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Trial record **1 of 1** for: CSAH100A2302

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Efficacy and Safety of Aliskiren/Amlodipine/Hydrochlorothiazide in Patients With Moderate-severe Hypertension

This study has been completed.

Sponsor:
Novartis

Information provided by:
Novartis

ClinicalTrials.gov Identifier:
NCT00765674

First received: October 2, 2008
Last updated: April 15, 2011
Last verified: April 2011
History of Changes

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Results First Received: January 12, 2011

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Caregiver, Investigator); Primary Purpose: Treatment
Condition:	Hypertension
Interventions:	Drug: Aliskiren Drug: Amlodipine Drug: Hydrochlorothiazide (HCTZ) Drug: Placebo

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
In the single-blind period, 1909 patients were enrolled, 1189 completed, and 720 discontinued. Of the 1191 randomized patients, 2 patients were randomized by error and discontinued in the single-blind period without taking double-blind medication.

Reporting Groups

	Description
Aliskiren / Amlodipine	Patients received an aliskiren 150 mg tablet plus an amlodipine 5 mg capsule for 4 weeks and then were force titrated up to aliskiren 300 mg plus amlodipine 10 mg for the remaining 4 weeks of the study. During the 8 weeks, patients also received a placebo tablet and a placebo capsule. Patients took a total of 4 pills each day orally with water in the morning at approximately 8:00 am, except on the morning of a study visit when they took their study medications after all visit procedures and assessments had been completed.

Aliskiren / Hydrochlorothiazide	Patients received an aliskiren 150 mg tablet plus a hydrochlorothiazide 12.5 mg capsule for 4 weeks and then were force titrated up to aliskiren 300 mg plus hydrochlorothiazide 25 mg for the remaining 4 weeks of the study. During the 8 weeks, patients also received a placebo capsule and a placebo tablet. Patients took a total of 4 pills each day orally with water in the morning at approximately 8:00 am, except on the morning of a study visit when they took their study medications after all visit procedures and assessments had been completed.
Amlodipine / Hydrochlorothiazide	Patients received an amlodipine 5 mg capsule plus a hydrochlorothiazide 12.5 mg capsule for 4 weeks and then were force titrated up to amlodipine 10 mg plus hydrochlorothiazide 25 mg for the remaining 4 weeks of the study. During the 8 weeks, patients also received 2 placebo tablets. Patients took a total of 4 pills each day orally with water in the morning at approximately 8:00 am, except on the morning of a study visit when they took their study medications after all visit procedures and assessments had been completed
Aliskiren / Amlodipine / Hydrochlorothiazide	Patients received an aliskiren 150 mg tablet, a HCTZ 12.5 mg capsule and a placebo capsule for the first 3 days of treatment. Amlodipine 5 mg was then added for the remainder of the first 4 weeks of treatment. At the end of 4 weeks, patients were force titrated up to aliskiren / amlodipine / hydrochlorothiazide 300/10/25 mg for the remaining 4 weeks of the study. During the 8 weeks, patients also received a placebo tablet. Patients took a total of 4 pills each day orally with water in the morning at approximately 8:00 am, except on the morning of a study visit when they took their study medications after all visit procedures and assessments had been completed

Participant Flow: Overall Study

	Aliskiren / Amlodipine	Aliskiren / Hydrochlorothiazide	Amlodipine / Hydrochlorothiazide	Aliskiren / Amlodipine / Hydrochlorothiazide
STARTED	287	298 [1]	296	310 [1]
COMPLETED	266	276	279	285
NOT COMPLETED	21	22	17	25
Adverse Event	7	2	8	11
Abnormal Laboratory Value(s)	0	0	1	0
Abnormal Test Procedure Result(s)	1	3	1	2
Lack of Efficacy	2	3	1	2
Protocol Violation	2	0	1	0
Withdrawal by Subject	5	7	3	8
Lost to Follow-up	4	6	2	1
Randomized in Error - No Study Drug	0	1	0	1

[1] 1 patient was randomized in error and discontinued without taking any double-blind study medication.

