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Trial record **1 of 1** for: CVAA489AFR01

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Efficacy of a Combination of Amlodipine/Valsartan on 24H Blood Pressure Control With One Nocturnal or Diurnal Intake a Day

This study has been completed.

Sponsor:
Novartis Pharmaceuticals

Information provided by:
Novartis

ClinicalTrials.gov Identifier:
NCT00700271

First received: December 11, 2007
Last updated: May 16, 2011
Last verified: May 2011
History of Changes

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Results First Received: December 15, 2010

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Efficacy Study; Intervention Model: Parallel Assignment; Masking: Open Label; Primary Purpose: Treatment
Condition:	Hypertension
Interventions:	Drug: Amlodipine Drug: Valsartan

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
Eligible patients entered a 4-week open-label amlodipine screening phase with amlodipine 5 mg taken orally once a day. At the end of the screening phase, patients whose blood pressure was not adequately controlled (defined as SBP/DBP >= 125/80 mmHg 24-hr mean) on ambulatory blood pressure monitoring were randomized to one of two treatment groups.

Reporting Groups

	Description
Morning Intake	After randomization, participants received a single daily oral dose of 5 mg amlodipine and 160 mg valsartan free combination therapy, taken in the morning between 6-10 am. At week 4, uncontrolled patients (msSBP >= 140 mmHg and/or msDBP >= 90 mmHg or msSBP >= 130 mmHg and/or msDBP >= 80 mmHg in the case of diabetes or renal insufficiency measured by using conventional methods) received amlodipine/valsartan 10/160 mg for 4 additional weeks. Patients who were controlled at Week 4 (msSBP < 140 mmHg and msDBP < 90 mmHg or msSBP < 130 mmHg and msDBP < 80 mmHg in the case of diabetes or renal insufficiency) continued their amlodipine/valsartan 5/160 mg treatment for the remaining 4 weeks of the study.
Evening Intake	After randomization participants received a single daily oral dose of 5 mg amlodipine and 160 mg valsartan free

	combination therapy, taken in the evening between 6-10 pm. At week 4, uncontrolled patients (msSBP >= 140 mmHg and/or msDBP >= 90 mmHg or msSBP >= 130 mmHg and/or msDBP >= 80 mmHg in the case of diabetes or renal insufficiency measured by using conventional methods) received amlodipine/valsartan 10/160 mg for 4 additional weeks. Patients who were controlled at Week 4 (msSBP < 140 mmHg and msDBP < 90 mmHg or msSBP < 130 mmHg and msDBP < 80 mmHg in the case of diabetes or renal insufficiency) continued their amlodipine/valsartan 5/160 mg treatment for the remaining 4 weeks of the study.

Participant Flow: Overall Study

	Morning Intake	Evening Intake
STARTED	278	268
COMPLETED	264	256
NOT COMPLETED	14	12
Adverse Event	4	6
Protocol Violation	1	0
Administrative Reasons	1	0
Withdrawal by Subject	6	4
Lost to Follow-up	2	2

Baseline Characteristics

Hide Baseline Characteristics

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
No text entered.

Reporting Groups

	Description
Morning Intake	After randomization, participants received a single daily oral dose of 5 mg amlodipine and 160 mg valsartan free combination therapy, taken in the morning between 6-10 am. At week 4, uncontrolled patients (msSBP >= 140 mmHg and/or msDBP >= 90 mmHg or msSBP >= 130 mmHg and/or msDBP >= 80 mmHg in the case of diabetes or renal insufficiency measured by using conventional methods) received amlodipine/valsartan 10/160 mg for 4 additional weeks. Patients who were controlled at Week 4 (msSBP < 140 mmHg and msDBP < 90 mmHg or msSBP < 130 mmHg and msDBP < 80 mmHg in the case of diabetes or renal insufficiency) continued their amlodipine/valsartan 5/160 mg treatment for the remaining 4 weeks of the study.
Evening Intake	After randomization participants received a single daily oral dose of 5 mg amlodipine and 160 mg valsartan free combination therapy, taken in the evening between 6-10 pm. At week 4, uncontrolled patients (msSBP >= 140 mmHg and/or msDBP >= 90 mmHg or msSBP >= 130 mmHg and/or msDBP >= 80 mmHg in the case of diabetes or renal insufficiency measured by using conventional methods) received amlodipine/valsartan 10/160 mg for 4 additional weeks. Patients who were controlled at Week 4 (msSBP < 140 mmHg and msDBP < 90 mmHg or msSBP < 130 mmHg and msDBP < 80 mmHg in the case of diabetes or renal insufficiency) continued their amlodipine/valsartan 5/160 mg treatment for the remaining 4 weeks of the study.
Total	Total of all reporting groups

Baseline Measures

	Morning Intake	Evening Intake	Total
Number of Participants [units: participants]	242	237	479
Age [1] [units: years] Mean (Standard Deviation)	55.8 (9.89)	56.2 (9.59)	56.0 (9.74)

Gender [units: participants]			
Female	114	111	225
Male	128	126	254

[1] Demographic data is provided for the Intent-to-Treat population, which included all the patients randomized and treated in the study and for whom two ABPM evaluations were available.

