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Trial record **1 of 1** for: CVAA489ADE06

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Efficacy and Safety of Valsartan and Amlodipine (± HCTZ) in Adults With Moderate, Inadequately Controlled Hypertension

This study has been completed.

Sponsor:
Novartis

Information provided by:
Novartis

ClinicalTrials.gov Identifier:
NCT00523744

First received: August 30, 2007
Last updated: June 8, 2011
Last verified: June 2011
History of Changes

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Results First Received: January 10, 2011

Study Type:	Interventional
Study Design:	Allocation: Non-Randomized; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Single Group Assignment; Masking: Open Label; Primary Purpose: Treatment
Condition:	Hypertension
Interventions:	Drug: Amlodipine Drug: Olmesartan medoxomil Drug: Amlodipine+valsartan 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
Amlodipine(AML)+Olmesartan, AML+Valsartan, AML+Valsartan+HCTZ	During the Treatment Phase 1, participants received 1 week of treatment with olmesartan 10 mg and amlodipine 5 mg once daily in free combination, followed by three weeks of treatment with olmesartan 20 mg plus amlodipine 10 mg once daily in free combination. During the Treatment Phase 2 participants received amlodipine 10 mg plus valsartan 160 mg for 4 weeks. During the Extension Phase, participants received 4 weeks treatment with amlodipine 10 mg plus valsartan 160 mg plus hydrochlorothiazide

	(HCTZ) 12.5 mg.

Participant Flow for 3 periods

Period 1: Phase 1 - Amlodipine+Olmesartan

	Amlodipine(AML)+Olmesartan, AML+Valsartan, AML+Valsartan+HCTZ
STARTED	257
COMPLETED	251
NOT COMPLETED	6
Adverse Event	2
Withdrawal by Subject	1
Lost to Follow-up	2
Administrative problems	1

Period 2: Phase 2 - Amlodipine+Valsartan

	Amlodipine(AML)+Olmesartan, AML+Valsartan, AML+Valsartan+HCTZ
STARTED	176 [1]
COMPLETED	173
NOT COMPLETED	3
Adverse Event	2
Lost to Follow-up	1

[1] Only patients with mean sitting diastolic BP ≥ 90 mmHg at the end of Phase 1 entered this phase.

Period 3: Phase 3 - Amlodipine+Valsartan+HCTZ

	Amlodipine(AML)+Olmesartan, AML+Valsartan, AML+Valsartan+HCTZ
STARTED	91 [1]
COMPLETED	91
NOT COMPLETED	0

[1] Only patients with systolic BP ≥ 140 mmHg or diastolic BP ≥ 90 mmHg at the end of Phase 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
Amlodipine(AML)+Olmesartan, AML+Valsartan, AML+Valsartan+HCTZ	During the Treatment Phase 1, participants received 1 week of treatment with olmesartan 10 mg and amlodipine 5 mg once daily in free combination, followed by three weeks of treatment with olmesartan 20 mg plus amlodipine 10 mg once daily in free combination. During the Treatment Phase 2 participants received amlodipine 10 mg plus valsartan 160 mg for 4 weeks. During the Extension Phase, participants received 4 weeks treatment with

	amlodipine 10 mg plus valsartan 160 mg plus hydrochlorothiazide (HCTZ) 12.5 mg.

Baseline Measures

	Amlodipine(AML)+Olmesartan, AML+Valsartan, AML+Valsartan+HCTZ
Number of Participants [units: participants]	**257**
Age [units: years] Mean (Standard Deviation)	
Phase 1 - Amlodipine+olmesartan	**58.8 (12.38)**
Phase 2 - Amlodipine+valsartan	**59.8 (11.84)**
Phase 3 - Amlodipine+valsartan+HCTZ	**60.9 (10.98)**
Gender, Customized [units: participants]	
Phase 1 - Amlodipine+olmesartan	**112**
Phase 1 - Amlodipine+olmesartan	**145**
Phase 2 - Amlodipine+valsartan	**76**
Phase 2 - Amlodipine+valsartan	**100**
Phase 3 - Amlodipine+valsartan+HCTZ	**32**
Phase 3 - Amlodipine+valsartan+HCTZ	**59**

