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Trial record **1 of 1** for: CVAA489A2318

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Safety, Tolerability, and Efficacy of Once Daily Amlodipine/Valsartan 5/80 as Compared to Amlodipine/Valsartan 5/40 or to Amlodipine 5 mg Monotherapy in Patients 65 Years of Age and Older With Essential Hypertension

This study has been completed.

Sponsor:
Novartis Pharmaceuticals

Information provided by:
Novartis

ClinicalTrials.gov Identifier:
NCT00699192

First received: June 9, 2008
Last updated: May 4, 2011
Last verified: May 2011
History of Changes

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Results First Received: January 11, 2011

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Investigator, Outcomes Assessor); Primary Purpose: Treatment
Condition:	Hypertension
Interventions:	Drug: Amlodipine 5 mg Drug: Valsartan 80 mg Drug: Valsartan 40 mg 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
965 patients were enrolled in the study. Of these, 819 met the criteria for entry into the double-blind phase of the study where efficacy and safety were evaluated.

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/Valsartan 5/80 mg	1 capsule amlodipine 5 mg, 1 capsule valsartan 80 mg once daily
Amlodipine/Valsartan 5/40 mg	1 capsule amlodipine 5 mg, 1 capsule valsartan 40 mg once daily
Amlodipine 5 mg	1 capsule amlodipine 5 mg, 1 capsule placebo to match valsartan once daily

Participant Flow: Overall Study

	Amlodipine/Valsartan 5/80 mg	Amlodipine/Valsartan 5/40 mg	Amlodipine 5 mg
STARTED	275	272	272
COMPLETED	259	260	261
NOT COMPLETED	16	12	11
Missing	1	1	1
Adverse Event	9	4	3
Abnormal test procedure result(s)	0	0	1
Lack of Efficacy	0	0	1
Withdrawal by Subject	3	2	4
Administrative problems	1	3	1
Protocol Violation	2	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
Amlodipine/Valsartan 5/80 mg	1 capsule amlodipine 5 mg, 1 capsule valsartan 80 mg once daily
Amlodipine/Valsartan 5/40 mg	1 capsule amlodipine 5 mg, 1 capsule valsartan 40 mg once daily
Amlodipine 5 mg	1 capsule amlodipine 5 mg, 1 capsule placebo to match valsartan once daily
Total	Total of all reporting groups

Baseline Measures

	Amlodipine/Valsartan 5/80 mg	Amlodipine/Valsartan 5/40 mg	Amlodipine 5 mg	Total
Number of Participants [units: participants]	275	272	272	819
Age [units: years] Mean (Standard Deviation)	71.8 (5.01)	71.6 (5.38)	71.4 (5.44)	71.6 (5.27)
Gender [units: participants]				
Female	152	138	142	432
Male	123	134	130	387

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	At study entry, blood pressure (BP) was measured in both arms with an automatic BP monitor. The arm with the higher systolic BP reading was used for all measurements throughout the study. At each study visit, 3 separate sitting BPs were obtained 23-26 hours post-dose with at least 2 minutes between measurements and with the cuff fully deflated. Mean BP was automatically calculated from the 3 readings. A negative change from baseline 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.
The Full Analysis Set (FAS) population: All randomized patients who had a baseline and at least one post-baseline assessment an efficacy variable. For the subjects who did not complete the Week 8 assessments, an LOCF (last observation carried forward) approach was used.

Reporting Groups

	Description
Amlodipine/Valsartan 5/80 mg	1 capsule amlodipine 5 mg, 1 capsule valsartan 80 mg once daily
Amlodipine/Valsartan 5/40 mg	1 capsule amlodipine 5 mg, 1 capsule valsartan 40 mg once daily
Amlodipine 5 mg	1 capsule amlodipine 5 mg, 1 capsule placebo to match valsartan once daily

Measured Values

	Amlodipine/Valsartan 5/80 mg	**Amlodipine/Valsartan 5/40 mg**	**Amlodipine 5 mg**
Number of Participants Analyzed [units: participants]	**272**	**269**	**268**
Change in Mean Sitting Systolic Blood Pressure (msSBP) From Baseline to End of Study (Week 8) [units: mmHg] Mean (Standard Deviation)	**-11.1 (12.68)**	**-12.3 (13.23)**	**-6.9 (14.00)**

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	At study entry, blood pressure (BP) was measured in both arms with an automatic BP monitor. The arm with the higher systolic BP reading was used for all measurements throughout the study. At each study visit, 3 separate sitting BPs were obtained 23-26 hours post-dose with at least 2 minutes between measurements and with the cuff fully deflated. Mean BP was automatically calculated from the 3 readings. A negative change from baseline 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.
The Full Analysis Set (FAS) population: All randomized patients who had a baseline and at least one post-baseline assessment an efficacy variable. For the subjects who did not complete the week 8 assessments, an LOCF (last observation carried forward) approach was used.

