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Trial record **1 of 1** for: CSPA100A2301

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An Assessment of Long Term Safety of the Combination of Aliskiren / Amlodipine in Patients With High Blood Pressure

This study has been completed.

Sponsor:
Novartis

Information provided by:
Novartis

ClinicalTrials.gov Identifier:
NCT00402103

First received: November 18, 2006
Last updated: March 8, 2011
Last verified: March 2011
History of Changes

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Results First Received: December 13, 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: Amlodipine Drug: Hydrochlorothiazide

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
Aliskiren/Amlodipine	Aliskiren and Amlodipine tablets once a day in the morning
Aliskiren/Amlodipine/HCTZ	Aliskiren and Amlodipine tablets and HCTZ capsules once a day in the morning

Participant Flow: Overall Study

	Aliskiren/Amlodipine	**Aliskiren/Amlodipine/HCTZ**
STARTED	**470**	**86**

COMPLETED	**379**	**73**
NOT COMPLETED	**91**	**13**
Adverse Event	**60**	**7**
Unsatisfactory therapeutic effect	**1**	**2**
Condition no longer requires study drug	**2**	**0**
Protocol Deviation	**8**	**0**
Patient withdrew consent	**12**	**1**
Lost to Follow-up	**6**	**3**
Administrative problems	**2**	**0**

Baseline Characteristics

Hide Baseline Characteristics

Population Description

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

Reporting Groups

	Description
Aliskiren/Amlodipine	Aliskiren and Amlodipine tablets once a day in the morning
Aliskiren/Amlodipine/HCTZ	Aliskiren and Amlodipine tablets and HCTZ capsules once a day in the morning
Total	Total of all reporting groups

Baseline Measures

	Aliskiren/Amlodipine	Aliskiren/Amlodipine/HCTZ	Total
Number of Participants [units: participants]	**470**	**86**	**556**
Age [units: years] Mean (Standard Deviation)	**54.2 (11.66)**	**55.7 (11.33)**	**54.4 (11.61)**
Gender [units: participants]			
Female	**196**	**30**	**226**
Male	**274**	**56**	**330**

Outcome Measures

Hide All Outcome Measures

1. Primary: Overall Percentage of Patients With Adverse Events [Time Frame: 52 weeks]

Measure Type	Primary
Measure Title	Overall Percentage of Patients With Adverse Events
Measure Description	No text entered.
Time Frame	52 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.
Treated Population

Reporting Groups

	Description
Aliskiren 150mg/ Amlodipine 5mg Alone	Aliskiren 150mg and Amlodipine 5mg tablets once a day in the morning
Aliskiren 300mg/ Amlodipine 10mg Alone	Aliskiren 300mg and Amlodipine 10mg tablets once a day in the morning
Aliskiren 300mg/ Amlodipine 10mg/ HCTZ	Aliskiren 300mg and Amlodipine 10mg tablets and HCTZ capsules once a day in the morning

Measured Values

	Aliskiren 150mg/ Amlodipine 5mg Alone	**Aliskiren 300mg/ Amlodipine 10mg Alone**	**Aliskiren 300mg/ Amlodipine 10mg/ HCTZ**
Number of Participants Analyzed [units: participants]	**556**	**546**	**86**
Overall Percentage of Patients With Adverse Events [units: Percentage of Participants]	**23.6**	**71.2**	**57.0**

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

2. Secondary: Change in Mean Sitting Diastolic Blood Pressure (msDBP)From Baseline to the Indicated Time Points [Time Frame: Baseline, Week 2, Week 4, Week 6, Week 10, Week 14, Week 28, Week 41 and Week 54]

Measure Type	Secondary
Measure Title	Change in Mean Sitting Diastolic Blood Pressure (msDBP)From Baseline to the Indicated Time Points
Measure Description	No text entered.
Time Frame	Baseline, Week 2, Week 4, Week 6, Week 10, Week 14, Week 28, Week 41 and Week 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, Last observation carried forward (LOCF). Total combined treated patients are 556 out of which 470 patients are treated with Aliskiren and Amlodipine combination only and 86 patients are treated with Ali/Amlo/HCTZ combination.