Outcome Measures

Hide All Outcome Measures

1. Primary: Change in Mean Sitting Diastolic Blood Pressure (msDBP) During the Core Phase of the Study [Time Frame: Baseline Phase 2 (Week 4) to end of Phase 2 (Week 8)]

Measure Type	Primary
Measure Title	Change in Mean Sitting Diastolic Blood Pressure (msDBP) During the Core Phase of the Study
Measure Description	The arm in which the highest sitting diastolic pressures were found at study entry was the arm used for all subsequent readings. A calibrated sphygmomanometer and appropriate size cuff were used to measure arterial sitting blood pressure (BP) at trough with the arm supported at the level of the heart. At each study visit, after having the patient in a sitting position for at least 5 minutes, systolic/diastolic blood pressure were measured 3 times at 1-2 minute intervals. A mean was calculated from the 3 measurements. A negative change indicates improvement.
Time Frame	Baseline Phase 2 (Week 4) to end of Phase 2 (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.
Intent-to-treat population (ITT): All patients who took at least one dose of amlodipine plus valsartan who had at least one primary efficacy parameter evaluation. Patients who dropped out were included in the ITT population if there was any BP measurement available; their last available blood pressure measurement was used for the analysis.

Reporting Groups

	Description
Amlodipine+Valsartan - Phase 2	Patients with uncontrolled mean sitting diastolic BP (msDBP ≥ 90 mmHg) at the end of Phase 1 were

	treated for 4 weeks with amlodipine 10 mg plus valsartan 160 mg taken orally in the morning.

Measured Values

	Amlodipine+Valsartan - Phase 2
Number of Participants Analyzed [units: participants]	**175**
Change in Mean Sitting Diastolic Blood Pressure (msDBP) During the Core Phase of the Study [units: mmHg] Mean (95% Confidence Interval)	**-9.13 (-10.19 to -8.06)**

No statistical analysis provided for Change in Mean Sitting Diastolic Blood Pressure (msDBP) During the Core Phase of the Study

2. Primary: Change in Mean Sitting Diastolic Blood Pressure (msDBP) During the Extension Phase of the Study [Time Frame: Baseline Phase 3 (Week 8) to end of Phase 3 (Week 12)]

Measure Type	Primary
Measure Title	Change in Mean Sitting Diastolic Blood Pressure (msDBP) During the Extension Phase of the Study
Measure Description	The arm in which the highest sitting diastolic pressures were found at study entry was the arm used for all subsequent readings. A calibrated sphygmomanometer and appropriate size cuff were used to measure arterial sitting blood pressure (BP) at trough with the arm supported at the level of the heart. At each study visit, after having the patient in a sitting position for at least 5 minutes, systolic/diastolic blood pressure were measured 3 times at 1-2 minute intervals. A mean was calculated from the 3 measurements. A negative change indicates improvement.
Time Frame	Baseline Phase 3 (Week 8) to end of Phase 3 (Week 12)
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.
Safety population: All patients who took at least one dose of amlodipine 10 mg plus valsartan 160 mg plus HCTZ 12.5 mg.

Reporting Groups

	Description
Amlodipine+Valsartan+HCTZ - Phase 3	Patients with uncontrolled mean sitting systolic or diastolic blood pressure (msDBP ≥ 90 mmHg and/or msSBP ≥ 140 mmHg) at the end of Phase 2 were offered a 4 week treatment extension with amlodipine 10 mg plus valsartan 160 mg plus hydrochlorothiazide (HCTZ) 12.5 mg taken orally in the morning.

