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Trial record **1 of 1** for: CVAA489A2404

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Efficacy and Safety of Valsartan/Amlodipine Compared to Amlodipine in Patients With Essential Hypertension

This study has been completed.

Sponsor:
Novartis Pharmaceuticals

Information provided by:
Novartis

ClinicalTrials.gov Identifier:
NCT00437645

First received: February 16, 2007
Last updated: November 3, 2014
Last verified: November 2014
History of Changes

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

Results First Received: August 17, 2009

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Caregiver, Investigator, Outcomes Assessor); Primary Purpose: Treatment
Condition:	Essential Hypertension
Interventions:	Drug: Valsartan 160 mg capsules Drug: Amlodipine 5 mg capsules 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
No text entered.

Reporting Groups

	Description
Valsartan/Amlodipine 160/5 mg	Twelve (12) weeks treatment with the combination of valsartan/amlodipine 160/5 mg. Together with the active medication, patients received a placebo that matched amlodipine 5 mg. The three capsules were taken by mouth with water once daily in the morning, regardless of meals. Patients were instructed not to take their study medication the morning of their study visits. Instead, they brought the study medication with them to the site and took it there as instructed by the investigator.
Amlodipine 10 mg	Eight (8) weeks of treatment with amlodipine 10 mg (two 5 mg capsules). Together with the active medication, the patients received a placebo that matched valsartan 160 mg. At Week 8, patients were

	switched and treated with the combination of valsartan/amlodipine 160/5 mg and a placebo that matched amlodipine 5 mg for an additional 4 weeks until the end of the study. The three capsules were taken by mouth with water once daily in the morning, regardless of meals. Patients were instructed not to take their study medication the morning of their study visits. Instead, they brought the study medication with them to the site and took it there as instructed by the investigator.

Participant Flow: Overall Study

	Valsartan/Amlodipine 160/5 mg	Amlodipine 10 mg
STARTED	**592**	**591**
COMPLETED	**557**	**476**
NOT COMPLETED	**35**	**115**
Adverse Event	**15**	**84**
Withdrawal by Subject	**10**	**22**
Protocol Violation	**3**	**3**
Lost to Follow-up	**2**	**3**
Administrative problems	**2**	**1**
Lack of Efficacy	**2**	**1**
Condition no longer requires study drug	**1**	**1**

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
Valsartan/Amlodipine 160/5 mg	Twelve (12) weeks treatment with the combination of valsartan/amlodipine 160/5 mg. Together with the active medication, patients received a placebo that matched amlodipine 5 mg. The three capsules were taken by mouth with water once daily in the morning, regardless of meals. Patients were instructed not to take their study medication the morning of their study visits. Instead, they brought the study medication with them to the site and took it there as instructed by the investigator.
Amlodipine 10 mg	Eight (8) weeks of treatment with amlodipine 10 mg (two 5 mg capsules). Together with the active medication, the patients received a placebo that matched valsartan 160 mg. At Week 8, patients were switched and treated with the combination of valsartan/amlodipine 160/5 mg and a placebo that matched amlodipine 5 mg for an additional 4 weeks until the end of the study. The three capsules were taken by mouth with water once daily in the morning, regardless of meals. Patients were instructed not to take their study medication the morning of their study visits. Instead, they brought the study medication with them to the site and took it there as instructed by the investigator.
Total	Total of all reporting groups

Baseline Measures

	Valsartan/Amlodipine 160/5 mg	Amlodipine 10 mg	Total
Number of Participants [units: participants]	**592**	**591**	**1183**
Age [units: Age (years)] Mean (Standard Deviation)			

Overall study	**65.6 (7.56)**	**65.4 (7.16)**	**65.5 (7.36)**
Gender [units: participants]			
Female	**285**	**284**	**569**
Male	**307**	**307**	**614**

Outcome Measures

Hide All Outcome Measures

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

Measure Type	Primary
Measure Title	Change in Mean Sitting Systolic Blood Pressure (msSBP) From Baseline to 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 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 (ITT) population: All randomized patients who had a baseline and at least one post-baseline efficacy assessment. For patients who discontinued prior to Week 8, the last post-baseline msSBP measurement collected was used for the analysis (last observation carried forward [LOCF]).