Reporting Groups

	Description
Amlodipine/Valsartan 5/80 mg	1 capsule amlodipine 5 mg, 1 capsule valsartan 80 mg once daily
Amlodipine/Valsartan 5/40 mg	1 capsule amlodipine 5 mg, 1 capsule valsartan 40 mg once daily
Amlodipine 5 mg	1 capsule amlodipine 5 mg, 1 capsule placebo to match valsartan once daily

Measured Values

	Amlodipine/Valsartan 5/80 mg	**Amlodipine/Valsartan 5/40 mg**	**Amlodipine 5 mg**
Number of Participants Analyzed [units: participants]	**272**	**269**	**268**
Change in Mean Sitting Diastolic Blood Pressure (msDBP) From Baseline to End of Study (Week 8) [units: mmHg] Mean (Standard Deviation)	**-4.2 (8.04)**	**-5.3 (8.19)**	**-1.7 (7.26)**

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 a Systolic Blood Pressure Response at Week 8 [Time Frame: Baseline to end of study (Week 8)]

Measure Type	Secondary
Measure Title	Percentage of Patients Achieving a Systolic Blood Pressure Response at Week 8
Measure Description	A systolic blood pressure response was defined as a msSBP < 140 mmHg or ≥ 15 mmHg reduction from baseline at the end of the study (Week 8). At study entry, blood pressure (BP) was measured in both arms with an automatic BP monitor. The arm with the higher systolic BP reading was used for all measurements throughout the study. At each study visit, 3 separate sitting BPs were obtained 23-26 hours post-dose with at least 2 minutes between measurements and with the cuff fully deflated. Mean BP was automatically calculated from the 3 readings.
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.
The Full Analysis Set (FAS) population: All randomized patients who had a baseline and at least one post-baseline assessment an efficacy variable. For the subjects who did not complete the week 8 assessments, an LOCF (last observation carried forward) approach was used.

Reporting Groups

	Description
Amlodipine/Valsartan 5/80 mg	1 capsule amlodipine 5 mg, 1 capsule valsartan 80 mg once daily
Amlodipine/Valsartan 5/40 mg	1 capsule amlodipine 5 mg, 1 capsule valsartan 40 mg once daily
Amlodipine 5 mg	1 capsule amlodipine 5 mg, 1 capsule placebo to match valsartan once daily

Measured Values

	Amlodipine/Valsartan	**Amlodipine/Valsartan**	**Amlodipine 5**

	5/80 mg	5/40 mg	mg
Number of Participants Analyzed [units: participants]	**272**	**269**	**268**
Percentage of Patients Achieving a Systolic Blood Pressure Response at Week 8 [units: Percentage of patients]	**46.0**	**48.3**	**34.0**

No statistical analysis provided for Percentage of Patients Achieving a Systolic Blood Pressure Response at Week 8

4. Secondary: Percentage of Patients Achieving Systolic 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 Systolic Blood Pressure Control at the End of the Study (Week 8)
Measure Description	Systolic blood pressure control was defined as a msSBP < 140 mmHg at the end of the study (Week 8). At study entry, blood pressure (BP) was measured in both arms with an automatic BP monitor. The arm with the higher systolic BP reading was used for all measurements throughout the study. At each study visit, 3 separate sitting BPs were obtained 23-26 hours post-dose with at least 2 minutes between measurements and with the cuff fully deflated. Mean BP was automatically calculated from the 3 readings.
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.
The Full Analysis Set (FAS) population: All randomized patients who had a baseline and at least one post-baseline assessment an efficacy variable. For the subjects who did not complete the week 8 assessments, an LOCF (last observation carried forward) approach was used.

Reporting Groups

	Description
Amlodipine/Valsartan 5/80 mg	1 capsule amlodipine 5 mg, 1 capsule valsartan 80 mg once daily
Amlodipine/Valsartan 5/40 mg	1 capsule amlodipine 5 mg, 1 capsule valsartan 40 mg once daily
Amlodipine 5 mg	1 capsule amlodipine 5 mg, 1 capsule placebo to match valsartan once daily

Measured Values

	Amlodipine/Valsartan 5/80 mg	**Amlodipine/Valsartan 5/40 mg**	**Amlodipine 5 mg**
Number of Participants Analyzed [units: participants]	**272**	**269**	**268**
Percentage of Patients Achieving Systolic Blood Pressure Control at the End of the Study (Week 8) [units: Percentage of patients]	**31.3**	**37.5**	**20.5**

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

5. Secondary: Percentage of Patients Achieving Overall 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 Overall Blood Pressure Control at the End of the Study (Week 8)
Measure Description	Overall blood pressure control was defined as a msSBP < 140 mmHg and msDBP < 90 mmHg at the end of the study (Week 8). At study entry, blood pressure (BP) was measured in both arms with an automatic BP monitor. The arm with the higher systolic BP reading was used for all measurements throughout the study. At each study visit, 3 separate sitting BPs were obtained 23-26 hours post-dose with at least 2 minutes between measurements and with the cuff fully deflated. Mean BP was automatically calculated from the 3 readings.
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.
The Full Analysis Set (FAS) population: All randomized patients who had a baseline and at least one post-baseline assessment an efficacy variable. For the subjects who did not complete the week 8 assessments, an LOCF (last observation carried forward) approach was used.