Outcome Measures

Hide All Outcome Measures

1. Primary: Absolute Reduction From Baseline in 24-hour Mean Systolic Blood Pressure (SBP) on Ambulatory Blood Pressure Monitoring [Time Frame: Baseline (Week 0, after completion of screening period) and Week 8 (after 8 weeks of combination therapy)]

Measure Type	Primary
Measure Title	Absolute Reduction From Baseline in 24-hour Mean Systolic Blood Pressure (SBP) on Ambulatory Blood Pressure Monitoring
Measure Description	Ambulatory Blood Pressure Monitoring (ABPM) over a 30-hour period was carried out in all patients at two visits during the study, 72 hours before visit 2 (baseline) and visit 4 (week 8). ABPM for visit 2 was carried out prior to randomization and the first dose of the amlodipine/valsartan combination study therapy. ABPM for visit four began after 12 weeks of treatment and before the last office blood pressure was taken. Covariates included baseline level, country, up-titration + treatment*country and treatment*up-titration interactions in case statistically significant at a 0.10 level.
Time Frame	Baseline (Week 0, after completion of screening period) and Week 8 (after 8 weeks of combination therapy)
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 Intent-to-treat (ITT) population included all patients randomized and treated in the study and for whom two Ambulatory Blood Pressure Monitoring (ABPM) evaluations are available.

Reporting Groups

	Description
Morning Intake	After randomization, participants received a single daily oral dose of 5 mg amlodipine and 160 mg valsartan free combination therapy, taken in the morning between 6-10 am. At week 4, uncontrolled patients (msSBP >= 140 mmHg and/or msDBP >= 90 mmHg or msSBP >= 130 mmHg and/or msDBP >= 80 mmHg in the case of diabetes or renal insufficiency measured by using conventional methods) received amlodipine/valsartan 10/160 mg for 4 additional weeks. Patients who were controlled at Week 4 (msSBP < 140 mmHg and msDBP < 90 mmHg or msSBP < 130 mmHg and msDBP < 80 mmHg in the case of diabetes or renal insufficiency) continued their amlodipine/valsartan 5/160 mg treatment for the remaining 4 weeks of the study.
Evening Intake	After randomization participants received a single daily oral dose of 5 mg amlodipine and 160 mg valsartan free combination therapy, taken in the evening between 6-10 pm. At week 4, uncontrolled patients (msSBP >= 140 mmHg and/or msDBP >= 90 mmHg or msSBP >= 130 mmHg and/or msDBP >= 80 mmHg in the case of diabetes or renal insufficiency measured by using conventional methods) received amlodipine/valsartan 10/160 mg for 4 additional weeks. Patients who were controlled at Week 4 (msSBP < 140 mmHg and msDBP < 90 mmHg or msSBP < 130 mmHg and msDBP < 80 mmHg in the case of diabetes or renal insufficiency) continued their amlodipine/valsartan 5/160 mg treatment for the remaining 4 weeks of the study.

Measured Values

	Morning Intake	Evening Intake
Number of Participants Analyzed [units: participants]	242	237

Absolute Reduction From Baseline in 24-hour Mean Systolic Blood Pressure (SBP) on Ambulatory Blood Pressure Monitoring [units: mmHg] Least Squares Mean (Standard Error)	**-12.01 (0.70)**	**-11.3 (0.71)**

No statistical analysis provided for Absolute Reduction From Baseline in 24-hour Mean Systolic Blood Pressure (SBP) on Ambulatory Blood Pressure Monitoring

2. Secondary: Absolute Reduction From Baseline in Diurnal Mean Systolic Blood Pressure (SBP)/Diastolic Blood Pressure (DBP) on Ambulatory Blood Pressure Monitoring [Time Frame: Baseline (Week 0, after completion of screening period) and Week 8 (after 8 weeks of combination therapy)]

Measure Type	Secondary
Measure Title	Absolute Reduction From Baseline in Diurnal Mean Systolic Blood Pressure (SBP)/Diastolic Blood Pressure (DBP) on Ambulatory Blood Pressure Monitoring
Measure Description	Ambulatory Blood Pressure Monitoring (ABPM) over a 30-hour period was carried out in all patients at two visits during the study, 72 hours before visit 2 (baseline) and visit 4 (week 8). ABPM for visit 2 was carried out prior to randomization and the first dose of the amlodipine/valsartan combination study therapy. ABPM for visit four began after 12 weeks of treatment and before the last office blood pressure was taken. Covariates included baseline level, country, up-titration + treatment*country and treatment*up-titration interactions in case statistically significant at a 0.10 level.
Time Frame	Baseline (Week 0, after completion of screening period) and Week 8 (after 8 weeks of combination therapy)
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 Intent-to-treat (ITT) population included all patients randomized and treated in the study and for whom two Ambulatory Blood Pressure Monitoring (ABPM) evaluations are available.