Reporting Groups

	Description
Valsartan/Amlodipine 160/5 mg	Twelve (12) weeks treatment with the combination of valsartan/amlodipine 160/5 mg. Together with the active medication, patients received a placebo that matched amlodipine 5 mg. The three capsules were taken by mouth with water once daily in the morning, regardless of meals. Patients were instructed not to take their study medication the morning of their study visits. Instead, they brought the study medication with them to the site and took it there as instructed by the investigator.
Amlodipine 10 mg	Eight (8) weeks of treatment with amlodipine 10 mg (two 5 mg capsules). Together with the active medication, the patients received a placebo that matched valsartan 160 mg. At Week 8, patients were switched and treated with the combination of valsartan/amlodipine 160/5 mg and a placebo that matched amlodipine 5 mg for an additional 4 weeks until the end of the study. The three capsules were taken by mouth with water once daily in the morning, regardless of meals. Patients were instructed not to take their study medication the morning of their study visits. Instead, they brought the study medication with them to the site and took it there as instructed by the investigator.

Measured Values

	Valsartan/Amlodipine 160/5 mg	**Amlodipine 10 mg**
Number of Participants Analyzed [units: participants]	**567**	**510**
Change in Mean Sitting Systolic Blood Pressure (msSBP) From Baseline to Week 8 [units: mmHg]	**-8.01 (0.5944)**	**-6.30 (0.6088)**

Least Squares Mean (Standard Error)		

Statistical Analysis 1 for Change in Mean Sitting Systolic Blood Pressure (msSBP) From Baseline to Week 8

Groups [1]	All groups
Non-Inferiority/Equivalence Test [2]	Yes
Method [3]	ANCOVA
Mean Difference (Final Values) [4]	-1.72
Standard Error of the mean	(0.65)
95% Confidence Interval	-3.00 to -0.44

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Details of power calculation, definition of non-inferiority margin, and other key parameters:
	Statistical analysis for non-inferiority of valsartan/amlodipine 160/5 mg to amlodipine 10 mg alone with a non-inferiority margin of 3 mm Hg
[3]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

2. Primary: Percentage of Patients With Peripheral Edema From Baseline to Week 8 [Time Frame: Baseline to Week 8]

Measure Type	Primary
Measure Title	Percentage of Patients With Peripheral Edema From Baseline to Week 8
Measure Description	Only occurrences of peripheral edema quantified as a reported adverse event coded as peripheral edema were included in the analysis. If a patient experienced more than one occurrence of peripheral edema between Day 1 and Week 8, it was only counted once in the analysis.
Time Frame	Baseline to Week 8
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Safety population: All randomized patients.

Reporting Groups

	Description
Valsartan/Amlodipine 160/5 mg	Twelve (12) weeks treatment with the combination of valsartan/amlodipine 160/5 mg. Together with the active medication, patients received a placebo that matched amlodipine 5 mg. The three capsules were taken by mouth with water once daily in the morning, regardless of meals. Patients were instructed not to take their study medication the morning of their study visits. Instead, they brought the study medication with them to the site and took it there as instructed by the investigator.
Amlodipine 10 mg	Eight (8) weeks of treatment with amlodipine 10 mg (two 5 mg capsules). Together with the active medication, the patients received a placebo that matched valsartan 160 mg. At Week 8, patients were switched and treated with the combination of valsartan/amlodipine 160/5 mg and a placebo that matched

	amlodipine 5 mg for an additional 4 weeks until the end of the study. The three capsules were taken by mouth with water once daily in the morning, regardless of meals. Patients were instructed not to take their study medication the morning of their study visits. Instead, they brought the study medication with them to the site and took it there as instructed by the investigator.

