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

ClinicalTrials.gov Identifier: NCT00523744

Recruitment Status : Completed
First Posted : August 31, 2007
Results First Posted : May 25, 2011
Last Update Posted : August 4, 2020

Sponsor:
Novartis

Information provided by:
Novartis

Study Details | Tabular View | Study Results | Disclaimer | How to Read a Study Record

Study Type
Interventional

Study Design
Allocation: Non-Randomized; Intervention Model: Single Group Assignment; Masking: None (Open Label); Primary Purpose: Treatment
Condition
Hypertension
Interventions
Drug: Amlodipine Drug: Olmesartan medoxomil Drug: Amlodipine+valsartan Drug: Hydrochlorothiazide
Enrollment
257

Participant Flow

Recruitment Details	
Pre-assignment Details	

	Arm/Group Title	Amlodipine(Al
	▼ Arm/Group Description	During the Treatment olmesartan 10 mg an three weeks of treatm free combination. Dur mg plus valsartan 160 received 4 weeks trea hydrochlorothiazide (H
Period Title: **Phase 1 - Amlodipine+Olmesartan**		
	Started	
	Completed	
	Not Completed	
	Reason Not Completed	
	Adverse Event	
	Withdrawal by Subject	
	Lost to Follow-up	
	Administrative problems	
Period Title: **Phase 2 - Amlodipine+Valsartan**		

Period Title: **Phase 2 - Amlodipine+Valsartan**

Started	
Completed	
Not Completed	
Reason Not Completed	
Adverse Event	
Lost to Follow-up	

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

Period Title: **Phase 3 - Amlodipine+Valsartan+HCTZ**

Started	
Completed	

Not Completed	

[1] Only patients with systolic BP ≥ 140 mmHg or diastolic BP ≥ 90 mmHg at the end of Phase 2.

Baseline Characteristics

Arm/Group Title		Amlodipine(Al
▼ Arm/Group Description		During the Treatment olmesartan 10 mg an three weeks of treatm free combination. Dur mg plus valsartan 160 received 4 weeks trea hydrochlorothiazide (H
Overall Number of Baseline Participants		
▼ Baseline Analysis Population Description		[Not Specified]
Age, Continuous Mean (Standard Deviation) Unit of measure: Years	Number Analyzed	
Phase 1 - Amlodipine+olmesartan		
Phase 2 - Amlodipine+valsartan		
Phase 3 - Amlodipine+valsartan+HCTZ		
Sex/Gender, Customized Measure Type: Number Unit of measure: Participants	Number Analyzed	
Phase 1 - Amlodipine+olmesartan - Female		
Phase 1 - Amlodipine+olmesartan - Male		

Phase 1 - Amlodipine+olmesartan - Male		
Phase 2 - Amlodipine+valsartan - Female		
Phase 2 - Amlodipine+valsartan - Male		
Phase 3 - Amlodipine+valsartan+HCTZ - Female		
Phase 3 - Amlodipine+valsartan+HCTZ - Male		

Outcome Measures

1. Primary Outcome

Title	Change in Mean Sitting Diastolic Blood Pressure (msDBP) During the Core Phas
▼ Description	The arm in which the highest sitting diastolic pressures were found at study entry sphygmomanometer and appropriate size cuff were used to measure arterial sitti the level of the heart. At each study visit, after having the patient in a sitting posit were measured 3 times at 1-2 minute intervals. A mean was calculated from the
Time Frame	Baseline Phase 2 (Week 4) to end of Phase 2 (Week 8)

▼ Outcome Measure Data

▼ Analysis Population Description

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

Arm/Group Title	Amlodipine+Valsartan - F
▼ Arm/Group Description:	Patients with uncontrolled mean sitting diastolic BP (msDBP ≥ 90 mmHg) at the mg plus valsartan 160 mg taken orally in the morning.
Overall Number of Participants Analyzed	175
Mean (95% Confidence Interval) Unit of Measure: mmHg	
	-9.13 (-10.19 to -8.06)

2. Primary Outcome

Title	Change in Mean Sitting Diastolic Blood Pressure (msDBP) During the Extension
▼ Description	The arm in which the highest sitting diastolic pressures were found at study entry