Reporting Groups

	Description
Morning Intake	After randomization, participants received a single daily oral dose of 5 mg amlodipine and 160 mg valsartan free combination therapy, taken in the morning between 6-10 am. At week 4, uncontrolled patients (msSBP >= 140 mmHg and/or msDBP >= 90 mmHg or msSBP >= 130 mmHg and/or msDBP >= 80 mmHg in the case of diabetes or renal insufficiency measured by using conventional methods) received amlodipine/valsartan 10/160 mg for 4 additional weeks. Patients who were controlled at Week 4 (msSBP < 140 mmHg and msDBP < 90 mmHg or msSBP < 130 mmHg and msDBP < 80 mmHg in the case of diabetes or renal insufficiency) continued their amlodipine/valsartan 5/160 mg treatment for the remaining 4 weeks of the study.
Evening Intake	After randomization participants received a single daily oral dose of 5 mg amlodipine and 160 mg valsartan free combination therapy, taken in the evening between 6-10 pm. At week 4, uncontrolled patients (msSBP >= 140 mmHg and/or msDBP >= 90 mmHg or msSBP >= 130 mmHg and/or msDBP >= 80 mmHg in the case of diabetes or renal insufficiency measured by using conventional methods) received amlodipine/valsartan 10/160 mg for 4 additional weeks. Patients who were controlled at Week 4 (msSBP < 140 mmHg and msDBP < 90 mmHg or msSBP < 130 mmHg and msDBP < 80 mmHg in the case of diabetes or renal insufficiency) continued their amlodipine/valsartan 5/160 mg treatment for the remaining 4 weeks of the study.

Measured Values

	Morning Intake	**Evening Intake**
Number of Participants Analyzed [units: participants]	**242**	**237**
Absolute Reduction From Baseline in Diurnal Mean Systolic Blood Pressure (SBP)/Diastolic Blood Pressure (DBP) on Ambulatory Blood Pressure Monitoring		

[units: mmHg] Least Squares Mean (Standard Error)		
Systolic Blood Pressure (SBP)	-13.50 (0.78)	-11.99 (0.8)
Diastolic Blood Pressure (DBP)	-7.56 (0.49)	-7.11 (0.5)

No statistical analysis provided for Absolute Reduction From Baseline in Diurnal Mean Systolic Blood Pressure (SBP)/Diastolic Blood Pressure (DBP) on Ambulatory Blood Pressure Monitoring

3. Secondary: Absolute Reduction From Baseline in Nocturnal Mean Systolic Blood Pressure (SBP)/Diastolic Blood Pressure (DBP) on Ambulatory Blood Pressure Monitoring [Time Frame: Baseline (Week 0, after completion of screening period) and Week 8 (after 8 weeks of combination therapy)]

Measure Type	Secondary
Measure Title	Absolute Reduction From Baseline in Nocturnal Mean Systolic Blood Pressure (SBP)/Diastolic Blood Pressure (DBP) on Ambulatory Blood Pressure Monitoring
Measure Description	Ambulatory Blood Pressure Monitoring (ABPM) over a 30-hour period was carried out in all patients at two visits during the study, 72 hours before visit 2 (baseline) and visit 4 (week 8). ABPM for visit 2 was carried out prior to randomization and the first dose of the amlodipine/valsartan combination study therapy. ABPM for visit four began after 12 weeks of treatment and before the last office blood pressure was taken. Covariates included baseline level, country, up-titration + treatment*country and treatment*up-titration interactions in case statistically significant at a 0.10 level.
Time Frame	Baseline (Week 0, after completion of screening period) and Week 8 (after 8 weeks of combination therapy)
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 Intent-to-treat (ITT) population included all patients randomized and treated in the study and for whom two Ambulatory Blood Pressure Monitoring (ABPM) evaluations are available.

Reporting Groups

	Description
Morning Intake	After randomization, participants received a single daily oral dose of 5 mg amlodipine and 160 mg valsartan free combination therapy, taken in the morning between 6-10 am. At week 4, uncontrolled patients (msSBP >= 140 mmHg and/or msDBP >= 90 mmHg or msSBP >= 130 mmHg and/or msDBP >= 80 mmHg in the case of diabetes or renal insufficiency measured by using conventional methods) received amlodipine/valsartan 10/160 mg for 4 additional weeks. Patients who were controlled at Week 4 (msSBP < 140 mmHg and msDBP < 90 mmHg or msSBP < 130 mmHg and msDBP < 80 mmHg in the case of diabetes or renal insufficiency) continued their amlodipine/valsartan 5/160 mg treatment for the remaining 4 weeks of the study.
Evening Intake	After randomization participants received a single daily oral dose of 5 mg amlodipine and 160 mg valsartan free combination therapy, taken in the evening between 6-10 pm. At week 4, uncontrolled patients (msSBP >= 140 mmHg and/or msDBP >= 90 mmHg or msSBP >= 130 mmHg and/or msDBP >= 80 mmHg in the case of diabetes or renal insufficiency measured by using conventional methods) received amlodipine/valsartan 10/160 mg for 4 additional weeks. Patients who were controlled at Week 4 (msSBP < 140 mmHg and msDBP < 90 mmHg or msSBP < 130 mmHg and msDBP < 80 mmHg in the case of diabetes or renal insufficiency) continued their amlodipine/valsartan 5/160 mg treatment for the remaining 4 weeks of the study.