Measured Values

	Valsartan/Amlodipine 160/5 mg	Amlodipine 10 mg
Number of Participants Analyzed [units: participants]	**592**	**591**
Percentage of Patients With Peripheral Edema From Baseline to Week 8 [units: Percentage of patients]	**6.6**	**31.1**

No statistical analysis provided for Percentage of Patients With Peripheral Edema From Baseline to Week 8

3. Secondary: Change in Mean Sitting Diastolic Blood Pressure (msDBP) From Baseline to Week 8 [Time Frame: Baseline to Week 8]

Measure Type	Secondary
Measure Title	Change in Mean Sitting Diastolic Blood Pressure (msDBP) From Baseline to 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 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 (ITT) population: All randomized patients who had a baseline and at least one post-baseline efficacy assessment. For patients who discontinued prior to Week 8, the last post-baseline msSBP measurement collected was used for the analysis (last observation carried forward [LOCF]).

Reporting Groups

	Description
Valsartan/Amlodipine 160/5 mg	Twelve (12) weeks treatment with the combination of valsartan/amlodipine 160/5 mg. Together with the active medication, patients received a placebo that matched amlodipine 5 mg. The three capsules were taken by mouth with water once daily in the morning, regardless of meals. Patients were instructed not to take their study medication the morning of their study visits. Instead, they brought the study medication with them to the site and took it there as instructed by the investigator.
Amlodipine 10 mg	Eight (8) weeks of treatment with amlodipine 10 mg (two 5 mg capsules). Together with the active medication, the patients received a placebo that matched valsartan 160 mg. At Week 8, patients were switched and treated with the combination of valsartan/amlodipine 160/5 mg and a placebo that matched amlodipine 5 mg for an additional 4 weeks until the end of the study. The three capsules were taken by mouth with water once daily in the morning, regardless of meals. Patients were instructed not to take their study medication the morning of their study visits. Instead, they brought the study medication with them to the site and took it there as instructed by the investigator.

Measured Values

	Valsartan/Amlodipine 160/5 mg	Amlodipine 10 mg
Number of Participants Analyzed	**567**	**510**

[units: participants]		
Change in Mean Sitting Diastolic Blood Pressure (msDBP) From Baseline to Week 8 **[units: mmHg]** **Least Squares Mean (Standard Error)**	**-4.65 (0.3616)**	**-4.13 (0.3690)**

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

4. Secondary: Change in Mean Sitting Systolic and Diastolic Blood Pressure (msSBP, msDBP) From Baseline to Weeks 4, 8, and 12 [Time Frame: Baseline to Weeks 4, 8, and 12]

Measure Type	Secondary
Measure Title	Change in Mean Sitting Systolic and Diastolic Blood Pressure (msSBP, msDBP) From Baseline to Weeks 4, 8, and 12
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 Weeks 4, 8, and 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.
Intent-to-treat (ITT) population: All randomized patients who had a baseline and at least one post-baseline efficacy assessment. For patients who discontinued prior to Week 8, the last post-baseline msSBP measurement collected was used for the analysis (last observation carried forward [LOCF]).

Reporting Groups

	Description
Valsartan/Amlodipine 160/5 mg	Twelve (12) weeks treatment with the combination of valsartan/amlodipine 160/5 mg. Together with the active medication, patients received a placebo that matched amlodipine 5 mg. The three capsules were taken by mouth with water once daily in the morning, regardless of meals. Patients were instructed not to take their study medication the morning of their study visits. Instead, they brought the study medication with them to the site and took it there as instructed by the investigator.
Amlodipine 10 mg	Eight (8) weeks of treatment with amlodipine 10 mg (two 5 mg capsules). Together with the active medication, the patients received a placebo that matched valsartan 160 mg. At Week 8, patients were switched and treated with the combination of valsartan/amlodipine 160/5 mg and a placebo that matched amlodipine 5 mg for an additional 4 weeks until the end of the study. The three capsules were taken by mouth with water once daily in the morning, regardless of meals. Patients were instructed not to take their study medication the morning of their study visits. Instead, they brought the study medication with them to the site and took it there as instructed by the investigator.