Reporting Groups

	Description
Aliskiren/Amlodipine	Aliskiren and Amlodipine tablets once a day in the morning
Aliskiren/Amlodipine/HCTZ	Aliskiren and Amlodipine tablets and HCTZ capsules once a day in the morning

Measured Values

	Aliskiren/Amlodipine	**Aliskiren/Amlodipine/HCTZ**

Number of Participants Analyzed [units: participants]	**470**	**86**
Change in Mean Sitting Diastolic Blood Pressure (msDBP)From Baseline to the Indicated Time Points [units: mm Hg] Mean (Standard Deviation)		
Week 2 (Visit 5)	**-8.7 (6.94)**	**-5.9 (6.05)**
Week 4 (Visit 6)	**-14.0 (6.88)**	**-11.9 (5.58)**
Week 6 (Visit 7)	**-15.7 (6.96)**	**-11.5 (7.36)**
Week 10 (Visit 8)	**-16.3 (6.69)**	**-9.3 (7.22)**
Week 14 (Visit 9)	**-17.1 (6.84)**	**-13.1 (7.64)**
Week 28 (Visit 10)	**-16.7 (7.15)**	**-14.7 (8.22)**
Week 41 (Visit 11)	**-17.0 (7.26)**	**-15.4 (6.86)**
Week 54 (Visit 12)	**-16.3 (7.13)**	**-15.3 (6.55)**
Week 54 (Visit 12) (LOCF)	**-15.7 (7.61)**	**-14.2 (7.90)**

No statistical analysis provided for Change in Mean Sitting Diastolic Blood Pressure (msDBP)From Baseline to the Indicated Time Points

3. Secondary: Percentage of Patients Achieving a Blood Pressure Control Target of <140/90 mmHg [Time Frame: Baseline, Week 2, Week 10, Week 28 and Week 54]

Measure Type	Secondary
Measure Title	Percentage of Patients Achieving a Blood Pressure Control Target of <140/90 mmHg
Measure Description	No text entered.
Time Frame	Baseline, Week 2, Week 10, Week 28 and Week 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, Last observation carried forward (LOCF). Total combined treated patients are 556 out of which 470 patients are treated with Aliskiren and Amlodipine combination only and 86 patients are treated with Ali/Amlo/HCTZ combination.

Reporting Groups

	Description
Aliskiren/Amlodipine	Aliskiren and Amlodipine tablets once a day in the morning
Aliskiren/Amlodipine/HCTZ	Aliskiren and Amlodipine tablets and HCTZ capsules once a day in the morning

Measured Values

	Aliskiren/Amlodipine	**Aliskiren/Amlodipine/HCTZ**
Number of Participants Analyzed [units: participants]	**470**	**86**
Percentage of Patients Achieving a Blood Pressure Control Target of <140/90 mmHg [units: Percentage of patients]		
Week 2 (Visit 5)	**35.3**	**8.1**

Week 10 (Visit 8)	**88.0**	**16.3**
Week 28 (Visit 10)	**88.2**	**56.8**
Week 54 (Visit 12)	**82.0**	**62.2**
Week 54 (Visit 12) (LOCF)	**77.3**	**58.1**

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

4. Secondary: Percentage of Patients Achieving a Response in Mean Sitting Diastolic Blood Pressure (msDBP) [Time Frame: Baseline, Week 2, Week 10, Week 28 and Week 54]

Measure Type	Secondary
Measure Title	Percentage of Patients Achieving a Response in Mean Sitting Diastolic Blood Pressure (msDBP)
Measure Description	No text entered.
Time Frame	Baseline, Week 2, Week 10, Week 28 and Week 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, Last observation carried forward (LOCF). Total combined treated patients are 556 out of which 470 patients are treated with Aliskiren and Amlodipine combination only and 86 patients are treated with Ali/Amlo/HCTZ combination.