Measured Values

	Amlodipine+Valsartan+HCTZ - Phase 3
Number of Participants Analyzed [units: participants]	**91**
Change in Mean Sitting Diastolic Blood Pressure (msDBP) During the Extension Phase of the Study [units: mmHg] Mean (95% Confidence Interval)	**-5.22 (-6.76 to -3.68)**

No statistical analysis provided for Change in Mean Sitting Diastolic Blood Pressure (msDBP) During the Extension Phase of the Study

3. Secondary: Change in Mean Sitting Systolic Blood Pressure (msSBP) During the Core Phase of the Study [Time Frame: Baseline Phase 2

(Week 4) to end of Phase 2 (Week 8)]

Measure Type	Secondary
Measure Title	Change in Mean Sitting Systolic Blood Pressure (msSBP) During the Core Phase of the Study
Measure Description	The arm in which the highest sitting diastolic pressures were found at study entry was the arm used for all subsequent readings. A calibrated sphygmomanometer and appropriate size cuff were used to measure arterial sitting blood pressure (BP) at trough with the arm supported at the level of the heart. At each study visit, after having the patient in a sitting position for at least 5 minutes, systolic/diastolic blood pressure were measured 3 times at 1-2 minute intervals. A mean was calculated from the 3 measurements. A negative change indicates improvement.
Time Frame	Baseline Phase 2 (Week 4) to end of Phase 2 (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.
Intent-to-treat population (ITT): All patients who took at least one dose of amlodipine plus valsartan who had at least one primary efficacy parameter evaluation. Patients who dropped out were included in the ITT population if there was any BP measurement available; their last available blood pressure measurement was used for the analysis.

Reporting Groups

	Description
Amlodipine+Valsartan - Phase 2	Patients with uncontrolled mean sitting diastolic BP (msDBP ≥ 90 mmHg) at the end of Phase 1 were treated for 4 weeks with amlodipine 10 mg plus valsartan 160 mg taken orally in the morning.

Measured Values

	Amlodipine+Valsartan - Phase 2
Number of Participants Analyzed [units: participants]	**175**
Change in Mean Sitting Systolic Blood Pressure (msSBP) During the Core Phase of the Study [units: mmHg] Mean (95% Confidence Interval)	**-7.87 (-9.33 to -6.11)**

No statistical analysis provided for Change in Mean Sitting Systolic Blood Pressure (msSBP) During the Core Phase of the Study

4. Secondary: Change in Sitting Pulse Pressure During the Core Phase of the Study [Time Frame: Baseline Phase 2 (Week 4) to end of Phase 2 (Week 8)]

Measure Type	Secondary
Measure Title	Change in Sitting Pulse Pressure During the Core Phase of the Study
Measure Description	Pulse pressure is systolic pressure (SP) minus diastolic pressure (DP). The arm in which the highest sitting DPs were found at study entry was the arm used for all subsequent readings. A calibrated sphygmomanometer and appropriate size cuff were used to measure arterial sitting blood pressure (BP) at trough with the arm supported at the level of the heart. At each study visit, after having the patient in a sitting position for at least 5 minutes, SP and DP were measured 3 times at 1-2 minute intervals. A mean was calculated from the 3 measurements. A negative change indicates improvement.
Time Frame	Baseline Phase 2 (Week 4) to end of Phase 2 (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.

Intent-to-treat population (ITT): All patients who took at least one dose of amlodipine plus valsartan who had at least one primary efficacy parameter evaluation. Patients who dropped out were included in the ITT population if there was any BP measurement available; their last available blood pressure measurement was used for the analysis.

Reporting Groups

	Description
Amlodipine+Valsartan - Phase 2	Patients with uncontrolled mean sitting diastolic BP (msDBP ≥ 90 mmHg) at the end of Phase 1 were treated for 4 weeks with amlodipine 10 mg plus valsartan 160 mg taken orally in the morning.

Measured Values

	Amlodipine+Valsartan - Phase 2
Number of Participants Analyzed [units: participants]	**175**
Change in Sitting Pulse Pressure During the Core Phase of the Study [units: mmHg] Mean (95% Confidence Interval)	**1.26 (0.49 to 3.01)**

No statistical analysis provided for Change in Sitting Pulse Pressure During the Core Phase of the Study

5. Secondary: Change in Sitting Pulse Rate During the Core Phase of the Study [Time Frame: Baseline Phase 2 (Week 4) to end of Phase 2 (Week 8)]

Measure Type	Secondary
Measure Title	Change in Sitting Pulse Rate During the Core Phase of the Study
Measure Description	Pulse rate was measured once for 30 seconds just prior to blood pressure measurements in the sitting position.
Time Frame	Baseline Phase 2 (Week 4) to end of Phase 2 (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.
Intent-to-treat population (ITT): All patients who took at least one dose of amlodipine plus valsartan who had at least one primary efficacy parameter evaluation. Patients who dropped out were included in the ITT population if there was any BP measurement available; their last available blood pressure measurement was used for the analysis.

