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Trial record **1 of 1** for: CVAA489ADE02

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Efficacy and Safety of Valsartan in Combination With Amlodipine Compared to Losartan Plus Hydrochlorothiazide in Patients With Hypertension and Left Ventricular Hypertrophy

This study has been completed.

Sponsor:
Novartis

Information provided by:
Novartis

ClinicalTrials.gov Identifier:
NCT00446563

First received: March 12, 2007
Last updated: May 6, 2011
Last verified: May 2011
History of Changes

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Results First Received: March 31, 2011

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Parallel Assignment; Masking: Open Label; Primary Purpose: Treatment
Condition:	Hypertension; Hypertrophy, Left Ventricular
Interventions:	Drug: Valsartan Drug: Amlodipine Drug: Hydrochlorothiazide Drug: Losartan

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 and Amlodipine	Participants received 160 mg Valsartan and 5 mg amlodipine orally once a day for 52 weeks. If blood pressure was not normalized at week 4, treatment was uptitrated to valsartan/amlodipine 160/10 mg. Participants with still uncontrolled hypertension could receive add-on antihypertensive medication.
Losartan and HCTZ	Participants received 100 mg losartan and 12.5 mg Hydrochlorothiazide (HCT) orally once a day for 52 weeks. If blood pressure was not normalized at week 4, treatment was uptitrated to losartan/HCT 100/25 mg, respectively, until end of study. Participants with still uncontrolled hypertension could receive add-on antihypertensive medication.

Participant Flow: Overall Study

	Valsartan and Amlodipine	Losartan and HCTZ
STARTED	43	47
COMPLETED	36	38
NOT COMPLETED	7	9
Adverse Event	4	3
Abnormal laboratory value(s)	0	1
Abnormal test procedure result(s)	1	0
Unsatisfactory therapeutic effect	0	3
Withdrawal by Subject	2	1
Administrative problems	0	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 and Amlodipine	Participants received 160 mg Valsartan and 5 mg amlodipine orally once a day for 52 weeks. If blood pressure was not normalized at week 4, treatment was uptitrated to valsartan/amlodipine 160/10 mg. Participants with still uncontrolled hypertension could receive add-on antihypertensive medication.
Losartan and HCTZ	Participants received 100 mg losartan and 12.5 mg Hydrochlorothiazide (HCT) orally once a day for 52 weeks. If blood pressure was not normalized at week 4, treatment was uptitrated to losartan/HCT 100/25 mg, respectively, until end of study. Participants with still uncontrolled hypertension could receive add-on antihypertensive medication.
Total	Total of all reporting groups

Baseline Measures

	Valsartan and Amlodipine	Losartan and HCTZ	Total
Number of Participants [units: participants]	43	47	90
Age [units: years] Mean (Standard Deviation)	58.2 (12.2)	57.2 (10.9)	57.7 (11.5)
Gender [units: participants]			
Female	12	13	25
Male	31	34	65

Outcome Measures

Hide All Outcome Measures

1. Primary: Change From Baseline in Left Ventricular Mass Index (LVMI) Measured Via Magnetic Resonance Imaging (MRI) [Time Frame: Baseline to week 52]

Measure Type	Primary
Measure Title	Change From Baseline in Left Ventricular Mass Index (LVMI) Measured Via Magnetic Resonance Imaging (MRI)
Measure Description	No text entered.
Time Frame	Baseline to week 52
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 intention-to-treat (ITT) population consisted of all patients who had a baseline MRI assessment. If patients dropped out prior to the scheduled observation period, every effort should have been taken to get a final MRI scan which could then be used for the ITT analysis.

Reporting Groups

	Description
Valsartan and Amlodipine	Participants received 160 mg Valsartan and 5 mg amlodipine orally once a day for 52 weeks. If blood pressure was not normalized at week 4, treatment was uptitrated to valsartan/amlodipine 160/10 mg. Participants with still uncontrolled hypertension could receive add-on antihypertensive medication.
Losartan and HCTZ	Participants received 100 mg losartan and 12.5 mg Hydrochlorothiazide (HCT) orally once a day for 52 weeks. If blood pressure was not normalized at week 4, treatment was uptitrated to losartan/HCT 100/25 mg, respectively, until end of study. Participants with still uncontrolled hypertension could receive add-on antihypertensive medication.