Measured Values

	Valsartan/Amlodipine 160/5 mg	**Amlodipine 10 mg**
Number of Participants Analyzed **[units: participants]**	**576**	**535**
Change in Mean Sitting Systolic and Diastolic Blood Pressure (msSBP, msDBP) From Baseline to Weeks 4, 8, and 12 **[units: mmHg]** **Least Squares Mean (Standard Error)**		

msSBP: Week 4 (n=576, 535)	**-8.40 (0.5559)**	**-6.48 (0.5676)**
msSBP: Week 8 (n=567, 510)	**-8.15 (0.6065)**	**-6.11 (0.6266)**
msSBP: Week 12 (n=569, 531)	**-9.08 (0.6968)**	**-7.82 (0.7088)**
msDBP: Week 4 (n=576, 535)	**-5.05 (0.3559)**	**-4.23 (0.3623)**
msDBP: Week 8 (n=576, 510)	**-4.68 (0.3632)**	**-3.97 (0.3736)**
msDBP: Week 12 (n=569, 531)	**-5.50 (0.03735)**	**-4.90 (0.3785)**

No statistical analysis provided for Change in Mean Sitting Systolic and Diastolic Blood Pressure (msSBP, msDBP) From Baseline to Weeks 4, 8, and 12

5. Secondary: Percentage of Patients Achieving a Systolic Response at Weeks 4, 8, and 12 [Time Frame: Baseline to Weeks 4, 8, and 12]

Measure Type	Secondary
Measure Title	Percentage of Patients Achieving a Systolic Response at Weeks 4, 8, and 12
Measure Description	Systolic response was defined as msSBP < 130 mmHg or at least a 20 mmHg reduction from baseline in msSBP at Weeks 4, 8, and 12. 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	Baseline to Weeks 4, 8, and 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.
Intent-to-treat (ITT) population: All randomized patients who had a baseline and at least one post-baseline efficacy assessment. For patients who discontinued prior to Week 8, the last post-baseline msSBP measurement collected was used for the analysis (last observation carried forward [LOCF]).

Reporting Groups

	Description
Valsartan/Amlodipine 160/5 mg	Twelve (12) weeks treatment with the combination of valsartan/amlodipine 160/5 mg. Together with the active medication, patients received a placebo that matched amlodipine 5 mg. The three capsules were taken by mouth with water once daily in the morning, regardless of meals. Patients were instructed not to take their study medication the morning of their study visits. Instead, they brought the study medication with them to the site and took it there as instructed by the investigator.
Amlodipine 10 mg	Eight (8) weeks of treatment with amlodipine 10 mg (two 5 mg capsules). Together with the active medication, the patients received a placebo that matched valsartan 160 mg. At Week 8, patients were switched and treated with the combination of valsartan/amlodipine 160/5 mg and a placebo that matched amlodipine 5 mg for an additional 4 weeks until the end of the study. The three capsules were taken by mouth with water once daily in the morning, regardless of meals. Patients were instructed not to take their study medication the morning of their study visits. Instead, they brought the study medication with them to the site and took it there as instructed by the investigator.