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	Patients received an aliskiren 150 mg tablet plus an amlodipine 5 mg capsule for 4 weeks and

	then were force titrated up to aliskiren 300 mg plus amlodipine 10 mg for the remaining 4 weeks of the study. During the 8 weeks, patients also received a placebo tablet and a placebo capsule. Patients took a total of 4 pills each day orally with water in the morning at approximately 8:00 am, except on the morning of a study visit when they took their study medications after all visit procedures and assessments had been completed.
Aliskiren / Hydrochlorothiazide	Patients received an aliskiren 150 mg tablet plus a hydrochlorothiazide 12.5 mg capsule for 4 weeks and then were force titrated up to aliskiren 300 mg plus hydrochlorothiazide 25 mg for the remaining 4 weeks of the study. During the 8 weeks, patients also received a placebo capsule and a placebo tablet. Patients took a total of 4 pills each day orally with water in the morning at approximately 8:00 am, except on the morning of a study visit when they took their study medications after all visit procedures and assessments had been completed.
Amlodipine / Hydrochlorothiazide	Patients received an amlodipine 5 mg capsule plus a hydrochlorothiazide 12.5 mg capsule for 4 weeks and then were force titrated up to amlodipine 10 mg plus hydrochlorothiazide 25 mg for the remaining 4 weeks of the study. During the 8 weeks, patients also received 2 placebo tablets. Patients took a total of 4 pills each day orally with water in the morning at approximately 8:00 am, except on the morning of a study visit when they took their study medications after all visit procedures and assessments had been completed
Aliskiren / Amlodipine / Hydrochlorothiazide	Patients received an aliskiren 150 mg tablet, a HCTZ 12.5 mg capsule and a placebo capsule for the first 3 days of treatment. Amlodipine 5 mg was then added for the remainder of the first 4 weeks of treatment. At the end of 4 weeks, patients were force titrated up to aliskiren / amlodipine / hydrochlorothiazide 300/10/25 mg for the remaining 4 weeks of the study. During the 8 weeks, patients also received a placebo tablet. Patients took a total of 4 pills each day orally with water in the morning at approximately 8:00 am, except on the morning of a study visit when they took their study medications after all visit procedures and assessments had been completed
Total	Total of all reporting groups

Baseline Measures

	Aliskiren / Amlodipine	Aliskiren / Hydrochlorothiazide	Amlodipine / Hydrochlorothiazide	Aliskiren / Amlodipine / Hydrochlorothiazide	Total
Number of Participants [units: participants]	**287**	**298**	**296**	**310**	**1191**
Age [units: years] Mean (Standard Deviation)	**54.4 (11.33)**	**55.5 (10.75)**	**55.1 (10.86)**	**55.4 (10.54)**	**55.1 (10.86)**
Age, Customized [units: participants]					
< 65 years	**237**	**242**	**233**	**251**	**963**
>=65 years	**50**	**56**	**63**	**59**	**228**
Gender [units: participants]					
Female	**115**	**123**	**110**	**123**	**471**
Male	**172**	**175**	**186**	**187**	**720**

Outcome Measures

Hide All Outcome Measures

1. Primary: Change in Mean Sitting Systolic Blood Pressure (msSBP) From Baseline to End of Study (Week 8) [Time Frame: Baseline to end of study (Week 8)]

Measure Type	Primary

Measure Title	Change in Mean Sitting Systolic Blood Pressure (msSBP) From Baseline to End of Study (Week 8)
Measure Description	Blood pressure (BP) was measured at trough (24±3 hours post-dose). The arm in which the highest sitting diastolic BP was found at study entry was used for all subsequent readings. If there was < 0.5 mmHg difference in BP between the 2 arms, the non-dominant arm was used. At each visit, after the patient was in a sitting position with the back supported and both feet placed on the floor for 5 minutes, systolic and diastolic BP were measured 3 times with an automated BP monitor and appropriate size cuff. Means of the 3 measurements were calculated. A negative change indicates lowered BP.
Time Frame	Baseline to end of study (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 population: All randomized patients who had post-baseline efficacy measurements.