Measured Values

	Valsartan and Amlodipine	**Losartan and HCTZ**
Number of Participants Analyzed [units: participants]	**43**	**47**
Change From Baseline in Left Ventricular Mass Index (LVMI) Measured Via Magnetic Resonance Imaging (MRI) [units: g/m^2] Mean (Standard Deviation)	**-7.1 (16.50)**	**-9.1 (18.89)**

No statistical analysis provided for Change From Baseline in Left Ventricular Mass Index (LVMI) Measured Via Magnetic Resonance Imaging (MRI)

2. Secondary: Change From Baseline to the End of Study in Left Ventricular Mass Index (LVMI) Normalized to Body Surface Area Assessed by MRI [Time Frame: Baseline to week 52]

Measure Type	Secondary
Measure Title	Change From Baseline to the End of Study in Left Ventricular Mass Index (LVMI) Normalized to Body Surface Area Assessed by MRI
Measure Description	No text entered.
Time Frame	Baseline to week 52
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 intention-to-treat (ITT) population consisted of all patients from the safety population who had a baseline MRI assessment. If patients dropped out prior to the scheduled observation period, every effort should have been taken to get a final MRI scan which could then be used for the ITT analysis.

Reporting Groups

	Description
Valsartan and Amlodipine	Participants received 160 mg Valsartan and 5 mg amlodipine orally once a day for 52 weeks. If blood pressure was not normalized at week 4, treatment was uptitrated to valsartan/amlodipine 160/10 mg. Participants with still uncontrolled hypertension could receive add-on antihypertensive medication.
Losartan and HCTZ	Participants received 100 mg losartan and 12.5 mg Hydrochlorothiazide (HCT) orally once a day for 52 weeks. If blood pressure was not normalized at week 4, treatment was uptitrated to losartan/HCT 100/25 mg, respectively, until end of study. Participants with still uncontrolled hypertension could receive add-on antihypertensive medication.

Measured Values

	Valsartan and Amlodipine	Losartan and HCTZ
Number of Participants Analyzed [units: participants]	**43**	**47**
Change From Baseline to the End of Study in Left Ventricular Mass Index (LVMI) Normalized to Body Surface Area Assessed by MRI [units: g/m^2] Mean (Standard Deviation)	**-3.5 (7.4)**	**-4.4 (9.3)**

No statistical analysis provided for Change From Baseline to the End of Study in Left Ventricular Mass Index (LVMI) Normalized to Body Surface Area Assessed by MRI

3. Secondary: Change From Baseline to the End of Study in Interventricular Septum Thickness (IVS) Assessed by MRI [Time Frame: Baseline to week 52]

Measure Type	Secondary
Measure Title	Change From Baseline to the End of Study in Interventricular Septum Thickness (IVS) Assessed by MRI
Measure Description	No text entered.
Time Frame	Baseline to week 52
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 intention-to-treat (ITT) population consisted of all patients from the safety population who had a baseline MRI assessment. If patients dropped out prior to the scheduled observation period, every effort should have been taken to get a final MRI scan which could then be used for the ITT analysis.

Reporting Groups

	Description
Valsartan and Amlodipine	Participants received 160 mg Valsartan and 5 mg amlodipine orally once a day for 52 weeks. If blood pressure was not normalized at week 4, treatment was uptitrated to valsartan/amlodipine 160/10 mg. Participants with still uncontrolled hypertension could receive add-on antihypertensive medication.
Losartan and HCTZ	Participants received 100 mg losartan and 12.5 mg Hydrochlorothiazide (HCT) orally once a day for 52 weeks. If blood pressure was not normalized at week 4, treatment was uptitrated to losartan/HCT 100/25 mg, respectively, until end of study. Participants with still uncontrolled hypertension could receive add-on antihypertensive medication.

Measured Values

	Valsartan and Amlodipine	Losartan and HCTZ
Number of Participants Analyzed [units: participants]	**43**	**47**
Change From Baseline to the End of Study in Interventricular Septum Thickness (IVS) Assessed by MRI [units: mm] Mean (Standard Deviation)	**-1.1 (1.5)**	**-0.6 (1.3)**

No statistical analysis provided for Change From Baseline to the End of Study in Interventricular Septum Thickness (IVS) Assessed by MRI

4. Secondary: Change From Baseline to the End of Study in Posterior Wall Thickness Assessed by MRI [Time Frame: Baseline to week 52]

Measure Type	Secondary
Measure Title	Change From Baseline to the End of Study in Posterior Wall Thickness Assessed by MRI
Measure Description	No text entered.
Time Frame	Baseline to week 52
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 intention-to-treat (ITT) population consisted of all patients from the safety population who had a baseline MRI assessment. If patients dropped out prior to the scheduled observation period, every effort should have been taken to get a final MRI scan which could then be used for the ITT analysis.