Measured Values

	Valsartan/Amlodipine 160/5 mg	**Amlodipine 10 mg**
Number of Participants Analyzed [units: participants]	**576**	**535**
Percentage of Patients Achieving a Systolic Response at Weeks 4, 8, and 12 [units: Percentage of patients]		

Week 4 (n=576, 535)	**35.07**	**25.42**
Week 8 (n=567, 510)	**34.22**	**25.49**
Week 12 (n=569, 531)	**37.96**	**31.26**

No statistical analysis provided for Percentage of Patients Achieving a Systolic Response at Weeks 4, 8, and 12

Serious Adverse Events

Hide Serious Adverse Events

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

Reporting Groups

	Description
Valsartan/Amlodipine 160/5 mg	Twelve (12) weeks treatment with the combination of valsartan/amlodipine 160/5 mg. Together with the active medication, patients received a placebo that matched amlodipine 5 mg. The three capsules were taken by mouth with water once daily in the morning, regardless of meals. Patients were instructed not to take their study medication the morning of their study visits. Instead, they brought the study medication with them to the site and took it there as instructed by the investigator.
Amlodipine 10 mg	Eight (8) weeks of treatment with amlodipine 10 mg (two 5 mg capsules). Together with the active medication, the patients received a placebo that matched valsartan 160 mg. At Week 8, patients were switched and treated with the combination of valsartan/amlodipine 160/5 mg and a placebo that matched amlodipine 5 mg for an additional 4 weeks until the end of the study. The three capsules were taken by mouth with water once daily in the morning, regardless of meals. Patients were instructed not to take their study medication the morning of their study visits. Instead, they brought the study medication with them to the site and took it there as instructed by the investigator.

Serious Adverse Events

	Valsartan/Amlodipine 160/5 mg	**Amlodipine 10 mg**
Total, serious adverse events		
# participants affected / at risk	**11/592 (1.86%)**	**8/591 (1.35%)**
Cardiac disorders		
Atrial fibrillation † 1		
# participants affected / at risk	**1/592 (0.17%)**	**0/591 (0.00%)**
Gastrointestinal disorders		
Gastrointestinal haemorrhage † 1		
# participants affected / at risk	**0/592 (0.00%)**	**1/591 (0.17%)**
Gastrointestinal necrosis † 1		
# participants affected / at risk	**0/592 (0.00%)**	**1/591 (0.17%)**
Inguinal hernia † 1		
# participants affected / at risk	**0/592 (0.00%)**	**1/591 (0.17%)**
General disorders		
Asthenia † 1		
# participants affected / at risk	**1/592 (0.17%)**	**0/591 (0.00%)**
Pyrexia † 1		
# participants affected / at risk	**1/592 (0.17%)**	**0/591 (0.00%)**
Hepatobiliary disorders		

Cholecystitis † [1]		
# participants affected / at risk	**2/592 (0.34%)**	**0/591 (0.00%)**
Cholelithiasis † [1]		
# participants affected / at risk	**1/592 (0.17%)**	**0/591 (0.00%)**
Infections and infestations		
Hantavirus pulmonary infection † [1]		
# participants affected / at risk	**1/592 (0.17%)**	**0/591 (0.00%)**
Urinary tract infection † [1]		
# participants affected / at risk	**1/592 (0.17%)**	**0/591 (0.00%)**
Injury, poisoning and procedural complications		
Drug toxicity † [1]		
# participants affected / at risk	**1/592 (0.17%)**	**0/591 (0.00%)**
Humerus fracture † [1]		
# participants affected / at risk	**0/592 (0.00%)**	**1/591 (0.17%)**
Ligament rupture † [1]		
# participants affected / at risk	**1/592 (0.17%)**	**0/591 (0.00%)**
Meniscus lesion † [1]		
# participants affected / at risk	**1/592 (0.17%)**	**0/591 (0.00%)**
Investigations		
Blood creatine phosphokinase increased † [1]		
# participants affected / at risk	**1/592 (0.17%)**	**0/591 (0.00%)**
Musculoskeletal and connective tissue disorders		
Arthralgia † [1]		
# participants affected / at risk	**1/592 (0.17%)**	**0/591 (0.00%)**
Bursitis † [1]		
# participants affected / at risk	**1/592 (0.17%)**	**0/591 (0.00%)**
Muscular weakness † [1]		
# participants affected / at risk	**0/592 (0.00%)**	**1/591 (0.17%)**
Myalgia † [1]		
# participants affected / at risk	**1/592 (0.17%)**	**0/591 (0.00%)**
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		
Colon cancer † [1]		
# participants affected / at risk	**1/592 (0.17%)**	**0/591 (0.00%)**
Pancreatic carcinoma † [1]		
# participants affected / at risk	**0/592 (0.00%)**	**1/591 (0.17%)**
Nervous system disorders		
Cerebrovascular accident † [1]		
# participants affected / at risk	**0/592 (0.00%)**	**1/591 (0.17%)**
Dysphasia † [1]		
# participants affected / at risk	**0/592 (0.00%)**	**1/591 (0.17%)**
Psychiatric disorders		
Neglect of personal appearance † [1]		
# participants affected / at risk	**0/592 (0.00%)**	**1/591 (0.17%)**

