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Trial record **1 of 1** for: CSPA100A2304

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Study to Evaluate the Efficacy and Safety of Combination Aliskiren/Amlodipine in Patients With Hypertension Not Adequately Responding to Amlodipine Alone

This study has been completed.

Sponsor:
Novartis

Information provided by:
Novartis

ClinicalTrials.gov Identifier:
NCT00778921

First received: October 23, 2008
Last updated: February 25, 2011
Last verified: February 2011
History of Changes

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

Results First Received: December 13, 2010

Study Type:	Interventional
Study Design:	Allocation: Randomized; Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Investigator); Primary Purpose: Treatment
Condition:	Hypertension
Interventions:	Drug: Amlodipine 10 mg Drug: Aliskiren 150 Drug: Amlodipine 300

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 300/10 mg	Oral tablets of combination aliskiren/amlodipine 300/10 mg taken once daily with water in the morning
Aliskiren/Amlodipine 150/10 mg	Oral tablets of combination aliskiren/amlodipine 150/10 mg taken once daily with water in the morning
Amlodipine 10 mg	Oral capsules of amlodipine 10 mg taken once daily with water in the morning

Participant Flow: Overall Study

	Aliskiren/Amlodipine 300/10 mg	Aliskiren/Amlodipine 150/10 mg	Amlodipine 10 mg
STARTED	**279**	**285**	**283**

COMPLETED	**261**	**266**	**255**
NOT COMPLETED	**18**	**19**	**28**
Adverse Event	**9**	**10**	**14**
Abnormal Laboratory Value(s)	**1**	**0**	**0**
Abnormal Test Procedure Result(s)	**0**	**0**	**2**
Unsatisfactory therapeutic response	**1**	**1**	**1**
Patient No Longer Requires Study Drug	**0**	**1**	**0**
Patient withdrew request	**3**	**1**	**6**
Lost to Follow-up	**0**	**2**	**1**
Administrative Problems	**1**	**2**	**0**
Protocol Violation	**3**	**0**	**2**
Not treated	**0**	**2**	**2**

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 300/10 mg	Oral tablets of combination aliskiren/amlodipine 300/10 mg taken once daily with water in the morning
Aliskiren/Amlodipine 150/10 mg	Oral tablets of combination aliskiren/amlodipine 150/10 mg taken once daily with water in the morning
Amlodipine 10 mg	Oral capsules of amlodipine 10 mg taken once daily with water in the morning
Total	Total of all reporting groups

Baseline Measures

	Aliskiren/Amlodipine 300/10 mg	Aliskiren/Amlodipine 150/10 mg	Amlodipine 10 mg	Total
Number of Participants [units: participants]	**279**	**285**	**283**	**847**
Age [units: years] Mean (Standard Deviation)	**55.2 (10.19)**	**54.4 (10.70)**	**54.3 (10.92)**	**54.6 (10.60)**
Gender [units: participants]				
Female	**116**	**113**	**99**	**328**
Male	**163**	**172**	**184**	**519**

Outcome Measures

Hide All Outcome Measures

1. Primary: Change in Mean Sitting Diastolic Blood Pressure (msDBP) From Baseline to End of Study [Time Frame: Baseline and Week 8]

Measure Type	Primary
Measure Title	Change in Mean Sitting Diastolic Blood Pressure (msDBP) From Baseline to End of Study
Measure Description	No text entered.
Time Frame	Baseline and 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

Reporting Groups

	Description
Aliskiren/Amlodipine 300/10 mg	Oral tablets of combination aliskiren/amlodipine 300/10 mg taken once daily with water in the morning
Aliskiren/Amlodipine 150/10 mg	Oral tablets of combination aliskiren/amlodipine 150/10 mg taken once daily with water in the morning
Amlodipine 10 mg	Oral capsules of amlodipine 10 mg taken once daily with water in the morning

Measured Values

	Aliskiren/Amlodipine 300/10 mg	**Aliskiren/Amlodipine 150/10 mg**	**Amlodipine 10 mg**
Number of Participants Analyzed [units: participants]	**277**	**281**	**279**
Change in Mean Sitting Diastolic Blood Pressure (msDBP) From Baseline to End of Study [units: mm Hg] Least Squares Mean (Standard Error)			
Change from baseline in msDBP	**-10.99 (0.462)**	**-8.95 (0.460)**	**-7.23 (0.459)**

No statistical analysis provided for Change in Mean Sitting Diastolic Blood Pressure (msDBP) From Baseline to End of Study

2. Secondary: Change in Mean Sitting Systolic Blood Pressure (msSBP) From Baseline to End of Study [Time Frame: Baseline and Week 8]

Measure Type	Secondary
Measure Title	Change in Mean Sitting Systolic Blood Pressure (msSBP) From Baseline to End of Study
Measure Description	No text entered.
Time Frame	Baseline and 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

Reporting Groups

	Description
Aliskiren/Amlodipine 300/10 mg	Oral tablets of combination aliskiren/amlodipine 300/10 mg taken once daily with water in the morning

Aliskiren/Amlodipine 150/10 mg	Oral tablets of combination aliskiren/amlodipine 150/10 mg taken once daily with water in the morning
Amlodipine 10 mg	Oral capsules of amlodipine 10 mg taken once daily with water in the morning

Measured Values

	Aliskiren/Amlodipine 300/10 mg	Aliskiren/Amlodipine 150/10 mg	Amlodipine 10 mg
Number of Participants Analyzed [units: participants]	**277**	**281**	**279**
Change in Mean Sitting Systolic Blood Pressure (msSBP) From Baseline to End of Study [units: mm Hg] Least Squares Mean (Standard Error)	**-14.42 (0.684)**	**-11.01 (0.681)**	**-8.20 (0.680)**