Measured Values

	Morning Intake	Evening Intake
Number of Participants Analyzed		

[units: participants]	**242**	**237**
Absolute Reduction From Baseline in Nocturnal Mean Systolic Blood Pressure (SBP)/Diastolic Blood Pressure (DBP) on Ambulatory Blood Pressure Monitoring [units: mmHg] Least Squares Mean (Standard Error)		
Systolic Blood Pressure (SBP)	**-9.68 (0.74)**	**-10.33 (0.76)**
Diastolic Blood Pressure (DBP)	**-5.01 (0.46)**	**-6.3 (0.47)**

No statistical analysis provided for Absolute Reduction From Baseline in Nocturnal Mean Systolic Blood Pressure (SBP)/Diastolic Blood Pressure (DBP) on Ambulatory Blood Pressure Monitoring

4. Secondary: Absolute Reduction From Baseline in 24-hour Mean Diastolic Blood Pressure (DBP) on Ambulatory Blood Pressure Monitoring [Time Frame: Baseline (Week 0, after completion of screening period) and Week 8 (after 8 weeks of combination therapy)]

Measure Type	Secondary
Measure Title	Absolute Reduction From Baseline in 24-hour Mean Diastolic Blood Pressure (DBP) on Ambulatory Blood Pressure Monitoring
Measure Description	Ambulatory Blood Pressure Monitoring (ABPM) over a 30-hour period was carried out in all patients at two visits during the study, 72 hours before visit 2 (baseline) and visit 4 (week 8). ABPM for visit 2 was carried out prior to randomization and the first dose of the amlodipine/valsartan combination study therapy. ABPM for visit four began after 12 weeks of treatment and before the last office blood pressure was taken. Covariates included baseline level, country, up-titration + treatment*country and treatment*up-titration interactions in case statistically significant at a 0.10 level.
Time Frame	Baseline (Week 0, after completion of screening period) and Week 8 (after 8 weeks of combination therapy)
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 Intent-to-treat (ITT) population included all patients randomized and treated in the study and for whom two Ambulatory Blood Pressure Monitoring (ABPM) evaluations are available.

Reporting Groups

	Description
Morning Intake	After randomization, participants received a single daily oral dose of 5 mg amlodipine and 160 mg valsartan free combination therapy, taken in the morning between 6-10 am. At week 4, uncontrolled patients (msSBP >= 140 mmHg and/or msDBP >= 90 mmHg or msSBP >= 130 mmHg and/or msDBP >= 80 mmHg in the case of diabetes or renal insufficiency measured by using conventional methods) received amlodipine/valsartan 10/160 mg for 4 additional weeks. Patients who were controlled at Week 4 (msSBP < 140 mmHg and msDBP < 90 mmHg or msSBP < 130 mmHg and msDBP < 80 mmHg in the case of diabetes or renal insufficiency) continued their amlodipine/valsartan 5/160 mg treatment for the remaining 4 weeks of the study.
Evening Intake	After randomization participants received a single daily oral dose of 5 mg amlodipine and 160 mg valsartan free combination therapy, taken in the evening between 6-10 pm. At week 4, uncontrolled patients (msSBP >= 140 mmHg and/or msDBP >= 90 mmHg or msSBP >= 130 mmHg and/or msDBP >= 80 mmHg in the case of diabetes or renal insufficiency measured by using conventional methods) received amlodipine/valsartan 10/160 mg for 4 additional weeks. Patients who were controlled at Week 4 (msSBP < 140 mmHg and msDBP < 90 mmHg or msSBP < 130 mmHg and msDBP < 80 mmHg in the case of diabetes or renal insufficiency) continued their amlodipine/valsartan 5/160 mg treatment for the remaining 4 weeks of the study.

Measured Values

	Morning	**Evening**

	Intake	Intake
Number of Participants Analyzed [units: participants]	**242**	**237**
Absolute Reduction From Baseline in 24-hour Mean Diastolic Blood Pressure (DBP) on Ambulatory Blood Pressure Monitoring [units: mmHg] Least Squares Mean (Standard Error)	**-6.53 (0.42)**	**-6.79 (0.43)**

No statistical analysis provided for Absolute Reduction From Baseline in 24-hour Mean Diastolic Blood Pressure (DBP) on Ambulatory Blood Pressure Monitoring

5. Secondary: Absolute Reduction From Baseline in 6-hour Mean Systolic Blood Pressure (SBP)/Diastolic Blood Pressure (DBP) on Ambulatory Blood Pressure Monitoring [Time Frame: Baseline (Week 0, after completion of screening period) and Week 8 (after 8 weeks of combination therapy)]

Measure Type	Secondary
Measure Title	Absolute Reduction From Baseline in 6-hour Mean Systolic Blood Pressure (SBP)/Diastolic Blood Pressure (DBP) on Ambulatory Blood Pressure Monitoring
Measure Description	Ambulatory Blood Pressure Monitoring (ABPM) over a 30-hour period was carried out in all patients at two visits during the study, 72 hours before visit 2 (baseline) and visit 4 (week 8). ABPM for visit 2 was carried out prior to randomization and the first dose of the amlodipine/valsartan combination study therapy. ABPM for visit four began after 12 weeks of treatment and before the last office blood pressure was taken. Covariates included baseline level, country, up-titration + treatment*country and treatment*up-titration interactions in case statistically significant at a 0.10 level.
Time Frame	Baseline (Week 0, after completion of screening period) and Week 8 (after 8 weeks of combination therapy)
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.
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Reporting Groups