Reporting Groups

	Description
Valsartan and Amlodipine	Participants received 160 mg Valsartan and 5 mg amlodipine orally once a day for 52 weeks. If blood pressure was not normalized at week 4, treatment was uptitrated to valsartan/amlodipine 160/10 mg. Participants with still uncontrolled hypertension could receive add-on antihypertensive medication.
Losartan and HCTZ	Participants received 100 mg losartan and 12.5 mg Hydrochlorothiazide (HCT) orally once a day for 52 weeks. If blood pressure was not normalized at week 4, treatment was uptitrated to losartan/HCT 100/25 mg, respectively, until end of study. Participants with still uncontrolled hypertension could receive add-on antihypertensive medication.

Measured Values

	Valsartan and Amlodipine	Losartan and HCTZ
Number of Participants Analyzed [units: participants]	**43**	**47**
Change From Baseline to the End of Study in Posterior Wall Thickness Assessed by MRI [units: mm] Mean (Standard Deviation)	**-0.4 (1.1)**	**-0.3 (1.2)**

No statistical analysis provided for Change From Baseline to the End of Study in Posterior Wall Thickness Assessed by MRI

5. Secondary: Change From Baseline to the End of Study in Left Ventricular Ejection Fraction (LVEF) Assessed by MRI [Time Frame: Baseline to week 52]

Measure Type	Secondary
Measure Title	Change From Baseline to the End of Study in Left Ventricular Ejection Fraction (LVEF) Assessed by MRI
Measure Description	Ejection fraction is a measurement of the percentage of blood that is pumped out of a filled ventricle with each heartbeat.
Time Frame	Baseline to week 52
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 intention-to-treat (ITT) population consisted of all patients from the safety population who had a baseline MRI assessment. If patients dropped out prior to the scheduled observation period, every effort should have been taken to get a final MRI scan which could then be used for the ITT analysis.

Reporting Groups

	Description
Valsartan and Amlodipine	Participants received 160 mg Valsartan and 5 mg amlodipine orally once a day for 52 weeks. If blood pressure was not normalized at week 4, treatment was uptitrated to valsartan/amlodipine 160/10 mg. Participants with still uncontrolled hypertension could receive add-on antihypertensive medication.
Losartan and HCTZ	Participants received 100 mg losartan and 12.5 mg Hydrochlorothiazide (HCT) orally once a day for 52 weeks. If blood pressure was not normalized at week 4, treatment was uptitrated to losartan/HCT 100/25 mg, respectively, until end of study. Participants with still uncontrolled hypertension could receive add-on antihypertensive medication.

Measured Values

	Valsartan and Amlodipine	**Losartan and HCTZ**
Number of Participants Analyzed [units: participants]	**43**	**47**
Change From Baseline to the End of Study in Left Ventricular Ejection Fraction (LVEF) Assessed by MRI [units: Percentage] Mean (Standard Deviation)	**-0.8 (6.7)**	**-0.4 (5.9)**

No statistical analysis provided for Change From Baseline to the End of Study in Left Ventricular Ejection Fraction (LVEF) Assessed by MRI

6. Secondary: Change From Baseline to the End of Study in Left Ventricular End-diastolic Volume (LVEDV) Assessed by MRI [Time Frame: Baseline to week 52]

Measure Type	Secondary
Measure Title	Change From Baseline to the End of Study in Left Ventricular End-diastolic Volume (LVEDV) Assessed by MRI
Measure Description	No text entered.
Time Frame	Baseline to week 52
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 intention-to-treat (ITT) population consisted of all patients from the safety population who had a baseline MRI assessment. If patients dropped out prior to the scheduled observation period, every effort should have been taken to get a final MRI scan which could then be used for the ITT analysis.

Reporting Groups

	Description
Valsartan and Amlodipine	Participants received 160 mg Valsartan and 5 mg amlodipine orally once a day for 52 weeks. If blood pressure was not normalized at week 4, treatment was uptitrated to valsartan/amlodipine 160/10 mg. Participants with still uncontrolled hypertension could receive add-on antihypertensive medication.
Losartan and HCTZ	Participants received 100 mg losartan and 12.5 mg Hydrochlorothiazide (HCT) orally once a day for 52 weeks. If blood pressure was not normalized at week 4, treatment was uptitrated to losartan/HCT 100/25 mg, respectively, until end of study. Participants with still uncontrolled hypertension could receive add-on antihypertensive medication.