Renal and urinary disorders		
Bladder tamponade † 1		
# participants affected / at risk	**1/592 (0.17%)**	**0/591 (0.00%)**
Haematuria † 1		
# participants affected / at risk	**1/592 (0.17%)**	**0/591 (0.00%)**
Renal impairment † 1		
# participants affected / at risk	**1/592 (0.17%)**	**0/591 (0.00%)**
Reproductive system and breast disorders		
Epididymitis † 1		
# participants affected / at risk	**0/592 (0.00%)**	**1/591 (0.17%)**
Respiratory, thoracic and mediastinal disorders		
Dyspnoea † 1		
# participants affected / at risk	**0/592 (0.00%)**	**1/591 (0.17%)**
Haemoptysis † 1		
# participants affected / at risk	**0/592 (0.00%)**	**1/591 (0.17%)**
Skin and subcutaneous tissue disorders		
Hyperhidrosis † 1		
# participants affected / at risk	**0/592 (0.00%)**	**1/591 (0.17%)**

† 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
Valsartan/Amlodipine 160/5 mg	Twelve (12) weeks treatment with the combination of valsartan/amlodipine 160/5 mg. Together with the active medication, patients received a placebo that matched amlodipine 5 mg. The three capsules were taken by mouth with water once daily in the morning, regardless of meals. Patients were instructed not to take their study medication the morning of their study visits. Instead, they brought the study medication with them to the site and took it there as instructed by the investigator.
Amlodipine 10 mg	Eight (8) weeks of treatment with amlodipine 10 mg (two 5 mg capsules). Together with the active medication, the patients received a placebo that matched valsartan 160 mg. At Week 8, patients were switched and treated with the combination of valsartan/amlodipine 160/5 mg and a placebo that matched amlodipine 5 mg for an additional 4 weeks until the end of the study. The three capsules were taken by mouth with water once daily in the morning, regardless of meals. Patients were instructed not to take their study medication the morning of their study visits. Instead, they brought the study medication with them to the site and took it there as instructed by the investigator.

Other Adverse Events

	Valsartan/Amlodipine 160/5 mg	**Amlodipine 10 mg**
Total, other (not including serious) adverse events		

# participants affected / at risk	**61/592 (10.30%)**	**201/591 (34.01%)**
General disorders		
Oedema peripheral † 1		
# participants affected / at risk	**43/592 (7.26%)**	**186/591 (31.47%)**
Nervous system disorders		
Headache † 1		
# participants affected / at risk	**18/592 (3.04%)**	**33/591 (5.58%)**

† 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:** Disclosure 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 by Novartis

Publications automatically indexed to this study:

Schrader J, Salvetti A, Calvo C, Akpinar E, Keeling L, Weisskopf M, Brunel P. The combination of amlodipine/valsartan 5/160 mg produces less peripheral oedema than amlodipine 10 mg in hypertensive patients not adequately controlled with amlodipine 5 mg. Int J Clin Pract. 2009 Feb;63(2):217-25. doi: 10.1111/j.1742-1241.2008.01977.x.

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