Reporting Groups

	Description
Aliskiren/Amlodipine	Aliskiren and Amlodipine tablets once a day in the morning
Aliskiren/Amlodipine/HCTZ	Aliskiren and Amlodipine tablets and HCTZ capsules once a day in the morning

Measured Values

	Aliskiren/Amlodipine	**Aliskiren/Amlodipine/HCTZ**
Number of Participants Analyzed [units: participants]	**470**	**86**
Percentage of Patients Achieving a Response in Mean Sitting Diastolic Blood Pressure (msDBP) [units: Percentage of patients]		
Week 2 (Visit 5)	**61.2**	**38.4**
Week 10 (Visit 8)	**96.8**	**61.6**
Week 28 (Visit 10)	**95.9**	**85.2**
Week 54 (Visit 12)	**93.2**	**89.2**
Week 54 (Visit 12) (LOCF)	**90.6**	**84.9**

No statistical analysis provided for Percentage of Patients Achieving a Response in Mean Sitting Diastolic Blood Pressure (msDBP)

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	No text entered.
Additional Description	No text entered.

Reporting Groups

	Description
Aliskiren 150mg/ Amlodipine 5mg Alone	Aliskiren 150mg and Amlodipine 5mg tablets once a day in the morning
Aliskiren 300mg/ Amlodipine 10mg Alone	Aliskiren 300mg and Amlodipine 10mg tablets once a day in the morning
Aliskiren 300mg/ Amlodipine 10mg/ HCTZ	Aliskiren 300mg and Amlodipine 10mg tablets and HCTZ capsules once a day in the morning

Serious Adverse Events

	Aliskiren 150mg/ Amlodipine 5mg Alone	Aliskiren 300mg/ Amlodipine 10mg Alone	Aliskiren 300mg/ Amlodipine 10mg/ HCTZ
Total, serious adverse events			
# participants affected / at risk	**0/556 (0.00%)**	**13/546 (2.38%)**	**2/86 (2.33%)**
Cardiac disorders			
Atrial fibrillation † 1			
# participants affected / at risk	**0/556 (0.00%)**	**1/546 (0.18%)**	**0/86 (0.00%)**
Gastrointestinal disorders			
Diarrhoea † 1			
# participants affected / at risk	**0/556 (0.00%)**	**1/546 (0.18%)**	**0/86 (0.00%)**
Intestinal ischaemia † 1			
# participants affected / at risk	**0/556 (0.00%)**	**1/546 (0.18%)**	**0/86 (0.00%)**
Infections and infestations			
Amoebiasis † 1			
# participants affected / at risk	**0/556 (0.00%)**	**1/546 (0.18%)**	**0/86 (0.00%)**
Gangrene † 1			
# participants affected / at risk	**0/556 (0.00%)**	**0/546 (0.00%)**	**1/86 (1.16%)**
Gastroenteritis † 1			
# participants affected / at risk	**0/556 (0.00%)**	**1/546 (0.18%)**	**0/86 (0.00%)**
Post procedural infection † 1			
# participants affected / at risk	**0/556 (0.00%)**	**1/546 (0.18%)**	**0/86 (0.00%)**
Respiratory tract infection † 1			
# participants affected / at risk	**0/556 (0.00%)**	**1/546 (0.18%)**	**0/86 (0.00%)**
Injury, poisoning and procedural complications			
Acetabulum fracture † 1			
# participants affected / at risk	**0/556 (0.00%)**	**1/546 (0.18%)**	**0/86 (0.00%)**
Fall † 1			
# participants affected / at risk	**0/556 (0.00%)**	**1/546 (0.18%)**	**0/86 (0.00%)**
Ligament injury † 1			
# participants affected / at risk	**0/556 (0.00%)**	**1/546 (0.18%)**	**0/86 (0.00%)**
Pubic rami fracture † 1			
# participants affected / at risk	**0/556 (0.00%)**	**1/546 (0.18%)**	**0/86 (0.00%)**
Metabolism and nutrition disorders			