Measured Values

	Valsartan and Amlodipine	**Losartan and HCTZ**
Number of Participants Analyzed [units: participants]	**43**	**47**
Change From Baseline to the End of Study in Left Ventricular End-diastolic Volume (LVEDV) Assessed by MRI [units: ml] Mean (Standard Deviation)	**0.1 (19.9)**	**-6.4 (22.9)**

No statistical analysis provided for Change From Baseline to the End of Study in Left Ventricular End-diastolic Volume (LVEDV) Assessed by MRI

7. Secondary: Change From Baseline to the End of Study in Left Ventricular End-diastolic Volume (LVEDV) Normalized to Body Surface Area Assessed by MRI [Time Frame: Baseline to week 52]

Measure Type	Secondary
Measure Title	Change From Baseline to the End of Study in Left Ventricular End-diastolic Volume (LVEDV) Normalized to Body Surface Area Assessed by MRI
Measure Description	No text entered.
Time Frame	Baseline to week 52
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 intention-to-treat (ITT) population consisted of all patients from the safety population who had a baseline MRI assessment. If patients dropped out prior to the scheduled observation period, every effort should have been taken to get a final MRI scan which could then be used for the ITT analysis.

Reporting Groups

	Description
Valsartan and Amlodipine	Participants received 160 mg Valsartan and 5 mg amlodipine orally once a day for 52 weeks. If blood pressure was not normalized at week 4, treatment was uptitrated to valsartan/amlodipine 160/10 mg. Participants with still uncontrolled hypertension could receive add-on antihypertensive medication.
Losartan and HCTZ	Participants received 100 mg losartan and 12.5 mg Hydrochlorothiazide (HCT) orally once a day for 52 weeks. If blood pressure was not normalized at week 4, treatment was uptitrated to losartan/HCT 100/25 mg, respectively,

	until end of study. Participants with still uncontrolled hypertension could receive add-on antihypertensive medication.

Measured Values

	Valsartan and Amlodipine	Losartan and HCTZ
Number of Participants Analyzed [units: participants]	**43**	**47**
Change From Baseline to the End of Study in Left Ventricular End-diastolic Volume (LVEDV) Normalized to Body Surface Area Assessed by MRI [units: ml] Mean (Standard Deviation)	**0.0 (9.6)**	**-3.0 (11.2)**

No statistical analysis provided for Change From Baseline to the End of Study in Left Ventricular End-diastolic Volume (LVEDV) Normalized to Body Surface Area Assessed by MRI

8. Secondary: Change From Baseline to the End of Study in Left Ventricular End-Systolic Volume (LVESV) Assessed by MRI [Time Frame: Baseline to week 52]

Measure Type	Secondary
Measure Title	Change From Baseline to the End of Study in Left Ventricular End-Systolic Volume (LVESV) Assessed by MRI
Measure Description	No text entered.
Time Frame	Baseline to week 52
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 intention-to-treat (ITT) population consisted of all patients from the safety population who had a baseline MRI assessment. If patients dropped out prior to the scheduled observation period, every effort should have been taken to get a final MRI scan which could then be used for the ITT analysis.

Reporting Groups

	Description
Valsartan and Amlodipine	Participants received 160 mg Valsartan and 5 mg amlodipine orally once a day for 52 weeks. If blood pressure was not normalized at week 4, treatment was uptitrated to valsartan/amlodipine 160/10 mg. Participants with still uncontrolled hypertension could receive add-on antihypertensive medication.
Losartan and HCTZ	Participants received 100 mg losartan and 12.5 mg Hydrochlorothiazide (HCT) orally once a day for 52 weeks. If blood pressure was not normalized at week 4, treatment was uptitrated to losartan/HCT 100/25 mg, respectively, until end of study. Participants with still uncontrolled hypertension could receive add-on antihypertensive medication.

Measured Values

	Valsartan and Amlodipine	Losartan and HCTZ
Number of Participants Analyzed [units: participants]	**43**	**47**
Change From Baseline to the End of Study in Left Ventricular End-Systolic Volume (LVESV) Assessed by MRI [units: ml] Mean (Standard Deviation)	**0.4 (10.3)**	**-1.5 (10.3)**

No statistical analysis provided for Change From Baseline to the End of Study in Left Ventricular End-Systolic Volume (LVESV) Assessed by MRI

9. Secondary: Change From Baseline to the End of Study in Left Ventricular End-Systolic Volume (LVESV) Normalized to Body Surface Area Assessed by MRI [Time Frame: Baseline to week 52]

Measure Type	Secondary
Measure Title	Change From Baseline to the End of Study in Left Ventricular End-Systolic Volume (LVESV) Normalized to Body Surface Area Assessed by MRI
Measure Description	No text entered.
Time Frame	Baseline to week 52
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 intention-to-treat (ITT) population consisted of all patients from the safety population who had a baseline MRI assessment. If patients dropped out prior to the scheduled observation period, every effort should have been taken to get a final MRI scan which could then be used for the ITT analysis.