No statistical analysis provided for Change in Mean Sitting Systolic Blood Pressure (msSBP) From Baseline to End of Study

3. Secondary: Number of Patients With Any Adverse Event and/or Serious Adverse Event in the Double-blind Period by Treatment Group [Time Frame: 8 weeks]

Measure Type	Secondary
Measure Title	Number of Patients With Any Adverse Event and/or Serious Adverse Event in the Double-blind Period by Treatment Group
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.
Analysis: Intention to Treat (ITT) Imputation Technique: Last Observation Carried Forward (LOCF)

Reporting Groups

	Description
Aliskiren/Amlodipine 300/10 mg	Oral tablets of combination aliskiren/amlodipine 300/10 mg taken once daily with water in the morning
Aliskiren/Amlodipine 150/10 mg	Oral tablets of combination aliskiren/amlodipine 150/10 mg taken once daily with water in the morning
Amlodipine 10 mg	Oral capsules of amlodipine 10 mg taken once daily with water in the morning

Measured Values

	Aliskiren/Amlodipine 300/10 mg	Aliskiren/Amlodipine 150/10 mg	Amlodipine 10 mg
Number of Participants Analyzed [units: participants]	**279**	**283**	**281**
Number of Patients With Any Adverse Event and/or Serious Adverse Event in the Double-blind Period by Treatment Group [units: Participants]	**87**	**99**	**92**

No statistical analysis provided for Number of Patients With Any Adverse Event and/or Serious Adverse Event in the Double-blind Period by Treatment Group

4. Secondary: Biomarker Assessment at Visit 2 (Single Blind Run in), Visit 5 (Randomization), and Visit 9 (EOS) [Time Frame: 12 weeks]

Results not yet reported. **Anticipated Reporting Date:** No text entered. **Safety Issue:** No

Serious Adverse Events

Hide Serious Adverse Events

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

Reporting Groups

	Description
Aliskiren 300mg/ Amlodipine 10mg	Aliskiren 300mg/ Amlodipine 10mg
Aliskiren 150mg/ Amlodipine 10mg	Aliskiren 150mg/ Amlodipine 10mg
Amlodipine 10mg	Amlodipine 10mg

Serious Adverse Events

	Aliskiren 300mg/ Amlodipine 10mg	Aliskiren 150mg/ Amlodipine 10mg	Amlodipine 10mg
Total, serious adverse events			
# participants affected / at risk	**4/279 (1.43%)**	**1/283 (0.35%)**	**0/281 (0.00%)**
Blood and lymphatic system disorders			
Lymphoid tissue hyperplasia † 1			
# participants affected / at risk	**1/279 (0.36%)**	**0/283 (0.00%)**	**0/281 (0.00%)**
Injury, poisoning and procedural complications			
Joint injury † 1			
# participants affected / at risk	**0/279 (0.00%)**	**1/283 (0.35%)**	**0/281 (0.00%)**
Tendon rupture † 1			
# participants affected / at risk	**1/279 (0.36%)**	**0/283 (0.00%)**	**0/281 (0.00%)**
Renal and urinary disorders			
Renal artery stenosis † 1			
# participants affected / at risk	**1/279 (0.36%)**	**0/283 (0.00%)**	**0/281 (0.00%)**
Respiratory, thoracic and mediastinal disorders			
Oropharyngeal pain † 1			
# participants affected / at risk	**1/279 (0.36%)**	**0/283 (0.00%)**	**0/281 (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	No text entered.

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
Aliskiren 300mg/ Amlodipine 10mg	Aliskiren 300mg/ Amlodipine 10mg
Aliskiren 150mg/ Amlodipine 10mg	Aliskiren 150mg/ Amlodipine 10mg
Amlodipine 10mg	Amlodipine 10mg

Other Adverse Events

	Aliskiren 300mg/ Amlodipine 10mg	Aliskiren 150mg/ Amlodipine 10mg	Amlodipine 10mg
Total, other (not including serious) adverse events			
# participants affected / at risk	**31/279 (11.11%)**	**35/283 (12.37%)**	**40/281 (14.23%)**
General disorders			
Oedema peripheral † 1			
# participants affected / at risk	**15/279 (5.38%)**	**23/283 (8.13%)**	**25/281 (8.90%)**
Infections and infestations			
Nasopharyngitis † 1			
# participants affected / at risk	**16/279 (5.73%)**	**15/283 (5.30%)**	**15/281 (5.34%)**

† 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:

Pfeiffer D, Rennie N, Papst CC, Zhang J. Efficacy and tolerability of aliskiren/amlodipine single-pill combinations in patients who did not respond fully to amlodipine monotherapy¥. Curr Vasc Pharmacol. 2012 Nov;10(6):773-80.

Responsible Party:	Study Director, Novartis Pharmaceuticals
ClinicalTrials.gov Identifier:	NCT00778921 History of Changes
Other Study ID Numbers:	**CSPA100A2304**
Study First Received:	October 23, 2008
Results First Received:	December 13, 2010
Last Updated:	February 25, 2011
Health Authority:	Argentina: Administracion Nacional de Medicamentos, Alimentos y Tecnologia Medica Germany: Federal Institute for Drugs and Medical Devices Poland: Office for Registration of Medicinal Products, Medical Devices and Biocidal Products Sweden: Medical Products Agency Slovakia: State Institute for Drug Control Turkey: Ministry of Health