Reporting Groups

	Description
Aliskiren / Amlodipine	Patients received an aliskiren 150 mg tablet plus an amlodipine 5 mg capsule for 4 weeks and then were force titrated up to aliskiren 300 mg plus amlodipine 10 mg for the remaining 4 weeks of the study. During the 8 weeks, patients also received a placebo tablet and a placebo capsule. Patients took a total of 4 pills each day orally with water in the morning at approximately 8:00 am, except on the morning of a study visit when they took their study medications after all visit procedures and assessments had been completed.
Aliskiren / Hydrochlorothiazide	Patients received an aliskiren 150 mg tablet plus a hydrochlorothiazide 12.5 mg capsule for 4 weeks and then were force titrated up to aliskiren 300 mg plus hydrochlorothiazide 25 mg for the remaining 4 weeks of the study. During the 8 weeks, patients also received a placebo capsule and a placebo tablet. Patients took a total of 4 pills each day orally with water in the morning at approximately 8:00 am, except on the morning of a study visit when they took their study medications after all visit procedures and assessments had been completed.
Amlodipine / Hydrochlorothiazide	Patients received an amlodipine 5 mg capsule plus a hydrochlorothiazide 12.5 mg capsule for 4 weeks and then were force titrated up to amlodipine 10 mg plus hydrochlorothiazide 25 mg for the remaining 4 weeks of the study. During the 8 weeks, patients also received 2 placebo tablets. Patients took a total of 4 pills each day orally with water in the morning at approximately 8:00 am, except on the morning of a study visit when they took their study medications after all visit procedures and assessments had been completed
Aliskiren / Amlodipine / Hydrochlorothiazide	Patients received an aliskiren 150 mg tablet, a HCTZ 12.5 mg capsule and a placebo capsule for the first 3 days of treatment. Amlodipine 5 mg was then added for the remainder of the first 4 weeks of treatment. At the end of 4 weeks, patients were force titrated up to aliskiren / amlodipine / hydrochlorothiazide 300/10/25 mg for the remaining 4 weeks of the study. During the 8 weeks, patients also received a placebo tablet. Patients took a total of 4 pills each day orally with water in the morning at approximately 8:00 am, except on the morning of a study visit when they took their study medications after all visit procedures and assessments had been completed

Measured Values

	Aliskiren / Amlodipine	**Aliskiren / Hydrochlorothiazide**	**Amlodipine / Hydrochlorothiazide**	**Aliskiren / Amlodipine / Hydrochlorothiazide**
Number of Participants Analyzed [units: participants]	**282**	**296**	**295**	**308**
Change in Mean Sitting Systolic Blood Pressure (msSBP) From Baseline to End of Study (Week 8) [units: mmHg] Least Squares Mean (Standard Error)	**-31.37 (0.90)**	**-27.99 (0.88)**	**-30.77 (0.88)**	**-37.92 (0.86)**

No statistical analysis provided for Change in Mean Sitting Systolic Blood Pressure (msSBP) From Baseline to End of Study (Week 8)

2. Secondary: Change in Mean Sitting Diastolic Blood Pressure (msDBP) From Baseline to End of Study (Week 8) [Time Frame: Baseline to end of study (Week 8)]

Measure Type	Secondary
Measure Title	Change in Mean Sitting Diastolic Blood Pressure (msDBP) From Baseline to End of Study (Week 8)
Measure Description	Blood pressure (BP) was measured at trough (24±3 hours post-dose). The arm in which the highest sitting diastolic BP was found at study entry was used for all subsequent readings. If there was < 0.5 mmHg difference in BP between the 2 arms, the non-dominant arm was used. At each visit, after the patient was in a sitting position with the back supported and both feet placed on the floor for 5 minutes, systolic and diastolic BP were measured 3 times with an automated BP monitor and appropriate size cuff. Means of the 3 measurements were calculated. A negative change indicates lowered BP.
Time Frame	Baseline to end of study (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 population: All randomized patients who had post-baseline efficacy measurements.