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Measured Values

	Morning Intake	Evening Intake

Number of Participants Analyzed [units: participants]	**242**	**237**
Absolute Reduction From Baseline in 6-hour Mean Systolic Blood Pressure (SBP)/Diastolic Blood Pressure (DBP) on Ambulatory Blood Pressure Monitoring [units: mmHg] Least Squares Mean (Standard Error)		
Systolic Blood Pressure (SBP)	**-12.16 (0.88)**	**-11.37 (0.90)**
Diastolic Blood Pressure (DBP)	**-7.71 (0.59)**	**-7.01 (0.60)**

No statistical analysis provided for Absolute Reduction From Baseline in 6-hour Mean Systolic Blood Pressure (SBP)/Diastolic Blood Pressure (DBP) on Ambulatory Blood Pressure Monitoring

6. Secondary: Mean Seated Systolic Blood Pressure (msSBP)/Mean Seated Diastolic Blood Pressure (msDBP) Variation Between Week 0 and Week 8 in Office Blood Pressure [Time Frame: Baseline (Week 0, after completion of screening period) and Week 8 (after 8 weeks of combination therapy)]

Measure Type	Secondary
Measure Title	Mean Seated Systolic Blood Pressure (msSBP)/Mean Seated Diastolic Blood Pressure (msDBP) Variation Between Week 0 and Week 8 in Office Blood Pressure
Measure Description	At each of the office visits, blood pressure was recorded in the morning between 08.00 and 11.00, before any antihypertensive treatment was taken. The patient remained in a sitting position for five minutes; the investigator then took three blood pressure and one pulse rate reading. The measurements were recorded at 1-2 minute intervals. Covariates included baseline level, country, up-titration + treatment*country and treatment*up-titration interactions in case statistically significant at a 0.10 level.
Time Frame	Baseline (Week 0, after completion of screening period) and Week 8 (after 8 weeks of combination therapy)
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 Intent-to-treat (ITT) population included all patients randomized and treated in the study and for whom two Ambulatory Blood Pressure Monitoring (ABPM) evaluations are available.

Reporting Groups

	Description
Morning Intake	After randomization, participants received a single daily oral dose of 5 mg amlodipine and 160 mg valsartan free combination therapy, taken in the morning between 6-10 am. At week 4, uncontrolled patients (msSBP >= 140 mmHg and/or msDBP >= 90 mmHg or msSBP >= 130 mmHg and/or msDBP >= 80 mmHg in the case of diabetes or renal insufficiency measured by using conventional methods) received amlodipine/valsartan 10/160 mg for 4 additional weeks. Patients who were controlled at Week 4 (msSBP < 140 mmHg and msDBP < 90 mmHg or msSBP < 130 mmHg and msDBP < 80 mmHg in the case of diabetes or renal insufficiency) continued their amlodipine/valsartan 5/160 mg treatment for the remaining 4 weeks of the study.
Evening Intake	After randomization participants received a single daily oral dose of 5 mg amlodipine and 160 mg valsartan free combination therapy, taken in the evening between 6-10 pm. At week 4, uncontrolled patients (msSBP >= 140 mmHg and/or msDBP >= 90 mmHg or msSBP >= 130 mmHg and/or msDBP >= 80 mmHg in the case of diabetes or renal insufficiency measured by using conventional methods) received amlodipine/valsartan 10/160 mg for 4 additional weeks. Patients who were controlled at Week 4 (msSBP < 140 mmHg and msDBP < 90 mmHg or msSBP < 130 mmHg and msDBP < 80 mmHg in the case of diabetes or renal insufficiency) continued their amlodipine/valsartan 5/160 mg treatment for the remaining 4 weeks of the study.

Measured Values

	Morning	**Evening**

	Intake	Intake
Number of Participants Analyzed [units: participants]	**231**	**232**
Mean Seated Systolic Blood Pressure (msSBP)/Mean Seated Diastolic Blood Pressure (msDBP) Variation Between Week 0 and Week 8 in Office Blood Pressure [units: mmHg] Least Squares Mean (Standard Error)		
Systolic Blood Pressure (SBP)	**-18.7 (0.9)**	**-17.3 (0.9)**
Diastolic Blood Pressure (DBP)	**-10.1 (0.6)**	**-8.6 (0.7)**

No statistical analysis provided for Mean Seated Systolic Blood Pressure (msSBP)/Mean Seated Diastolic Blood Pressure (msDBP) Variation Between Week 0 and Week 8 in Office Blood Pressure

7. Secondary: Mean Seated Systolic Blood Pressure (msSBP)/Mean Seated Diastolic Blood Pressure (msDBP) Variation Between Week -4 to Week 8 in Office Blood Pressure [Time Frame: Screening visit (Week -4, prior to 4-week open-label screening phase) and Week 8 (after 8 weeks of combination therapy)]

Measure Type	Secondary
Measure Title	Mean Seated Systolic Blood Pressure (msSBP)/Mean Seated Diastolic Blood Pressure (msDBP) Variation Between Week -4 to Week 8 in Office Blood Pressure
Measure Description	At each of the office visits, blood pressure was recorded in the morning between 08.00 and 11.00, before any antihypertensive treatment was taken. The patient remained in a sitting position for five minutes; the investigator then took three blood pressure and one pulse rate reading. The measurements were recorded at 1-2 minute intervals. Covariates included baseline level, country, up-titration + treatment*country and treatment*up-titration interactions in case statistically significant at a 0.10 level.
Time Frame	Screening visit (Week -4, prior to 4-week open-label screening phase) and Week 8 (after 8 weeks of combination therapy)
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 Intent-to-treat (ITT) population included all patients randomized and treated in the study and for whom two Ambulatory Blood Pressure Monitoring (ABPM) evaluations are available.