Reporting Groups

	Description
Amlodipine+Valsartan - Phase 2	Patients with uncontrolled mean sitting diastolic BP (msDBP ≥ 90 mmHg) at the end of Phase 1 were treated for 4 weeks with amlodipine 10 mg plus valsartan 160 mg taken orally in the morning.

Measured Values

	Amlodipine+Valsartan - Phase 2
Number of Participants Analyzed [units: participants]	**175**
Change in Sitting Pulse Rate During the Core Phase of the Study [units: BPM (beats per minute)] Mean (95% Confidence Interval)	**-1.93 (-3.06 to -0.79)**

No statistical analysis provided for Change in Sitting Pulse Rate During the Core Phase of the Study

6. Secondary: Percentage of Patients Who Achieved Normalized Blood Pressure During the Core Phase of the Study [Time Frame: Baseline Phase 2 (Week 4) to end of Phase 2 (Week 8)]

Measure Type	Secondary
Measure Title	Percentage of Patients Who Achieved Normalized Blood Pressure During the Core Phase of the Study
Measure Description	Normalized Blood Pressure was defined as a msSBP < 140 mmHg and/or a msDBP < 90 mmHg.
Time Frame	Baseline Phase 2 (Week 4) to end of Phase 2 (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.
Intent-to-treat population (ITT): All patients who took at least one dose of amlodipine plus valsartan who had at least one primary efficacy parameter evaluation. Patients who dropped out were included in the ITT population if there was any BP measurement available; their last available blood pressure measurement was used for the analysis.

Reporting Groups

	Description
Amlodipine+Valsartan - Phase 2	Patients with uncontrolled mean sitting diastolic BP (msDBP ≥ 90 mmHg) at the end of Phase 1 were treated for 4 weeks with amlodipine 10 mg plus valsartan 160 mg taken orally in the morning.

Measured Values

	Amlodipine+Valsartan - Phase 2
Number of Participants Analyzed [units: participants]	**175**
Percentage of Patients Who Achieved Normalized Blood Pressure During the Core Phase of the Study [units: Percentage of participants]	
msSBP < 140 mmHg	**44.6**
msDBP < 90 mmHg	**72.6**

No statistical analysis provided for Percentage of Patients Who Achieved Normalized Blood Pressure During the Core Phase of the Study

7. Secondary: Percentage of Patients Who Achieved a Protocol-defined Blood Pressure Response During the Core Phase of the Study [Time Frame: Baseline of Phase 2 (Week 4) to end of Phase 2 (Week 8)]

Measure Type	Secondary
Measure Title	Percentage of Patients Who Achieved a Protocol-defined Blood Pressure Response During the Core Phase of the Study
Measure Description	Blood pressure response was defined as msSBP < 140 mmHg or a 20 mmHg decrease in msSBP at the end of Phase 2 (Week 8) compared to Baseline in Phase 2 (week 4) or a msDBP < 90 mmHg or a 10 mmHg decrease in msDBP at the end of Phase 2 compared to Baseline in Phase 2.
Time Frame	Baseline of Phase 2 (Week 4) to end of Phase 2 (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.

Intent-to-treat population (ITT): All patients who took at least one dose of amlodipine plus valsartan who had at least one primary efficacy parameter evaluation. Patients who dropped out were included in the ITT population if there was any BP measurement available; their last available blood pressure measurement was used for the analysis.

Reporting Groups

	Description
Amlodipine+Valsartan - Phase 2	Patients with uncontrolled mean sitting diastolic BP (msDBP ≥ 90 mmHg) at the end of Phase 1 were treated for 4 weeks with amlodipine 10 mg plus valsartan 160 mg taken orally in the morning.