Reporting Groups

	Description
Aliskiren / Amlodipine	Patients received an aliskiren 150 mg tablet plus an amlodipine 5 mg capsule for 4 weeks and then were force titrated up to aliskiren 300 mg plus amlodipine 10 mg for the remaining 4 weeks of the study. During the 8 weeks, patients also received a placebo tablet and a placebo capsule. Patients took a total of 4 pills each day orally with water in the morning at approximately 8:00 am, except on the morning of a study visit when they took their study medications after all visit procedures and assessments had been completed.
Aliskiren / Hydrochlorothiazide	Patients received an aliskiren 150 mg tablet plus a hydrochlorothiazide 12.5 mg capsule for 4 weeks and then were force titrated up to aliskiren 300 mg plus hydrochlorothiazide 25 mg for the remaining 4 weeks of the study. During the 8 weeks, patients also received a placebo capsule and a placebo tablet. Patients took a total of 4 pills each day orally with water in the morning at approximately 8:00 am, except on the morning of a study visit when they took their study medications after all visit procedures and assessments had been completed.
Amlodipine / Hydrochlorothiazide	Patients received an amlodipine 5 mg capsule plus a hydrochlorothiazide 12.5 mg capsule for 4 weeks and then were force titrated up to amlodipine 10 mg plus hydrochlorothiazide 25 mg for the remaining 4 weeks of the study. During the 8 weeks, patients also received 2 placebo tablets. Patients took a total of 4 pills each day orally with water in the morning at approximately 8:00 am, except on the morning of a study visit when they took their study medications after all visit procedures and assessments had been completed
Aliskiren / Amlodipine / Hydrochlorothiazide	Patients received an aliskiren 150 mg tablet, a HCTZ 12.5 mg capsule and a placebo capsule for the first 3 days of treatment. Amlodipine 5 mg was then added for the remainder of the first 4 weeks of treatment. At the end of 4 weeks, patients were force titrated up to aliskiren / amlodipine / hydrochlorothiazide 300/10/25 mg for the remaining 4 weeks of the study. During the 8 weeks, patients also received a placebo tablet. Patients took a total of 4 pills each day orally with water in the morning at approximately 8:00 am, except on the morning of a study visit when they took their study medications after all visit procedures and assessments had been completed

Measured Values

	Aliskiren / Amlodipine	**Aliskiren / Hydrochlorothiazide**	**Amlodipine / Hydrochlorothiazide**	**Aliskiren / Amlodipine / Hydrochlorothiazide**
Number of Participants Analyzed				

[units: participants]	**282**	**296**	**295**	**308**
Change in Mean Sitting Diastolic Blood Pressure (msDBP) From Baseline to End of Study (Week 8) [units: mmHg] Least Squares Mean (Standard Error)	**-18.03 (0.57)**	**-14.32 (0.55)**	**-17.03 (0.55)**	**-20.63 (0.54)**

No statistical analysis provided for Change in Mean Sitting Diastolic Blood Pressure (msDBP) From Baseline to End of Study (Week 8)

3. Secondary: Percentage of Patients Achieving Blood Pressure Control at the End of the Study (Week 8) [Time Frame: End of study (Week 8)]

Measure Type	Secondary
Measure Title	Percentage of Patients Achieving Blood Pressure Control at the End of the Study (Week 8)
Measure Description	Blood pressure control was defined as a msSBP/msDBP < 140/90 mmHg at the end of the study (Week 8). Blood pressure (BP) was measured at trough (24±3 hours post-dose). The arm in which the highest sitting diastolic BP was found at study entry was used for all subsequent readings. At each visit, after the patient was in a sitting position with the back supported and both feet placed on the floor for 5 minutes, systolic and diastolic BP were measured 3 times with an automated BP monitor and appropriate size cuff. Means of the 3 measurements were calculated.
Time Frame	End of study (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 population: All randomized patients who had post-baseline efficacy measurements.