Reporting Groups

	Description
Morning Intake	After randomization, participants received a single daily oral dose of 5 mg amlodipine and 160 mg valsartan free combination therapy, taken in the morning between 6-10 am. At week 4, uncontrolled patients (msSBP >= 140 mmHg and/or msDBP >= 90 mmHg or msSBP >= 130 mmHg and/or msDBP >= 80 mmHg in the case of diabetes or renal insufficiency measured by using conventional methods) received amlodipine/valsartan 10/160 mg for 4 additional weeks. Patients who were controlled at Week 4 (msSBP < 140 mmHg and msDBP < 90 mmHg or msSBP < 130 mmHg and msDBP < 80 mmHg in the case of diabetes or renal insufficiency) continued their amlodipine/valsartan 5/160 mg treatment for the remaining 4 weeks of the study.
Evening Intake	After randomization participants received a single daily oral dose of 5 mg amlodipine and 160 mg valsartan free combination therapy, taken in the evening between 6-10 pm. At week 4, uncontrolled patients (msSBP >= 140 mmHg and/or msDBP >= 90 mmHg or msSBP >= 130 mmHg and/or msDBP >= 80 mmHg in the case of diabetes or renal insufficiency measured by using conventional methods) received amlodipine/valsartan 10/160 mg for 4 additional weeks. Patients who were controlled at Week 4 (msSBP < 140 mmHg and msDBP < 90 mmHg or msSBP < 130 mmHg and msDBP < 80 mmHg in the case of diabetes or renal insufficiency) continued their amlodipine/valsartan 5/160 mg treatment for the remaining 4 weeks of the study.

Measured Values

	Morning Intake	Evening Intake
Number of Participants Analyzed [units: participants]	**231**	**232**
Mean Seated Systolic Blood Pressure (msSBP)/Mean Seated Diastolic Blood Pressure (msDBP) Variation Between Week -4 to Week 8 in Office Blood Pressure [units: mmHg] Mean (Standard Error)		
Systolic Blood Pressure (SBP)	**-32.2 (1.1)**	**-29 (1.2)**
Diastolic Blood Pressure (DBP)	**-16.6 (0.8)**	**-14.3 (0.8)**

No statistical analysis provided for Mean Seated Systolic Blood Pressure (msSBP)/Mean Seated Diastolic Blood Pressure (msDBP) Variation Between Week -4 to Week 8 in Office Blood Pressure

8. Secondary: Percentage of Participants With 24-hour Mean Systolic Blood Pressure (SBP)/Diastolic Blood Pressure (DBP) < 125/80 mmHg at Endpoint With Ambulatory Blood Pressure Monitoring [Time Frame: Visit 4 (week 8)]

Measure Type	Secondary
Measure Title	Percentage of Participants With 24-hour Mean Systolic Blood Pressure (SBP)/Diastolic Blood Pressure (DBP) < 125/80 mmHg at Endpoint With Ambulatory Blood Pressure Monitoring
Measure Description	Ambulatory Blood Pressure Monitoring (ABPM) over a 30-hour period was carried out in all patients at two visits during the study, 72 hours before visit 2 (baseline) and visit 4 (week 8). ABPM for visit four began after 12 weeks of treatment and before the last office blood pressure was taken.
Time Frame	Visit 4 (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 Intent-to-treat (ITT) population included all patients randomized and treated in the study and for whom two Ambulatory Blood Pressure Monitoring (ABPM) evaluations are available.

Reporting Groups

	Description
Morning Intake	After randomization, participants received a single daily oral dose of 5 mg amlodipine and 160 mg valsartan free combination therapy, taken in the morning between 6-10 am. At week 4, uncontrolled patients (msSBP >= 140 mmHg and/or msDBP >= 90 mmHg or msSBP >= 130 mmHg and/or msDBP >= 80 mmHg in the case of diabetes or renal insufficiency measured by using conventional methods) received amlodipine/valsartan 10/160 mg for 4 additional weeks. Patients who were controlled at Week 4 (msSBP < 140 mmHg and msDBP < 90 mmHg or msSBP < 130 mmHg and msDBP < 80 mmHg in the case of diabetes or renal insufficiency) continued their amlodipine/valsartan 5/160 mg treatment for the remaining 4 weeks of the study.
Evening Intake	After randomization participants received a single daily oral dose of 5 mg amlodipine and 160 mg valsartan free combination therapy, taken in the evening between 6-10 pm. At week 4, uncontrolled patients (msSBP >= 140 mmHg and/or msDBP >= 90 mmHg or msSBP >= 130 mmHg and/or msDBP >= 80 mmHg in the case of diabetes or renal insufficiency measured by using conventional methods) received amlodipine/valsartan 10/160 mg for 4 additional weeks. Patients who were controlled at Week 4 (msSBP < 140 mmHg and msDBP < 90 mmHg or msSBP < 130 mmHg and msDBP < 80 mmHg in the case of diabetes or renal insufficiency) continued their amlodipine/valsartan 5/160 mg treatment for the remaining 4 weeks of the study.