Description	The arm in which the highest sitting diastolic pressures were found at study entry sphygmomanometer and appropriate size cuff were used to measure arterial sitti the level of the heart. At each study visit, after having the patient in a sitting posit were measured 3 times at 1-2 minute intervals. A mean was calculated from the
Time Frame	Baseline Phase 3 (Week 8) to end of Phase 3 (Week 12)

▼ Outcome Measure Data

▼ Analysis Population Description

Safety population: All patients who took at least one dose of amlodipine 10 mg plus valsartan 160 mg plus H

Arm/Group Title	Amlodipine+Valsartan+HCTZ
▼ Arm/Group Description:	Patients with uncontrolled mean sitting systolic or diastolic blood pressure (msDE Phase 2 were offered a 4 week treatment extension with amlodipine 10 mg plus taken orally in the morning.
Overall Number of Participants Analyzed	91
Mean (95% Confidence Interval) Unit of Measure: mmHg	
	-5.22 (-6.76 to -3.68)

3. Secondary Outcome

Title	Change in Mean Sitting Systolic Blood Pressure (msSBP) During the Core Phase
▼ Description	The arm in which the highest sitting diastolic pressures were found at study entry sphygmomanometer and appropriate size cuff were used to measure arterial sitti the level of the heart. At each study visit, after having the patient in a sitting posit were measured 3 times at 1-2 minute intervals. A mean was calculated from the
Time Frame	Baseline Phase 2 (Week 4) to end of Phase 2 (Week 8)

▼ Outcome Measure Data

▼ Analysis Population Description

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

Arm/Group Title	Amlodipine+Valsartan - F

Arm/Group Description:	Patients with uncontrolled mean sitting diastolic BP (msDBP ≥ 90 mmHg) at the mg plus valsartan 160 mg taken orally in the morning.
Overall Number of Participants Analyzed	175
Mean (95% Confidence Interval) Unit of Measure: mmHg	
	-7.87 (-9.33 to -6.11)

4. Secondary Outcome

Title	Change in Sitting Pulse Pressure During the Core Phase of the Study
Description	Pulse pressure is systolic pressure (SP) minus diastolic pressure (DP). The arm the arm used for all subsequent readings. A calibrated sphygmomanometer and blood pressure (BP) at trough with the arm supported at the level of the heart. At for at least 5 minutes, SP and DP were measured 3 times at 1-2 minute intervals negative change indicates improvement.
Time Frame	Baseline Phase 2 (Week 4) to end of Phase 2 (Week 8)

Outcome Measure Data

Analysis Population Description

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

Arm/Group Title	Amlodipine+Valsartan - F
Arm/Group Description:	Patients with uncontrolled mean sitting diastolic BP (msDBP ≥ 90 mmHg) at the mg plus valsartan 160 mg taken orally in the morning.
Overall Number of Participants Analyzed	175
Mean (95% Confidence Interval) Unit of Measure: mmHg	
	1.26 (0.49 to 3.01)

5. Secondary Outcome

Title	Change in Sitting Pulse Rate During the Core Phase of the Study
▼ Description	Pulse rate was measured once for 30 seconds just prior to blood pressure measu
Time Frame	Baseline Phase 2 (Week 4) to end of Phase 2 (Week 8)

▼ Outcome Measure Data

▼ Analysis Population Description

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

Arm/Group Title	Amlodipine+Valsartan - F
▼ Arm/Group Description:	Patients with uncontrolled mean sitting diastolic BP (msDBP ≥ 90 mmHg) at the mg plus valsartan 160 mg taken orally in the morning.
Overall Number of Participants Analyzed	175
Mean (95% Confidence Interval) Unit of Measure: BPM (beats per minute)	
	-1.93 (-3.06 to -0.79)

6. Secondary Outcome

Title	Percentage of Patients Who Achieved Normalized Blood Pressure During the Co
▼ Description	Normalized Blood Pressure was defined as a msSBP < 140 mmHg and/or a msD
Time Frame	Baseline Phase 2 (Week 4) to end of Phase 2 (Week 8)