Reporting Groups

	Description
Aliskiren / Amlodipine	Patients received an aliskiren 150 mg tablet plus an amlodipine 5 mg capsule for 4 weeks and then were force titrated up to aliskiren 300 mg plus amlodipine 10 mg for the remaining 4 weeks of the study. During the 8 weeks, patients also received a placebo tablet and a placebo capsule. Patients took a total of 4 pills each day orally with water in the morning at approximately 8:00 am, except on the morning of a study visit when they took their study medications after all visit procedures and assessments had been completed.
Aliskiren / Hydrochlorothiazide	Patients received an aliskiren 150 mg tablet plus a hydrochlorothiazide 12.5 mg capsule for 4 weeks and then were force titrated up to aliskiren 300 mg plus hydrochlorothiazide 25 mg for the remaining 4 weeks of the study. During the 8 weeks, patients also received a placebo capsule and a placebo tablet. Patients took a total of 4 pills each day orally with water in the morning at approximately 8:00 am, except on the morning of a study visit when they took their study medications after all visit procedures and assessments had been completed.
Amlodipine / Hydrochlorothiazide	Patients received an amlodipine 5 mg capsule plus a hydrochlorothiazide 12.5 mg capsule for 4 weeks and then were force titrated up to amlodipine 10 mg plus hydrochlorothiazide 25 mg for the remaining 4 weeks of the study. During the 8 weeks, patients also received 2 placebo tablets. Patients took a total of 4 pills each day orally with water in the morning at approximately 8:00 am, except on the morning of a study visit when they took their study medications after all visit procedures and assessments had been completed
Aliskiren / Amlodipine / Hydrochlorothiazide	Patients received an aliskiren 150 mg tablet, a HCTZ 12.5 mg capsule and a placebo capsule for the first 3 days of treatment. Amlodipine 5 mg was then added for the remainder of the first 4 weeks of treatment. At the end of 4 weeks, patients were force titrated up to aliskiren / amlodipine / hydrochlorothiazide 300/10/25 mg for the remaining 4 weeks of the study. During the 8 weeks, patients also received a placebo tablet. Patients took a total of 4 pills each day orally with water in the morning at approximately 8:00 am, except on the morning of a study visit when they took their study medications after all visit procedures and assessments had been completed

Measured Values

	Aliskiren / Amlodipine	Aliskiren / Hydrochlorothiazide	Amlodipine / Hydrochlorothiazide	Aliskiren / Amlodipine / Hydrochlorothiazide
Number of Participants Analyzed [units: participants]	**283**	**296**	**295**	**192**
Percentage of Patients Achieving Blood Pressure Control at the End of the Study (Week 8) [units: Percentage of patients]	**41.3**	**33.1**	**39.0**	**62.3**

No statistical analysis provided for Percentage of Patients Achieving Blood Pressure Control at the End of the Study (Week 8)

4. Secondary: Change in Mean 24-hour Ambulatory Systolic and Diastolic Blood Pressure From Baseline to End of Study (Week 8) [Time Frame: Baseline to end of study (Week 8)]

Measure Type	Secondary
Measure Title	Change in Mean 24-hour Ambulatory Systolic and Diastolic Blood Pressure From Baseline to End of Study (Week 8)
Measure Description	Twenty-four hour ambulatory blood pressure monitoring (ABPM) was performed in a subset of patients twice during the study, once at baseline and again at Week 8. The ABPM device was placed on the non-dominant arm between 7:00 and 10:00 am and verification readings obtained. If they were successful, the investigator initiated the 24 hour reading and instructed the patient regarding ABPM procedures. On the next day, the ABPM device was removed if it had been worn for a minimum of 24 hours. The ABPM data were downloaded and evaluated on site.
Time Frame	Baseline to end of study (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 population: All randomized patients who had post-baseline efficacy measurements.