Measured Values

	Morning Intake	Evening Intake
Number of Participants Analyzed [units: participants]	**242**	**237**
Percentage of Participants With 24-hour Mean Systolic Blood Pressure (SBP)/Diastolic Blood Pressure (DBP) < 125/80 mmHg at Endpoint With Ambulatory Blood Pressure Monitoring [units: Percentage of Participants]	**47.6**	**46.9**

No statistical analysis provided for Percentage of Participants With 24-hour Mean Systolic Blood Pressure (SBP)/Diastolic Blood Pressure (DBP) < 125/80 mmHg at Endpoint With Ambulatory Blood Pressure Monitoring

9. Secondary: Percentage of Participants With Diurnal Mean Systolic Blood Pressure (SBP)/Diastolic Blood Pressure (DBP) < 135/85 mmHg at Endpoint With Ambulatory Blood Pressure Monitoring [Time Frame: Visit 4 (week 8)]

Measure Type	Secondary
Measure Title	Percentage of Participants With Diurnal Mean Systolic Blood Pressure (SBP)/Diastolic Blood Pressure (DBP) < 135/85 mmHg at Endpoint With Ambulatory Blood Pressure Monitoring
Measure Description	Ambulatory Blood Pressure Monitoring (ABPM) over a 30-hour period was carried out in all patients at two visits during the study, 72 hours before visit 2 (baseline) and visit 4 (week 8). ABPM for visit four began after 12 weeks of treatment and before the last office blood pressure was taken.
Time Frame	Visit 4 (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 Intent-to-treat (ITT) population included all patients randomized and treated in the study and for whom two Ambulatory Blood Pressure Monitoring (ABPM) evaluations are available.

Reporting Groups

	Description
Morning Intake	After randomization, participants received a single daily oral dose of 5 mg amlodipine and 160 mg valsartan free combination therapy, taken in the morning between 6-10 am. At week 4, uncontrolled patients (msSBP >= 140 mmHg and/or msDBP >= 90 mmHg or msSBP >= 130 mmHg and/or msDBP >= 80 mmHg in the case of diabetes or renal insufficiency measured by using conventional methods) received amlodipine/valsartan 10/160 mg for 4 additional weeks. Patients who were controlled at Week 4 (msSBP < 140 mmHg and msDBP < 90 mmHg or msSBP < 130 mmHg and msDBP < 80 mmHg in the case of diabetes or renal insufficiency) continued their amlodipine/valsartan 5/160 mg treatment for the remaining 4 weeks of the study.
Evening Intake	After randomization participants received a single daily oral dose of 5 mg amlodipine and 160 mg valsartan free combination therapy, taken in the evening between 6-10 pm. At week 4, uncontrolled patients (msSBP >= 140 mmHg and/or msDBP >= 90 mmHg or msSBP >= 130 mmHg and/or msDBP >= 80 mmHg in the case of diabetes or renal insufficiency measured by using conventional methods) received amlodipine/valsartan 10/160 mg for 4 additional weeks. Patients who were controlled at Week 4 (msSBP < 140 mmHg and msDBP < 90 mmHg or msSBP < 130 mmHg and msDBP < 80 mmHg in the case of diabetes or renal insufficiency) continued their amlodipine/valsartan 5/160 mg treatment for the remaining 4 weeks of the study.

Measured Values

	Morning Intake	Evening Intake
Number of Participants Analyzed [units: participants]	**242**	**237**
Percentage of Participants With Diurnal Mean Systolic Blood Pressure (SBP)/Diastolic Blood Pressure (DBP) < 135/85 mmHg at Endpoint With Ambulatory Blood Pressure Monitoring	**65.3**	**58.2**

[units: Percentage of Participants]		

No statistical analysis provided for Percentage of Participants With Diurnal Mean Systolic Blood Pressure (SBP)/Diastolic Blood Pressure (DBP) < 135/85 mmHg at Endpoint With Ambulatory Blood Pressure Monitoring

10. Secondary: Percentage of Participants With Nocturnal Mean Systolic Blood Pressure (SBP)/Diastolic Blood Pressure (DBP) < 120/70 mmHg at Endpoint With Ambulatory Blood Pressure Monitoring [Time Frame: Visit 4 (week 8)]

Measure Type	Secondary
Measure Title	Percentage of Participants With Nocturnal Mean Systolic Blood Pressure (SBP)/Diastolic Blood Pressure (DBP) < 120/70 mmHg at Endpoint With Ambulatory Blood Pressure Monitoring
Measure Description	Ambulatory Blood Pressure Monitoring (ABPM) over a 30-hour period was carried out in all patients at two visits during the study, 72 hours before visit 2 (baseline) and visit 4 (week 8). ABPM for visit four began after 12 weeks of treatment and before the last office blood pressure was taken.
Time Frame	Visit 4 (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 Intent-to-treat (ITT) population included all patients randomized and treated in the study and for whom two Ambulatory Blood Pressure Monitoring (ABPM) evaluations are available.