Reporting Groups

	Description
Valsartan and Amlodipine	Participants received 160 mg Valsartan and 5 mg amlodipine orally once a day for 52 weeks. If blood pressure was not normalized at week 4, treatment was uptitrated to valsartan/amlodipine 160/10 mg. Participants with still uncontrolled hypertension could receive add-on antihypertensive medication.
Losartan and HCTZ	Participants received 100 mg losartan and 12.5 mg Hydrochlorothiazide (HCT) orally once a day for 52 weeks. If blood pressure was not normalized at week 4, treatment was uptitrated to losartan/HCT 100/25 mg, respectively, until end of study. Participants with still uncontrolled hypertension could receive add-on antihypertensive medication.

Measured Values

	Valsartan and Amlodipine	**Losartan and HCTZ**
Number of Participants Analyzed [units: participants]	**43**	**47**
Change From Baseline to the End of Study in Left Ventricular End-Systolic Volume (LVESV) Normalized to Body Surface Area Assessed by MRI [units: ml] Mean (Standard Deviation)	**0.2 (5.1)**	**-0.8 (5.1)**

No statistical analysis provided for Change From Baseline to the End of Study in Left Ventricular End-Systolic Volume (LVESV) Normalized to Body Surface Area Assessed by MRI

10. Secondary: Change From Baseline to the End of Study in Left Atrial (LA) Area Assessed by MRI [Time Frame: Baseline to week 52]

Measure Type	Secondary
Measure Title	Change From Baseline to the End of Study in Left Atrial (LA) Area Assessed by MRI
Measure Description	No text entered.
Time Frame	Baseline to week 52

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 intention-to-treat (ITT) population consisted of all patients from the safety population who had a baseline MRI assessment. If patients dropped out prior to the scheduled observation period, every effort should have been taken to get a final MRI scan which could then be used for the ITT analysis.

Reporting Groups

	Description
Valsartan and Amlodipine	Participants received 160 mg Valsartan and 5 mg amlodipine orally once a day for 52 weeks. If blood pressure was not normalized at week 4, treatment was uptitrated to valsartan/amlodipine 160/10 mg. Participants with still uncontrolled hypertension could receive add-on antihypertensive medication.
Losartan and HCTZ	Participants received 100 mg losartan and 12.5 mg Hydrochlorothiazide (HCT) orally once a day for 52 weeks. If blood pressure was not normalized at week 4, treatment was uptitrated to losartan/HCT 100/25 mg, respectively, until end of study. Participants with still uncontrolled hypertension could receive add-on antihypertensive medication.

Measured Values

	Valsartan and Amlodipine	**Losartan and HCTZ**
Number of Participants Analyzed [units: participants]	**43**	**47**
Change From Baseline to the End of Study in Left Atrial (LA) Area Assessed by MRI [units: cm^2] Mean (Standard Deviation)	**-0.6 (3.2)**	**-1.0 (4.5)**

No statistical analysis provided for Change From Baseline to the End of Study in Left Atrial (LA) Area Assessed by MRI

11. Secondary: Change From Baseline to the End of Study in the Ascending Aortic Diameter Assessed by MRI [Time Frame: Baseline to week 52]

Measure Type	Secondary
Measure Title	Change From Baseline to the End of Study in the Ascending Aortic Diameter Assessed by MRI
Measure Description	No text entered.
Time Frame	Baseline to week 52
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 intention-to-treat (ITT) population consisted of all patients from the safety population who had a baseline MRI assessment. If patients dropped out prior to the scheduled observation period, every effort should have been taken to get a final MRI scan which could then be used for the ITT analysis.

Reporting Groups

	Description
Valsartan and Amlodipine	Participants received 160 mg Valsartan and 5 mg amlodipine orally once a day for 52 weeks. If blood pressure was not normalized at week 4, treatment was uptitrated to valsartan/amlodipine 160/10 mg. Participants with still uncontrolled hypertension could receive add-on antihypertensive medication.

Losartan and HCTZ	Participants received 100 mg losartan and 12.5 mg Hydrochlorothiazide (HCT) orally once a day for 52 weeks. If blood pressure was not normalized at week 4, treatment was uptitrated to losartan/HCT 100/25 mg, respectively, until end of study. Participants with still uncontrolled hypertension could receive add-on antihypertensive medication.