Reporting Groups

	Description
Aliskiren / Amlodipine	Patients received an aliskiren 150 mg tablet plus an amlodipine 5 mg capsule for 4 weeks and then were force titrated up to aliskiren 300 mg plus amlodipine 10 mg for the remaining 4 weeks of the study. During the 8 weeks, patients also received a placebo tablet and a placebo capsule. Patients took a total of 4 pills each day orally with water in the morning at approximately 8:00 am, except on the morning of a study visit when they took their study medications after all visit procedures and assessments had been completed.
Aliskiren / Hydrochlorothiazide	Patients received an aliskiren 150 mg tablet plus a hydrochlorothiazide 12.5 mg capsule for 4 weeks and then were force titrated up to aliskiren 300 mg plus hydrochlorothiazide 25 mg for the remaining 4 weeks of the study. During the 8 weeks, patients also received a placebo capsule and a placebo tablet. Patients took a total of 4 pills each day orally with water in the morning at approximately 8:00 am, except on the morning of a study visit when they took their study medications after all visit procedures and assessments had been completed.
Amlodipine / Hydrochlorothiazide	Patients received an amlodipine 5 mg capsule plus a hydrochlorothiazide 12.5 mg capsule for 4 weeks and then were force titrated up to amlodipine 10 mg plus hydrochlorothiazide 25 mg for the remaining 4 weeks of the study. During the 8 weeks, patients also received 2 placebo tablets. Patients took a total of 4 pills each day orally with water in the morning at approximately 8:00 am, except on the morning of a study visit when they took their study medications after all visit procedures and assessments had been completed
Aliskiren / Amlodipine / Hydrochlorothiazide	Patients received an aliskiren 150 mg tablet, a HCTZ 12.5 mg capsule and a placebo capsule for the first 3 days of treatment. Amlodipine 5 mg was then added for the remainder of the first

	4 weeks of treatment. At the end of 4 weeks, patients were force titrated up to aliskiren / amlodipine / hydrochlorothiazide 300/10/25 mg for the remaining 4 weeks of the study. During the 8 weeks, patients also received a placebo tablet. Patients took a total of 4 pills each day orally with water in the morning at approximately 8:00 am, except on the morning of a study visit when they took their study medications after all visit procedures and assessments had been completed

Measured Values

	Aliskiren / Amlodipine	Aliskiren / Hydrochlorothiazide	Amlodipine / Hydrochlorothiazide	Aliskiren / Amlodipine / Hydrochlorothiazide
Number of Participants Analyzed [units: participants]	**138**	**155**	**136**	**147**
Change in Mean 24-hour Ambulatory Systolic and Diastolic Blood Pressure From Baseline to End of Study (Week 8) [units: mmHg] Least Squares Mean (Standard Error)				
Systolic BP	**-20.30 (0.52)**	**-16.27 (0.51)**	**-18.67 (0.53)**	**-25.29 (0.51)**
Diastolic BP	**-13.29 (0.36)**	**-9.57 (0.35)**	**-11.20 (0.37)**	**-15.90 (0.35)**

No statistical analysis provided for Change in Mean 24-hour Ambulatory Systolic and Diastolic Blood Pressure From Baseline to End of Study (Week 8)

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	During the 8 week double blind treatment
Additional Description	Safety Set. All patients who received double-blind trial medication.

Reporting Groups

	Description
Aliskiren / Amlodipine	Patients received an aliskiren 150 mg tablet plus an amlodipine 5 mg capsule for 4 weeks and then were force titrated up to aliskiren 300 mg plus amlodipine 10 mg for the remaining 4 weeks of the study. During the 8 weeks, patients also received a placebo tablet and a placebo capsule. Patients took a total of 4 pills each day orally with water in the morning at approximately 8:00 am, except on the morning of a study visit when they took their study medications after all visit procedures and assessments had been completed.
Aliskiren / Hydrochlorothiazide	Patients received an aliskiren 150 mg tablet plus a hydrochlorothiazide 12.5 mg capsule for 4 weeks and then were force titrated up to aliskiren 300 mg plus hydrochlorothiazide 25 mg for the remaining 4 weeks of the study. During the 8 weeks, patients also received a placebo capsule and a placebo tablet. Patients took a total of 4 pills each day orally with water in the morning at approximately 8:00 am, except on the morning of a study visit when they took their study medications after all visit procedures and assessments had been completed.
Amlodipine / Hydrochlorothiazide	Patients received an amlodipine 5 mg capsule plus a hydrochlorothiazide 12.5 mg capsule for 4 weeks and then were force titrated up to amlodipine 10 mg plus hydrochlorothiazide 25 mg for the remaining 4 weeks of the study. During the 8 weeks, patients also received 2 placebo tablets. Patients took a total of 4 pills each day orally with water in the morning at approximately 8:00 am, except on the morning of a study visit when they took their study medications after all visit procedures and assessments had been completed
Aliskiren / Amlodipine / Hydrochlorothiazide	Patients received an aliskiren 150 mg tablet, a HCTZ 12.5 mg capsule and a placebo capsule for the first 3 days of treatment. Amlodipine 5 mg was then added for the remainder of the first 4 weeks of treatment. At the end of 4 weeks, patients were force titrated up to aliskiren /