Measured Values

	Amlodipine+Valsartan - Phase 2
Number of Participants Analyzed [units: participants]	**175**
Percentage of Patients Who Achieved a Protocol-defined Blood Pressure Response During the Core Phase of the Study [units: Percentage of participants]	
msSBP response	**47.4**
msDBP response	**73.1**

No statistical analysis provided for Percentage of Patients Who Achieved a Protocol-defined Blood Pressure Response During the Core Phase of the Study

8. Secondary: Change in Mean Sitting Systolic Blood Pressure (msSBP) During the Extension Phase of the Study [Time Frame: Baseline Phase 3 (Week 8) to end of Phase 3 (Week 12)]

Measure Type	Secondary
Measure Title	Change in Mean Sitting Systolic Blood Pressure (msSBP) During the Extension Phase of the Study
Measure Description	The arm in which the highest sitting diastolic pressures were found at study entry was the arm used for all subsequent readings. A calibrated sphygmomanometer and appropriate size cuff were used to measure arterial sitting blood pressure (BP) at trough with the arm supported at the level of the heart. At each study visit, after having the patient in a sitting position for at least 5 minutes, systolic/diastolic blood pressure were measured 3 times at 1-2 minute intervals. A mean was calculated from the 3 measurements. A negative change indicates improvement.
Time Frame	Baseline Phase 3 (Week 8) to end of Phase 3 (Week 12)
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.
Safety population: All patients who took at least one dose of amlodipine 10 mg plus valsartan 160 mg plus HCTZ 12.5 mg.

Reporting Groups

	Description
Amlodipine+Valsartan+HCTZ - Phase 3	Patients with uncontrolled mean sitting systolic or diastolic blood pressure (msDBP ≥ 90 mmHg and/or msSBP ≥ 140 mmHg) at the end of Phase 2 were offered a 4 week treatment extension with amlodipine 10 mg plus valsartan 160 mg plus hydrochlorothiazide (HCTZ) 12.5 mg taken orally in the morning.

Measured Values

	Amlodipine+Valsartan+HCTZ - Phase 3

Number of Participants Analyzed [units: participants]	**91**
Change in Mean Sitting Systolic Blood Pressure (msSBP) During the Extension Phase of the Study [units: mmHg] Mean (95% Confidence Interval)	**-10.84 (-12.94 to -8.75)**

No statistical analysis provided for Change in Mean Sitting Systolic Blood Pressure (msSBP) During the Extension Phase of the Study

9. Secondary: Change in Sitting Pulse Pressure During the Extension Phase of the Study [Time Frame: Baseline Phase 3 (Week 8) to end of Phase 3 (Week 12)]

Measure Type	Secondary
Measure Title	Change in Sitting Pulse Pressure During the Extension Phase of the Study
Measure Description	Pulse pressure is systolic pressure (SP) minus diastolic pressure (DP). The arm in which the highest sitting DPs were found at study entry was the arm used for all subsequent readings. A calibrated sphygmomanometer and appropriate size cuff were used to measure arterial sitting blood pressure (BP) at trough with the arm supported at the level of the heart. At each study visit, after having the patient in a sitting position for at least 5 minutes, SP and DP were measured 3 times at 1-2 minute intervals. A mean was calculated from the 3 measurements. A negative change indicates improvement.
Time Frame	Baseline Phase 3 (Week 8) to end of Phase 3 (Week 12)
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.
Safety population: All patients who took at least one dose of amlodipine 10 mg plus valsartan 160 mg plus HCTZ 12.5 mg.

Reporting Groups

	Description
Amlodipine+Valsartan+HCTZ - Phase 3	Patients with uncontrolled mean sitting systolic or diastolic blood pressure (msDBP ≥ 90 mmHg and/or msSBP ≥ 140 mmHg) at the end of Phase 2 were offered a 4 week treatment extension with amlodipine 10 mg plus valsartan 160 mg plus hydrochlorothiazide (HCTZ) 12.5 mg taken orally in the morning.