Measured Values

	Valsartan and Amlodipine	Losartan and HCTZ
Number of Participants Analyzed [units: participants]	**43**	**47**
Change From Baseline to the End of Study in the Ascending Aortic Diameter Assessed by MRI [units: mm] Mean (Standard Deviation)	**0.1 (1.9)**	**-0.8 (1.6)**

No statistical analysis provided for Change From Baseline to the End of Study in the Ascending Aortic Diameter Assessed by MRI

12. Secondary: Change From Baseline to End of Study in Levels of N-terminal Pro-B Type Natriuretic Peptide (NT-proBNP) [Time Frame: Baseline to week 52]

Measure Type	Secondary
Measure Title	Change From Baseline to End of Study in Levels of N-terminal Pro-B Type Natriuretic Peptide (NT-proBNP)
Measure Description	No text entered.
Time Frame	Baseline to week 52
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 safety population consisted of the sample of all randomized patients who applied study medication at least once.

Reporting Groups

	Description
Valsartan and Amlodipine	Participants received 160 mg Valsartan and 5 mg amlodipine orally once a day for 52 weeks. If blood pressure was not normalized at week 4, treatment was uptitrated to valsartan/amlodipine 160/10 mg. Participants with still uncontrolled hypertension could receive add-on antihypertensive medication.
Losartan and HCTZ	Participants received 100 mg losartan and 12.5 mg Hydrochlorothiazide (HCT) orally once a day for 52 weeks. If blood pressure was not normalized at week 4, treatment was uptitrated to losartan/HCT 100/25 mg, respectively, until end of study. Participants with still uncontrolled hypertension could receive add-on antihypertensive medication.

Measured Values

	Valsartan and Amlodipine	Losartan and HCTZ
Number of Participants Analyzed [units: participants]	**43**	**47**
Change From Baseline to End of Study in Levels of N-terminal Pro-B Type Natriuretic Peptide (NT-proBNP) [units: pg/ml] Mean (Standard Deviation)	**-4.5 (56.41)**	**-40.1 (74.09)**

No statistical analysis provided for Change From Baseline to End of Study in Levels of N-terminal Pro-B Type Natriuretic Peptide (NT-proBNP)

13. Secondary: Change From Baseline to End of Study in Levels of High-sensitivity C-reactive Protein (Hs-CRP) [Time Frame: Baseline to week 52]

Measure Type	Secondary
Measure Title	Change From Baseline to End of Study in Levels of High-sensitivity C-reactive Protein (Hs-CRP)
Measure Description	No text entered.
Time Frame	Baseline to week 52
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 safety population consisted of the sample of all randomized patients who applied study medication at least once.

Reporting Groups

	Description
Valsartan and Amlodipine	Participants received 160 mg Valsartan and 5 mg amlodipine orally once a day for 52 weeks. If blood pressure was not normalized at week 4, treatment was uptitrated to valsartan/amlodipine 160/10 mg. Participants with still uncontrolled hypertension could receive add-on antihypertensive medication.
Losartan and HCTZ	Participants received 100 mg losartan and 12.5 mg Hydrochlorothiazide (HCT) orally once a day for 52 weeks. If blood pressure was not normalized at week 4, treatment was uptitrated to losartan/HCT 100/25 mg, respectively, until end of study. Participants with still uncontrolled hypertension could receive add-on antihypertensive medication.

Measured Values

	Valsartan and Amlodipine	**Losartan and HCTZ**
Number of Participants Analyzed [units: participants]	**43**	**47**
Change From Baseline to End of Study in Levels of High-sensitivity C-reactive Protein (Hs-CRP) [units: mg/l] Mean (Standard Deviation)	**0.8 (6.09)**	**-2.1 (9.90)**

No statistical analysis provided for Change From Baseline to End of Study in Levels of High-sensitivity C-reactive Protein (Hs-CRP)

14. Secondary: Percentage of Participants Achieving Target Blood Pressure at Week 52 [Time Frame: Week 52]

Measure Type	Secondary
Measure Title	Percentage of Participants Achieving Target Blood Pressure at Week 52
Measure Description	Target blood pressure defined as having a mean sitting systolic blood pressure (MSSBP) < 140 mm Hg and a mean sitting diastolic blood pressure (MSDBP) < 90 mm Hg.
Time Frame	Week 52
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 intention-to-treat (ITT) population consisted of all patients from the safety population who had a baseline MRI assessment. If patients dropped out prior to the scheduled observation period, every effort should have been taken to get a final MRI scan which could then be used for the ITT analysis.