	amlodipine / hydrochlorothiazide 300/10/25 mg for the remaining 4 weeks of the study. During the 8 weeks, patients also received a placebo tablet. Patients took a total of 4 pills each day orally with water in the morning at approximately 8:00 am, except on the morning of a study visit when they took their study medications after all visit procedures and assessments had been completed

Serious Adverse Events

	Aliskiren / Amlodipine	Aliskiren / Hydrochlorothiazide	Amlodipine / Hydrochlorothiazide	Aliskiren / Amlodipine / Hydrochlorothiazide
Total, serious adverse events				
# participants affected / at risk	**3/287 (1.05%)**	**2/297 (0.67%)**	**2/295 (0.68%)**	**6/309 (1.94%)**
Cardiac disorders				
Acute coronary syndrome † 1				
# participants affected / at risk	**0/287 (0.00%)**	**0/297 (0.00%)**	**0/295 (0.00%)**	**1/309 (0.32%)**
Arrhythmia supraventricular † 1				
# participants affected / at risk	**0/287 (0.00%)**	**0/297 (0.00%)**	**0/295 (0.00%)**	**1/309 (0.32%)**
Endocrine disorders				
Goitre † 1				
# participants affected / at risk	**0/287 (0.00%)**	**0/297 (0.00%)**	**0/295 (0.00%)**	**1/309 (0.32%)**
Infections and infestations				
Hepatitis A † 1				
# participants affected / at risk	**1/287 (0.35%)**	**0/297 (0.00%)**	**0/295 (0.00%)**	**0/309 (0.00%)**
Tubo-ovarian abscess † 1				
# participants affected / at risk	**0/287 (0.00%)**	**1/297 (0.34%)**	**0/295 (0.00%)**	**0/309 (0.00%)**
Nervous system disorders				
Cerebrovascular accident † 1				
# participants affected / at risk	**0/287 (0.00%)**	**0/297 (0.00%)**	**1/295 (0.34%)**	**0/309 (0.00%)**
Syncope † 1				
# participants affected / at risk	**0/287 (0.00%)**	**0/297 (0.00%)**	**0/295 (0.00%)**	**1/309 (0.32%)**
Pregnancy, puerperium and perinatal conditions				
Ectopic pregnancy † 1				
# participants affected / at risk	**1/287 (0.35%)**	**0/297 (0.00%)**	**0/295 (0.00%)**	**0/309 (0.00%)**
Psychiatric disorders				
Psychosomatic disease † 1				
# participants affected / at risk	**0/287 (0.00%)**	**0/297 (0.00%)**	**0/295 (0.00%)**	**1/309 (0.32%)**
Renal and urinary disorders				
Stress urinary incontinence † 1				
# participants affected / at risk	**0/287 (0.00%)**	**1/297 (0.34%)**	**0/295 (0.00%)**	**0/309 (0.00%)**

Respiratory, thoracic and mediastinal disorders				
Epistaxis † 1				
# participants affected / at risk	**0/287 (0.00%)**	**0/297 (0.00%)**	**1/295 (0.34%)**	**0/309 (0.00%)**
Nasal septum deviation † 1				
# participants affected / at risk	**1/287 (0.35%)**	**0/297 (0.00%)**	**0/295 (0.00%)**	**0/309 (0.00%)**
Vascular disorders				
Hypertension † 1				
# participants affected / at risk	**0/287 (0.00%)**	**0/297 (0.00%)**	**0/295 (0.00%)**	**1/309 (0.32%)**

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

Other Adverse Events

Hide Other Adverse Events

Time Frame	During the 8 week double blind treatment
Additional Description	Safety Set. All patients who received double-blind trial medication.