Measured Values

	Amlodipine+Valsartan+HCTZ - Phase 3
Number of Participants Analyzed [units: participants]	**91**
Change in Sitting Pulse Pressure During the Extension Phase of the Study [units: mmHg] Mean (95% Confidence Interval)	**-5.62 (-7.74 to -3.50)**

No statistical analysis provided for Change in Sitting Pulse Pressure During the Extension Phase of the Study

10. Secondary: Change in Sitting Pulse Rate During the Extension Phase of the Study [Time Frame: Baseline Phase 3 (Week 8) to end of Phase 3 (week 12)]

Measure Type	Secondary
Measure Title	Change in Sitting Pulse Rate During the Extension Phase of the Study

Measure Description	Pulse rate was measured once for 30 seconds just prior to blood pressure measurements in the sitting position.
Time Frame	Baseline Phase 3 (Week 8) to end of Phase 3 (week 12)
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.
Safety population: All patients who took at least one dose of amlodipine 10 mg plus valsartan 160 mg plus HCTZ 12.5 mg.

Reporting Groups

	Description
Amlodipine+Valsartan+HCTZ - Phase 3	Patients with uncontrolled mean sitting systolic or diastolic blood pressure (msDBP ≥ 90 mmHg and/or msSBP ≥ 140 mmHg) at the end of Phase 2 were offered a 4 week treatment extension with amlodipine 10 mg plus valsartan 160 mg plus hydrochlorothiazide (HCTZ) 12.5 mg taken orally in the morning.

Measured Values

	Amlodipine+Valsartan+HCTZ - Phase 3
Number of Participants Analyzed [units: participants]	**91**
Change in Sitting Pulse Rate During the Extension Phase of the Study [units: BPM (beats per minute)] Mean (95% Confidence Interval)	**0.09 (-1.36 to 1.54)**

No statistical analysis provided for Change in Sitting Pulse Rate During the Extension Phase of the Study

11. Secondary: Percentage of Patients Who Achieved Normalized Blood Pressure During the Extension Phase of the Study [Time Frame: Baseline Phase 3 (Week 8) to end of Phase 3 (Week 12)]

Measure Type	Secondary
Measure Title	Percentage of Patients Who Achieved Normalized Blood Pressure During the Extension Phase of the Study
Measure Description	Normalized Blood Pressure was defined as a msSBP < 140 mmHg and/or a msDBP < 90 mmHg.
Time Frame	Baseline Phase 3 (Week 8) to end of Phase 3 (Week 12)
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.
Safety population: All patients who took at least one dose of amlodipine 10 mg plus valsartan 160 mg plus HCTZ 12.5 mg.

Reporting Groups

	Description
Amlodipine+Valsartan+HCTZ - Phase 3	Patients with uncontrolled mean sitting systolic or diastolic blood pressure (msDBP ≥ 90 mmHg and/or msSBP ≥ 140 mmHg) at the end of Phase 2 were offered a 4 week treatment extension with amlodipine 10 mg plus valsartan 160 mg plus hydrochlorothiazide (HCTZ) 12.5 mg taken orally in the morning.

Measured Values

	Amlodipine+Valsartan+HCTZ - Phase 3

Number of Participants Analyzed [units: participants]	**91**
Percentage of Patients Who Achieved Normalized Blood Pressure During the Extension Phase of the Study [units: Percentage of participants]	
msSBP < 140 mmHg	**59.3**
msDBP < 90 mmHg	**83.5**

No statistical analysis provided for Percentage of Patients Who Achieved Normalized Blood Pressure During the Extension Phase of the Study

12. Secondary: Percentage of Patients Who Achieved a Protocol-defined Blood Pressure Response During the Extension Phase of the Study [Time Frame: Baseline of Phase 3 (Week 8) to end of Phase 3 (Week 12)]

Measure Type	Secondary
Measure Title	Percentage of Patients Who Achieved a Protocol-defined Blood Pressure Response During the Extension Phase of the Study
Measure Description	Blood pressure response was defined as msSBP < 140 mmHg or a 20 mmHg decrease in msSBP at the end of Phase 3 compared to Baseline in Phase 3 or a msDBP < 90 mmHg or a 10 mmHg decrease in msDBP at the end of Phase 3 compared to Baseline in Phase 3.
Time Frame	Baseline of Phase 3 (Week 8) to end of Phase 3 (Week 12)
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.
Safety population: All patients who took at least one dose of amlodipine 10 mg plus valsartan 160 mg plus HCTZ 12.5 mg.

