00%)**	**0/137 (0.00%)**	**1/601 (0.17%)**
Psychiatric disorders						
Substance abuse † 1						
# participants affected / at risk	**0/601 (0.00%)**	**1/585 (0.17%)**	**1/601 (0.17%)**	**0/306 (0.00%)**	**0/137 (0.00%)**	**1/601 (0.17%)**
Respiratory, thoracic						

and mediastinal disorders						
Asthma † 1						
# participants affected / at risk	**0/601 (0.00%)**	**0/585 (0.00%)**	**0/601 (0.00%)**	**1/306 (0.33%)**	**0/137 (0.00%)**	**1/601 (0.17%)**
Pulmonary congestion † 1						
# participants affected / at risk	**0/601 (0.00%)**	**1/585 (0.17%)**	**1/601 (0.17%)**	**0/306 (0.00%)**	**0/137 (0.00%)**	**1/601 (0.17%)**
Vascular disorders						
Aortic aneurysm † 1						
# participants affected / at risk	**0/601 (0.00%)**	**1/585 (0.17%)**	**1/601 (0.17%)**	**0/306 (0.00%)**	**0/137 (0.00%)**	**1/601 (0.17%)**
Deep vein thrombosis † 1						
# participants affected / at risk	**0/601 (0.00%)**	**0/585 (0.00%)**	**0/601 (0.00%)**	**0/306 (0.00%)**	**1/137 (0.73%)**	**1/601 (0.17%)**
Hypertension † 1						
# participants affected / at risk	**0/601 (0.00%)**	**1/585 (0.17%)**	**1/601 (0.17%)**	**0/306 (0.00%)**	**0/137 (0.00%)**	**1/601 (0.17%)**
Hypotension † 1						
# participants affected / at risk	**0/601 (0.00%)**	**1/585 (0.17%)**	**1/601 (0.17%)**	**0/306 (0.00%)**	**0/137 (0.00%)**	**1/601 (0.17%)**

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

Other Adverse Events

Hide Other Adverse Events

Time Frame	18 months
Additional Description	All patients who received at least one dose of study medication.

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
Core Period: Aliskiren 150 mg / Valsartan 160 mg Alone	Core Period: Aliskiren 150 mg /Valsartan 160 mg alone
Core Period: Aliskiren 300 mg / Valsartan 320 mg Alone	Core Period: Aliskiren 300 mg /Valsartan 320 mg alone
Core Period: Aliskiren / Valsartan	Core Period: Aliskiren/Valsartan
Core and Extension: Aliskiren / Valsartan / HCTZ 12.5 mg	Core and Extension: Aliskiren / Valsartan / HCTZ 12.5 mg
Core and Extension: Aliskiren / Valsartan / HCTZ 25 mg	Core and Extension: Aliskiren/Valsartan/HCTZ 25 mg
Core and Extension: Total	Core and Extension: Total includes all study patients, treated with Aliskiren/Valsartan or Aliskiren//valsartan/HCTZ during core or extension.

Other Adverse Events

	Core Period: Aliskiren 150 mg /	**Core Period: Aliskiren 300 mg /**	**Core Period:**	**Core and Extension:**	**Core and Extension:**	**Core and**

	Valsartan 160 mg Alone	Valsartan 320 mg Alone	Aliskiren / Valsartan	Aliskiren / Valsartan / HCTZ 12.5 mg	Aliskiren / Valsartan / HCTZ 25 mg	Extension: Total
Total, other (not including serious) adverse events						
# participants affected / at risk	**49/601 (8.15%)**	**185/585 (31.62%)**	**215/601 (35.77%)**	**47/306 (15.36%)**	**26/137 (18.98%)**	**251/601 (41.76%)**
Gastrointestinal disorders						
Diarrhoea † 1						
# participants affected / at risk	**8/601 (1.33%)**	**27/585 (4.62%)**	**34/601 (5.66%)**	**9/306 (2.94%)**	**1/137 (0.73%)**	**42/601 (6.99%)**
Infections and infestations						
Bronchitis † 1						
# participants affected / at risk	**3/601 (0.50%)**	**24/585 (4.10%)**	**27/601 (4.49%)**	**6/306 (1.96%)**	**3/137 (2.19%)**	**34/601 (5.66%)**
Nasopharyngitis † 1						
# participants affected / at risk	**6/601 (1.00%)**	**39/585 (6.67%)**	**43/601 (7.15%)**	**10/306 (3.27%)**	**6/137 (4.38%)**	**54/601 (8.99%)**
Upper respiratory tract infection † 1						
# participants affected / at risk	**2/601 (0.33%)**	**25/585 (4.27%)**	**28/601 (4.66%)**	**9/306 (2.94%)**	**2/137 (1.46%)**	**38/601 (6.32%)**
Musculoskeletal and connective tissue disorders						
Back pain † 1						
# participants affected / at risk	**4/601 (0.67%)**	**19/585 (3.25%)**	**21/601 (3.49%)**	**5/306 (1.63%)**	**6/137 (4.38%)**	**32/601 (5.32%)**
Nervous system disorders						
Dizziness † 1						
# participants affected / at risk	**15/601 (2.50%)**	**39/585 (6.67%)**	**49/601 (8.15%)**	**6/306 (1.96%)**	**7/137 (5.11%)**	**61/601 (10.15%)**
Headache † 1						
# participants affected / at risk	**16/601 (2.66%)**	**33/585 (5.64%)**	**45/601 (7.49%)**	**4/306 (1.31%)**	**2/137 (1.46%)**	**50/601 (8.32%)**

Respiratory, thoracic and mediastinal disorders						
Cough † 1						
# participants affected / at risk	**1/601 (0.17%)**	**23/585 (3.93%)**	**24/601 (3.99%)**	**5/306 (1.63%)**	**5/137 (3.65%)**	**31/601 (5.16%)**

† 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
Open label study with no comparator treatment/arm.

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:

Chrysant SG, Murray AV, Hoppe UC, Dattani D, Patel S, Ritter S, Zhang J. Long-term safety and efficacy of aliskiren and valsartan combination with or without the addition of HCT in patients with hypertension. Curr Med Res Opin. 2010 Dec;26(12):2841-9. doi: 10.1185/03007995.2010.528282. Epub 2010 Nov 9.

Responsible Party: External Affairs, Novartis

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