Reporting Groups

	Description
Valsartan and Amlodipine	Participants received 160 mg Valsartan and 5 mg amlodipine orally once a day for 52 weeks. If blood pressure was not normalized at week 4, treatment was uptitrated to valsartan/amlodipine 160/10 mg. Participants with still uncontrolled hypertension could receive add-on antihypertensive medication.
Losartan and HCTZ	Participants received 100 mg losartan and 12.5 mg Hydrochlorothiazide (HCT) orally once a day for 52 weeks. If blood pressure was not normalized at week 4, treatment was uptitrated to losartan/HCT 100/25 mg, respectively, until end of study. Participants with still uncontrolled hypertension could receive add-on antihypertensive medication.

Measured Values

	Valsartan and Amlodipine	**Losartan and HCTZ**
Number of Participants Analyzed [units: participants]	**43**	**47**
Percentage of Participants Achieving Target Blood Pressure at Week 52 [units: Percentage of participants]	**53.5**	**14.9**

No statistical analysis provided for Percentage of Participants Achieving Target Blood Pressure at Week 52

15. Secondary: Percentage of Participants Who Experienced Adverse Events (AEs) [Time Frame: Baseline to week 52]

Measure Type	Secondary
Measure Title	Percentage of Participants Who Experienced Adverse Events (AEs)
Measure Description	An adverse event was the appearance or worsening of any undesirable sign, symptom, or medical condition occurring after obtaining informed consent even if the event was not considered to be related to study drug. Medical conditions/diseases present before obtaining informed consent were only considered adverse events if they worsened after study start. Abnormal laboratory values or test results constituted adverse events only if they induced clinical signs or symptoms, required study drug discontinuation or required therapy.
Time Frame	Baseline to week 52
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.
The safety population consisted of the sample of all randomized patients who applied study medication at least once.

Reporting Groups

	Description
Valsartan and Amlodipine	Participants received 160 mg Valsartan and 5 mg amlodipine orally once a day for 52 weeks. If blood pressure was not normalized at week 4, treatment was uptitrated to valsartan/amlodipine 160/10 mg. Participants with still uncontrolled hypertension could receive add-on antihypertensive medication.
Losartan and HCTZ	Participants received 100 mg losartan and 12.5 mg Hydrochlorothiazide (HCT) orally once a day for 52 weeks. If blood pressure was not normalized at week 4, treatment was uptitrated to losartan/HCT 100/25 mg, respectively, until end of study. Participants with still uncontrolled hypertension could receive add-on antihypertensive medication.

Measured Values

	Valsartan and Amlodipine	Losartan and HCTZ
Number of Participants Analyzed [units: participants]	**43**	**47**
Percentage of Participants Who Experienced Adverse Events (AEs) [units: Percentage of participants]	**69.8**	**68.1**

No statistical analysis provided for Percentage of Participants Who Experienced Adverse Events (AEs)

Serious Adverse Events

Hide Serious Adverse Events

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

Reporting Groups

	Description
Valsartan and Amlodipine	Participants received 160 mg Valsartan and 5 mg amlodipine orally once a day for 52 weeks. If blood pressure was not normalized at week 4, treatment was uptitrated to valsartan/amlodipine 160/10 mg. Participants with still uncontrolled hypertension could receive add-on antihypertensive medication.
Losartan and HCTZ	Participants received 100 mg losartan and 12.5 mg Hydrochlorothiazide (HCT) orally once a day for 52 weeks. If blood pressure was not normalized at week 4, treatment was uptitrated to losartan/HCT 100/25 mg, respectively, until end of study. Participants with still uncontrolled hypertension could receive add-on antihypertensive medication.

Serious Adverse Events

	Valsartan and Amlodipine	Losartan and HCTZ
Total, serious adverse events		
# participants affected / at risk	**2/43 (4.65%)**	**6/47 (12.77%)**
Cardiac disorders		
BRADYCARDIA † 1		
# participants affected / at risk	**0/43 (0.00%)**	**1/47 (2.13%)**
CORONARY ARTERY DISEASE † 1		
# participants affected / at risk	**1/43 (2.33%)**	**0/47 (0.00%)**
MYOCARDIAL INFARCTION † 1		
# participants affected / at risk	**1/43 (2.33%)**	**0/47 (0.00%)**
TACHYCARDIA † 1		
# participants affected / at risk	**0/43 (0.00%)**	**1/47 (2.13%)**
Congenital, familial and genetic disorders		
HYDROCELE † 1		
# participants affected / at risk	**1/43 (2.33%)**	**0/47 (0.00%)**
Gastrointestinal disorders		
ABDOMINAL PAIN † 1		
# participants affected / at risk	**0/43 (0.00%)**	**1/47 (2.13%)**
ANAL HAEMORRHAGE † 1		
# participants affected / at risk	**0/43 (0.00%)**	**1/47 (2.13%)**