Reporting Groups

	Description
Amlodipine+Valsartan+HCTZ - Phase 3	Patients with uncontrolled mean sitting systolic or diastolic blood pressure (msDBP ≥ 90 mmHg and/or msSBP ≥ 140 mmHg) at the end of Phase 2 were offered a 4 week treatment extension with amlodipine 10 mg plus valsartan 160 mg plus hydrochlorothiazide (HCTZ) 12.5 mg taken orally in the morning.

Measured Values

	Amlodipine+Valsartan+HCTZ - Phase 3
Number of Participants Analyzed [units: participants]	**91**
Percentage of Patients Who Achieved a Protocol-defined Blood Pressure Response During the Extension Phase of the Study [units: Percentage of participants]	
msSBP response	**61.5**
msDBP response	**83.5**

No statistical analysis provided for Percentage of Patients Who Achieved a Protocol-defined Blood Pressure Response During the Extension Phase of the Study

Serious Adverse Events

Hide Serious Adverse Events

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

Reporting Groups

	Description
Phase 1 - Amlodipine+Olmesartan	4 weeks treatment with amlodipine 10 mg plus olmesartan 20 mg taken orally once daily in the morning.
Phase 2 - Amlodipine+Valsartan	Patients with uncontrolled mean sitting diastolic BP (msDBP ≥ 90 mmHg) at the end of Phase 1 were treated for 4 weeks with amlodipine 10 mg plus valsartan 160 mg taken orally in the morning.
Phase 3 - Amlodipine+Valsartan+HCTZ	Patients with uncontrolled mean sitting systolic or diastolic blood pressure (msDBP ≥ 90 mmHg and/or msSBP ≥ 140 mmHg) at the end of Phase 2 were offered a 4 week treatment extension with amlodipine 10 mg plus valsartan 160 mg plus hydrochlorothiazide (HCTZ) 12.5 mg taken orally in the morning.

Serious Adverse Events

	Phase 1 - Amlodipine+Olmesartan	Phase 2 - Amlodipine+Valsartan	Phase 3 - Amlodipine+Valsartan+HCTZ
Total, serious adverse events			
# participants affected / at risk	**1/257 (0.39%)**	**0/176 (0.00%)**	**0/91 (0.00%)**
Ear and labyrinth disorders			
SUDDEN HEARING LOSS † 1			
# participants affected / at risk	**1/257 (0.39%)**	**0/176 (0.00%)**	**0/91 (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
Phase 1 - Amlodipine+Olmesartan	4 weeks treatment with amlodipine 10 mg plus olmesartan 20 mg taken orally once daily in the morning.
Phase 2 - Amlodipine+Valsartan	Patients with uncontrolled mean sitting diastolic BP (msDBP ≥ 90 mmHg) at the end of Phase 1 were treated for 4 weeks with amlodipine 10 mg plus valsartan 160 mg taken orally in the morning.
Phase 3 - Amlodipine+Valsartan+HCTZ	Patients with uncontrolled mean sitting systolic or diastolic blood pressure (msDBP ≥ 90 mmHg and/or msSBP ≥ 140 mmHg) at the end of Phase 2 were offered a 4 week treatment extension with amlodipine 10 mg plus valsartan 160 mg plus hydrochlorothiazide (HCTZ) 12.5 mg taken orally in the morning.

Other Adverse Events

	Phase 1 - Amlodipine+Olmesartan	Phase 2 - Amlodipine+Valsartan	Phase 3 - Amlodipine+Valsartan+HCTZ
Total, other (not including serious) adverse events			
# participants affected / at risk	**0/257 (0.00%)**	**0/176 (0.00%)**	**0/91 (0.00%)**

Limitations and Caveats

Hide Limitations and Caveats

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

More Information

Hide More Information

Certain Agreements:

Principal Investigators are **NOT** employed by the organization sponsoring the study.

There **IS** an agreement between Principal Investigators and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.

The agreement is:

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

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

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

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

Results Point of Contact:

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

No publications provided

Responsible Party:	External Affairs, Novartis Pharmaceuticals
ClinicalTrials.gov Identifier:	NCT00523744 History of Changes
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