Diabetes mellitus † 1			
# participants affected / at risk	**0/556 (0.00%)**	**1/546 (0.18%)**	**0/86 (0.00%)**
Hypovolaemia † 1			
# participants affected / at risk	**0/556 (0.00%)**	**1/546 (0.18%)**	**0/86 (0.00%)**
Musculoskeletal and connective tissue disorders			
Osteoarthritis † 1			
# participants affected / at risk	**0/556 (0.00%)**	**1/546 (0.18%)**	**0/86 (0.00%)**
Rotator cuff syndrome † 1			
# participants affected / at risk	**0/556 (0.00%)**	**1/546 (0.18%)**	**0/86 (0.00%)**
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Malignant melanoma † 1			
# participants affected / at risk	**0/556 (0.00%)**	**1/546 (0.18%)**	**0/86 (0.00%)**
Prostate cancer metastatic † 1			
# participants affected / at risk	**0/556 (0.00%)**	**1/546 (0.18%)**	**0/86 (0.00%)**
Psychiatric disorders			
Depression † 1			
# participants affected / at risk	**0/556 (0.00%)**	**1/546 (0.18%)**	**0/86 (0.00%)**
Suicide attempt † 1			
# participants affected / at risk	**0/556 (0.00%)**	**1/546 (0.18%)**	**0/86 (0.00%)**
Renal and urinary disorders			
Renal failure acute † 1			
# participants affected / at risk	**0/556 (0.00%)**	**1/546 (0.18%)**	**0/86 (0.00%)**
Respiratory, thoracic and mediastinal disorders			
Asthma † 1			
# participants affected / at risk	**0/556 (0.00%)**	**1/546 (0.18%)**	**0/86 (0.00%)**
Pulmonary embolism † 1			
# participants affected / at risk	**0/556 (0.00%)**	**1/546 (0.18%)**	**0/86 (0.00%)**
Vascular disorders			
Deep vein thrombosis † 1			
# participants affected / at risk	**0/556 (0.00%)**	**1/546 (0.18%)**	**0/86 (0.00%)**
Hypotension † 1			
# participants affected / at risk	**0/556 (0.00%)**	**0/546 (0.00%)**	**1/86 (1.16%)**

† 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	No text entered.

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
Aliskiren 150mg/ Amlodipine 5mg Alone	Aliskiren 150mg and Amlodipine 5mg tablets once a day in the morning
Aliskiren 300mg/ Amlodipine 10mg Alone	Aliskiren 300mg and Amlodipine 10mg tablets once a day in the morning
Aliskiren 300mg/ Amlodipine 10mg/ HCTZ	Aliskiren 300mg and Amlodipine 10mg tablets and HCTZ capsules once a day in the morning

Other Adverse Events

	Aliskiren 150mg/ Amlodipine 5mg Alone	Aliskiren 300mg/ Amlodipine 10mg Alone	Aliskiren 300mg/ Amlodipine 10mg/ HCTZ
Total, other (not including serious) adverse events			
# participants affected / at risk	**14/556 (2.52%)**	**138/546 (25.27%)**	**21/86 (24.42%)**
General disorders			
Oedema peripheral † 1			
# participants affected / at risk	**8/556 (1.44%)**	**108/546 (19.78%)**	**12/86 (13.95%)**
Infections and infestations			
Upper respiratory tract infection † 1			
# participants affected / at risk	**5/556 (0.90%)**	**32/546 (5.86%)**	**5/86 (5.81%)**
Musculoskeletal and connective tissue disorders			
Muscle spasms † 1			
# participants affected / at risk	**1/556 (0.18%)**	**5/546 (0.92%)**	**5/86 (5.81%)**

† 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:

Littlejohn TW 3rd, Trenkwalder P, Hollanders G, Zhao Y, Liao W. Long-term safety, tolerability and efficacy of combination therapy with aliskiren and amlodipine in patients with hypertension. Curr Med Res Opin. 2009 Apr;25(4):951-9. doi: 10.1185/03007990902785845 .

Responsible Party:	External Affairs, Novartis
ClinicalTrials.gov Identifier:	NCT00402103 History of Changes
Other Study ID Numbers:	**CSPA100A2301**
Study First Received:	November 18, 2006
Results First Received:	December 13, 2010
Last Updated:	March 8, 2011
Health Authority:	United States: Food and Drug Administration Belgium: Ministry of Social Affairs, Public Health and the Environment Denmark: Danish Medicines Agency Finland: Finnish Medicines Agency Germany: Federal Institute for Drugs and Medical Devices India: Ministry of Health Switzerland: Swissmedic