DIARRHOEA † 1		
# participants affected / at risk	**0/43 (0.00%)**	**1/47 (2.13%)**
Hepatobiliary disorders		
CHOLECYSTITIS † 1		
# participants affected / at risk	**1/43 (2.33%)**	**0/47 (0.00%)**
Infections and infestations		
ERYSIPELAS † 1		
# participants affected / at risk	**0/43 (0.00%)**	**1/47 (2.13%)**
VESTIBULAR NEURONITIS † 1		
# participants affected / at risk	**0/43 (0.00%)**	**1/47 (2.13%)**
Metabolism and nutrition disorders		
HYPERTRIGLYCERIDAEMIA † 1		
# participants affected / at risk	**0/43 (0.00%)**	**1/47 (2.13%)**
HYPOKALAEMIA † 1		
# participants affected / at risk	**0/43 (0.00%)**	**1/47 (2.13%)**
Musculoskeletal and connective tissue disorders		
OSTEOARTHRITIS † 1		
# participants affected / at risk	**0/43 (0.00%)**	**1/47 (2.13%)**
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		
COLON CANCER † 1		
# participants affected / at risk	**0/43 (0.00%)**	**1/47 (2.13%)**
METASTATIC NEOPLASM † 1		
# participants affected / at risk	**1/43 (2.33%)**	**0/47 (0.00%)**
Nervous system disorders		
THALAMIC INFARCTION † 1		
# participants affected / at risk	**0/43 (0.00%)**	**1/47 (2.13%)**

† 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 and Amlodipine	Participants received 160 mg Valsartan and 5 mg amlodipine orally once a day for 52 weeks. If blood pressure was not normalized at week 4, treatment was uptitrated to valsartan/amlodipine 160/10 mg. Participants with still uncontrolled hypertension could receive add-on antihypertensive medication.
Losartan and HCTZ	Participants received 100 mg losartan and 12.5 mg Hydrochlorothiazide (HCT) orally once a day for 52 weeks. If

	blood pressure was not normalized at week 4, treatment was uptitrated to losartan/HCT 100/25 mg, respectively, until end of study. Participants with still uncontrolled hypertension could receive add-on antihypertensive medication.

Other Adverse Events

	Valsartan and Amlodipine	Losartan and HCTZ
Total, other (not including serious) adverse events		
# participants affected / at risk	**15/43 (34.88%)**	**16/47 (34.04%)**
Gastrointestinal disorders		
DIARRHOEA † 1		
# participants affected / at risk	**1/43 (2.33%)**	**4/47 (8.51%)**
NAUSEA † 1		
# participants affected / at risk	**1/43 (2.33%)**	**3/47 (6.38%)**
General disorders		
OEDEMA PERIPHERAL † 1		
# participants affected / at risk	**4/43 (9.30%)**	**0/47 (0.00%)**
Infections and infestations		
BRONCHITIS † 1		
# participants affected / at risk	**3/43 (6.98%)**	**0/47 (0.00%)**
NASOPHARYNGITIS † 1		
# participants affected / at risk	**3/43 (6.98%)**	**7/47 (14.89%)**
Musculoskeletal and connective tissue disorders		
BACK PAIN † 1		
# participants affected / at risk	**5/43 (11.63%)**	**2/47 (4.26%)**
Nervous system disorders		
HEADACHE † 1		
# participants affected / at risk	**0/43 (0.00%)**	**3/47 (6.38%)**
Skin and subcutaneous tissue disorders		
ECZEMA † 1		
# participants affected / at risk	**2/43 (4.65%)**	**3/47 (6.38%)**

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

Limitations and Caveats

Hide Limitations and Caveats

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

More Information

Hide More Information

Certain Agreements:

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

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

The agreement is:

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

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

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

☑ **Restriction Description:** The terms and conditions of Novartis' agreements with its investigators may vary. However, Novartis does not prohibit any investigator from publishing. Any publications from a single-site are postponed until the publication of the pooled data (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:	NCT00446563 History of Changes
Other Study ID Numbers:	**CVAA489ADE02**
Study First Received:	March 12, 2007
Results First Received:	March 31, 2011
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Health Authority:	Germany: Federal Institute for Drugs and Medical Devices