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
Aliskiren / Amlodipine	Patients received an aliskiren 150 mg tablet plus an amlodipine 5 mg capsule for 4 weeks and then were force titrated up to aliskiren 300 mg plus amlodipine 10 mg for the remaining 4 weeks of the study. During the 8 weeks, patients also received a placebo tablet and a placebo capsule. Patients took a total of 4 pills each day orally with water in the morning at approximately 8:00 am, except on the morning of a study visit when they took their study medications after all visit procedures and assessments had been completed.
Aliskiren / Hydrochlorothiazide	Patients received an aliskiren 150 mg tablet plus a hydrochlorothiazide 12.5 mg capsule for 4 weeks and then were force titrated up to aliskiren 300 mg plus hydrochlorothiazide 25 mg for the remaining 4 weeks of the study. During the 8 weeks, patients also received a placebo capsule and a placebo tablet. Patients took a total of 4 pills each day orally with water in the morning at approximately 8:00 am, except on the morning of a study visit when they took their study medications after all visit procedures and assessments had been completed.
Amlodipine / Hydrochlorothiazide	Patients received an amlodipine 5 mg capsule plus a hydrochlorothiazide 12.5 mg capsule for 4 weeks and then were force titrated up to amlodipine 10 mg plus hydrochlorothiazide 25 mg for the remaining 4 weeks of the study. During the 8 weeks, patients also received 2 placebo tablets. Patients took a total of 4 pills each day orally with water in the morning at approximately 8:00 am, except on the morning of a study visit when they took their study medications after all visit procedures and assessments had been completed
Aliskiren / Amlodipine / Hydrochlorothiazide	Patients received an aliskiren 150 mg tablet, a HCTZ 12.5 mg capsule and a placebo capsule for the first 3 days of treatment. Amlodipine 5 mg was then added for the remainder of the first 4 weeks of treatment. At the end of 4 weeks, patients were force titrated up to aliskiren / amlodipine / hydrochlorothiazide 300/10/25 mg for the remaining 4 weeks of the study. During the 8 weeks, patients also received a placebo tablet. Patients took a total of 4 pills each day orally with water in the morning at approximately 8:00 am, except on the morning of a study visit when they took their study medications after all visit procedures and assessments had been completed

Other Adverse Events

	Aliskiren / Amlodipine	Aliskiren / Hydrochlorothiazide	Amlodipine / Hydrochlorothiazide	Aliskiren / Amlodipine / Hydrochlorothiazide
Total, other (not including serious) adverse events				
# participants affected / at risk	**32/287 (11.15%)**	**17/297 (5.72%)**	**26/295 (8.81%)**	**29/309 (9.39%)**
General disorders				
Oedema peripheral † 1				
# participants affected / at risk	**23/287 (8.01%)**	**6/297 (2.02%)**	**12/295 (4.07%)**	**22/309 (7.12%)**
Nervous system disorders				
Headache † 1				
# participants affected / at risk	**9/287 (3.14%)**	**12/297 (4.04%)**	**15/295 (5.08%)**	**11/309 (3.56%)**

† 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 (ie, 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:	NCT00765674 History of Changes
Other Study ID Numbers:	**CSAH100A2302**
Study First Received:	October 2, 2008
Results First Received:	January 12, 2011
Last Updated:	April 15, 2011
Health Authority:	Germany: Federal Institute for Drugs and Medical Devices Canada: Health Canada Italy: National Institute of Health Sweden: Medical Products Agency Romania: National Medicines Agency Australia: Department of Health and Ageing Therapeutic Goods Administration United States: Food and Drug Administration Denmark: Danish Medicines Agency Israel: Ministry of Health Lithuania: State Medicine Control Agency - Ministry of Health Zanzibar: Ministry of Health and Social Welfare Latvia: State Agency of Medicines