▼ Outcome Measure Data

▼ Analysis Population Description

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

Arm/Group Title	Amlodipine+Valsartan - F
▼ Arm/Group Description:	Patients with uncontrolled mean sitting diastolic BP (msDBP ≥ 90 mmHg) at the mg plus valsartan 160 mg taken orally in the morning

Description:	mg plus valsartan 160 mg taken orally in the morning.
Overall Number of Participants Analyzed	175
Measure Type: Number Unit of Measure: Percentage of participants	
msSBP < 140 mmHg	44.6
msDBP < 90 mmHg	72.6

7. Secondary Outcome

Title	Percentage of Patients Who Achieved a Protocol-defined Blood Pressure Respo
▼ Description	Blood pressure response was defined as msSBP < 140 mmHg or a 20 mmHg de to Baseline in Phase 2 (week 4) or a msDBP < 90 mmHg or a 10 mmHg decreas Phase 2.
Time Frame	Baseline of Phase 2 (Week 4) to end of Phase 2 (Week 8)

▼ Outcome Measure Data

▼ Analysis Population Description

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

Arm/Group Title	Amlodipine+Valsartan - F
▼ Arm/Group Description:	Patients with uncontrolled mean sitting diastolic BP (msDBP ≥ 90 mmHg) at the mg plus valsartan 160 mg taken orally in the morning.
Overall Number of Participants Analyzed	175
Measure Type: Number Unit of Measure: Percentage of participants	
msSBP response	47.4
msDBP response	73.1

8. Secondary Outcome

Title	Change in Mean Sitting Systolic Blood Pressure (msSBP) During the Extension F
▼ Description	The arm in which the highest sitting diastolic pressure were found at study entr

Description	The arm in which the highest sitting diastolic pressures were found at study entry sphygmomanometer and appropriate size cuff were used to measure arterial sitti the level of the heart. At each study visit, after having the patient in a sitting posit were measured 3 times at 1-2 minute intervals. A mean was calculated from the
Time Frame	Baseline Phase 3 (Week 8) to end of Phase 3 (Week 12)

Outcome Measure Data

Analysis Population Description

Safety population: All patients who took at least one dose of amlodipine 10 mg plus valsartan 160 mg plus H

Arm/Group Title	Amlodipine+Valsartan+HCTZ
Arm/Group Description:	Patients with uncontrolled mean sitting systolic or diastolic blood pressure (msDE Phase 2 were offered a 4 week treatment extension with amlodipine 10 mg plus taken orally in the morning.
Overall Number of Participants Analyzed	91
Mean (95% Confidence Interval) Unit of Measure: mmHg	
	-10.84 (-12.94 to -8.75)

9. Secondary Outcome

Title	Change in Sitting Pulse Pressure During the Extension Phase of the Study
Description	Pulse pressure is systolic pressure (SP) minus diastolic pressure (DP). The arm the arm used for all subsequent readings. A calibrated sphygmomanometer and blood pressure (BP) at trough with the arm supported at the level of the heart. At for at least 5 minutes, SP and DP were measured 3 times at 1-2 minute intervals negative change indicates improvement.
Time Frame	Baseline Phase 3 (Week 8) to end of Phase 3 (Week 12)

Outcome Measure Data

Analysis Population Description

Safety population: All patients who took at least one dose of amlodipine 10 mg plus valsartan 160 mg plus H

Arm/Group Title	Amlodipine+Valsartan+HCTZ
Arm/Group	Patients with uncontrolled mean sitting systolic or diastolic blood pressure (msDE

Arm/Group Description:	Patients with uncontrolled mean sitting systolic or diastolic blood pressure (msDBP Phase 2 were offered a 4 week treatment extension with amlodipine 10 mg plus taken orally in the morning.
Overall Number of Participants Analyzed	91
Mean (95% Confidence Interval) Unit of Measure: mmHg	
	-5.62 (-7.74 to -3.50)

10. Secondary Outcome

Title	Change in Sitting Pulse Rate During the Extension Phase of the Study
▼ Description	Pulse rate was measured once for 30 seconds just prior to blood pressure measu
Time Frame	Baseline Phase 3 (Week 8) to end of Phase 3 (week 12)

▼ Outcome Measure Data

▼ Analysis Population Description
Safety population: All patients who took at least one dose of amlodipine 10 mg plus valsartan 160 mg plus H