Reporting Groups

	Description
Amlodipine/Valsartan 5/80 mg	1 capsule amlodipine 5 mg, 1 capsule valsartan 80 mg once daily
Amlodipine/Valsartan 5/40 mg	1 capsule amlodipine 5 mg, 1 capsule valsartan 40 mg once daily
Amlodipine 5 mg	1 capsule amlodipine 5 mg, 1 capsule placebo to match valsartan once daily

Measured Values

	Amlodipine/Valsartan 5/80 mg	Amlodipine/Valsartan 5/40 mg	Amlodipine 5 mg
Number of Participants Analyzed [units: participants]	**272**	**269**	**268**
Percentage of Patients Achieving Overall Blood Pressure Control at the End of the Study (Week 8) [units: Percentage of patients]	**30.9**	**36.4**	**19.0**

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

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	8 weeks
Additional Description	Adverse events (AE) could be volunteered by the subject, discovered during general questioning by the investigator, or detected through physical examination, laboratory test, or other means. Medical conditions/diseases present before starting study treatment were only considered AEs if they worsened after starting study treatment.

Reporting Groups

	Description
Amlodipine/Valsartan 5/80 mg	1 capsule amlodipine 5 mg, 1 capsule valsartan 80 mg once daily
Amlodipine/Valsartan 5/40 mg	1 capsule amlodipine 5 mg, 1 capsule valsartan 40 mg once daily
Amlodipine 5 mg	1 capsule amlodipine 5 mg, 1 capsule placebo to match valsartan once daily

Serious Adverse Events

	Amlodipine/Valsartan 5/80 mg	Amlodipine/Valsartan 5/40 mg	Amlodipine 5 mg
Total, serious adverse events			
# participants affected / at risk	**5/274 (1.82%)**	**2/272 (0.74%)**	**1/272 (0.37%)**
Cardiac disorders			
Angina pectoris † 1			
# participants affected / at risk	**1/274 (0.36%)**	**0/272 (0.00%)**	**0/272 (0.00%)**
Atrial fibrillation † 1			
# participants affected / at risk	**1/274 (0.36%)**	**0/272 (0.00%)**	**0/272 (0.00%)**
Tachyarrhythmia † 1			
# participants affected / at risk	**0/274 (0.00%)**	**0/272 (0.00%)**	**1/272 (0.37%)**
Eye disorders			
Ophthalmoplegia † 1			
# participants affected / at risk	**0/274 (0.00%)**	**1/272 (0.37%)**	**0/272 (0.00%)**
Musculoskeletal and connective tissue disorders			
Back pain † 1			
# participants affected / at risk	**1/274 (0.36%)**	**0/272 (0.00%)**	**0/272 (0.00%)**
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Gastric cancer † 1			
# participants affected / at risk	**0/274 (0.00%)**	**1/272 (0.37%)**	**0/272 (0.00%)**
Lentigo maligna stage unspecified † 1			
# participants affected / at risk	**1/274 (0.36%)**	**0/272 (0.00%)**	**0/272 (0.00%)**
Nervous system disorders			
Cerebrovascular accident † 1			
# participants affected / at risk	**1/274 (0.36%)**	**0/272 (0.00%)**	**0/272 (0.00%)**
Vascular disorders			
Hypertensive crisis † 1			
# participants affected / at risk	**1/274 (0.36%)**	**0/272 (0.00%)**	**0/272 (0.00%)**

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

Other Adverse Events

Hide Other Adverse Events

Time Frame	8 weeks
Additional Description	Adverse events (AE) could be volunteered by the subject, discovered during general questioning by the investigator, or detected through physical examination, laboratory test, or other means. Medical conditions/diseases present before starting study treatment were only considered AEs if they worsened after starting study treatment.

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description

Amlodipine/Valsartan 5/80 mg	1 capsule amlodipine 5 mg, 1 capsule valsartan 80 mg once daily
Amlodipine/Valsartan 5/40 mg	1 capsule amlodipine 5 mg, 1 capsule valsartan 40 mg once daily
Amlodipine 5 mg	1 capsule amlodipine 5 mg, 1 capsule placebo to match valsartan once daily

Other Adverse Events

	Amlodipine/Valsartan 5/80 mg	Amlodipine/Valsartan 5/40 mg	Amlodipine 5 mg
Total, other (not including serious) adverse events			
# participants affected / at risk	**0/274 (0.00%)**	**0/272 (0.00%)**	**0/272 (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: NCT00699192 History of Changes
Other Study ID Numbers: **CVAA489A2318**
Study First Received: June 9, 2008
Results First Received: January 11, 2011

Last Updated:	May 4, 2011
Health Authority:	Czech Republic: State Institute for Drug Control Finland: Finnish Medicines Agency France: Afssaps - Agence française de sécurité sanitaire des produits de santé (Saint-Denis) Germany: Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM) Hungary: Országos Gyógyszerészeti Intézet Italy: Ministry of Health Slovakia: State Institute for Drug Control Spain: Spanish Agency of Medicines Sweden: Medical Products Agency Poland: Office for Registration of Medicinal Products, Medical Devices and Biocidal Products