Arm/Group Title	Amlodipine+Valsartan+HCTZ
▼ Arm/Group Description:	Patients with uncontrolled mean sitting systolic or diastolic blood pressure (msDBP Phase 2 were offered a 4 week treatment extension with amlodipine 10 mg plus taken orally in the morning.
Overall Number of Participants Analyzed	91
Mean (95% Confidence Interval) Unit of Measure: BPM (beats per minute)	
	0.09 (-1.36 to 1.54)

11. Secondary Outcome

Title	Percentage of Patients Who Achieved Normalized Blood Pressure During the Ex
▼ Description	Normalized Blood Pressure was defined as a msSBP < 140 mmHg and/or a msD
Time Frame	Baseline Phase 3 (Week 8) to end of Phase 3 (Week 12)

▼ Outcome Measure Data

▼ Analysis Population Description
Safety population: All patients who took at least one dose of amlodipine 10 mg plus valsartan 160 mg plus H

Arm/Group Title	Amlodipine+Valsartan+HCTZ
▼ Arm/Group Description:	Patients with uncontrolled mean sitting systolic or diastolic blood pressure (msDE Phase 2 were offered a 4 week treatment extension with amlodipine 10 mg plus taken orally in the morning.
Overall Number of Participants Analyzed	91

Measure Type: Number Unit of Measure: Percentage of participants	
msSBP < 140 mmHg	59.3
msDBP < 90 mmHg	83.5

12. Secondary Outcome

Title	Percentage of Patients Who Achieved a Protocol-defined Blood Pressure Respo
▼ Description	Blood pressure response was defined as msSBP < 140 mmHg or a 20 mmHg de in Phase 3 or a msDBP < 90 mmHg or a 10 mmHg decrease in msDBP at the er
Time Frame	Baseline of Phase 3 (Week 8) to end of Phase 3 (Week 12)

▼ Outcome Measure Data

▼ Analysis Population Description
Safety population: All patients who took at least one dose of amlodipine 10 mg plus valsartan 160 mg plus H

Arm/Group Title	Amlodipine+Valsartan+HCTZ
▼ Arm/Group Description:	Patients with uncontrolled mean sitting systolic or diastolic blood pressure (msDE Phase 2 were offered a 4 week treatment extension with amlodipine 10 mg plus taken orally in the morning.
Overall Number of Participants Analyzed	91
Measure Type: Number Unit of Measure: Percentage of	

Percentage of participants	
msSBP response	61.5
msDBP response	83.5

Adverse Events

Time Frame	[Not Specified]
Adverse Event Reporting Description	[Not Specified]

Arm/Group Title	Phase 1 - Amlodipine+Olmesartan	Phase 2 - Amlod
▼ Arm/Group Description	4 weeks treatment with amlodipine 10 mg plus olmesartan 20 mg taken orally once daily in the morning.	Patients with uncontr diastolic BP (msDBP end of Phase 1 were with amlodipine 10 m 160 mg taken orally i

All-Cause Mortality

	Phase 1 - Amlodipine+Olmesartan	Phase 2 - Amlod
	Affected / at Risk (%)	Affected / a
Total	--/--	--/

▼ Serious Adverse Events

	Phase 1 - Amlodipine+Olmesartan	Phase 2 - Amlod
	Affected / at Risk (%)	Affected / a
Total	1/257 (0.39%)	0/176 ((
Ear and labyrinth disorders		
SUDDEN HEARING LOSS † 1	1/257 (0.39%)	0/176 ((

† Indicates events were collected by systematic assessment

1 Term from vocabulary, MedDRA

▼ Other (Not Including Serious) Adverse Events

Frequency Threshold for Reporting Other Adverse Events	5%	
	Phase 1 - Amlodipine+Olmesartan	**Phase 2 - Amlod**
	Affected / at Risk (%)	Affected / a
Total	0/257 (0.00%)	0/176 (

Limitations and Caveats

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[Not Specified]

More Information

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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 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:
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Responsible Party:
External Affairs, Novartis Pharmaceuticals

ClinicalTrials.gov Identifier:
NCT00523744 History of Changes

Other Study ID Numbers:
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