Reporting Groups

	Description
Morning Intake	After randomization, participants received a single daily oral dose of 5 mg amlodipine and 160 mg valsartan free combination therapy, taken in the morning between 6-10 am. At week 4, uncontrolled patients (msSBP >= 140 mmHg and/or msDBP >= 90 mmHg or msSBP >= 130 mmHg and/or msDBP >= 80 mmHg in the case of diabetes or renal insufficiency measured by using conventional methods) received amlodipine/valsartan 10/160 mg for 4 additional weeks. Patients who were controlled at Week 4 (msSBP < 140 mmHg and msDBP < 90 mmHg or msSBP < 130 mmHg and msDBP < 80 mmHg in the case of diabetes or renal insufficiency) continued their amlodipine/valsartan 5/160 mg treatment for the remaining 4 weeks of the study.
Evening Intake	After randomization participants received a single daily oral dose of 5 mg amlodipine and 160 mg valsartan free combination therapy, taken in the evening between 6-10 pm. At week 4, uncontrolled patients (msSBP >= 140 mmHg and/or msDBP >= 90 mmHg or msSBP >= 130 mmHg and/or msDBP >= 80 mmHg in the case of diabetes or renal insufficiency measured by using conventional methods) received amlodipine/valsartan 10/160 mg for 4 additional weeks. Patients who were controlled at Week 4 (msSBP < 140 mmHg and msDBP < 90 mmHg or msSBP < 130 mmHg and msDBP < 80 mmHg in the case of diabetes or renal insufficiency) continued their amlodipine/valsartan 5/160 mg treatment for the remaining 4 weeks of the study.

Measured Values

	Morning Intake	**Evening Intake**
Number of Participants Analyzed [units: participants]	**242**	**237**
Percentage of Participants With Nocturnal Mean Systolic Blood Pressure (SBP)/Diastolic Blood Pressure (DBP) < 120/70 mmHg at Endpoint With Ambulatory Blood Pressure Monitoring [units: Percentage of participants]	**41.3**	**46.8**

No statistical analysis provided for Percentage of Participants With Nocturnal Mean Systolic Blood Pressure (SBP)/Diastolic Blood Pressure (DBP) < 120/70 mmHg at Endpoint With Ambulatory Blood Pressure Monitoring

11. Secondary: Percentage of Participants With Controlled Office Mean Seated Systolic Blood Pressure (msSBP)/Mean Seated Diastolic Blood Pressure (msDBP) at Endpoint [Time Frame: Visit 4 (week 8)]

Measure Type	Secondary
Measure Title	Percentage of Participants With Controlled Office Mean Seated Systolic Blood Pressure (msSBP)/Mean Seated Diastolic Blood Pressure (msDBP) at Endpoint
Measure Description	At each of the office visits, blood pressure was recorded in the morning between 08.00 and 11.00, before any antihypertensive treatment was taken. The patient remained in a sitting position for 5 minutes; the investigator then took 3 blood pressure and 1 pulse rate reading. The measurements were recorded at 1-2 minute intervals. BP Control is defined as msSBP/msDBP <149/90 mmHg and/or <130/80 mmHg if diabetes or renal insufficiency (RI).
Time Frame	Visit 4 (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 Intent-to-treat (ITT) population included all patients randomized and treated in the study and for whom two Ambulatory Blood Pressure Monitoring (ABPM) evaluations are available.

Reporting Groups

	Description
Morning Intake	After randomization, participants received a single daily oral dose of 5 mg amlodipine and 160 mg valsartan free combination therapy, taken in the morning between 6-10 am. At week 4, uncontrolled patients (msSBP >= 140 mmHg and/or msDBP >= 90 mmHg or msSBP >= 130 mmHg and/or msDBP >= 80 mmHg in the case of diabetes or renal insufficiency measured by using conventional methods) received amlodipine/valsartan 10/160 mg for 4 additional weeks. Patients who were controlled at Week 4 (msSBP < 140 mmHg and msDBP < 90 mmHg or msSBP < 130 mmHg and msDBP < 80 mmHg in the case of diabetes or renal insufficiency) continued their amlodipine/valsartan 5/160 mg treatment for the remaining 4 weeks of the study.
Evening Intake	After randomization participants received a single daily oral dose of 5 mg amlodipine and 160 mg valsartan free combination therapy, taken in the evening between 6-10 pm. At week 4, uncontrolled patients (msSBP >= 140 mmHg and/or msDBP >= 90 mmHg or msSBP >= 130 mmHg and/or msDBP >= 80 mmHg in the case of diabetes or renal insufficiency measured by using conventional methods) received amlodipine/valsartan 10/160 mg for 4 additional weeks. Patients who were controlled at Week 4 (msSBP < 140 mmHg and msDBP < 90 mmHg or msSBP < 130 mmHg and msDBP < 80 mmHg in the case of diabetes or renal insufficiency) continued their amlodipine/valsartan 5/160 mg treatment for the remaining 4 weeks of the study.

Measured Values

	Morning Intake	Evening Intake
Number of Participants Analyzed [units: participants]	**242**	**237**
Percentage of Participants With Controlled Office Mean Seated Systolic Blood Pressure (msSBP)/Mean Seated Diastolic Blood Pressure (msDBP) at Endpoint [units: Percentage of participants]	**71.1**	**72.6**

No statistical analysis provided for Percentage of Participants With Controlled Office Mean Seated Systolic Blood Pressure (msSBP)/Mean Seated Diastolic Blood Pressure (msDBP) at Endpoint

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	No text entered.

Additional Description	No text entered.

Reporting Groups

	Description
Morning Intake	After randomization, participants received a single daily oral dose of 5 mg amlodipine and 160 mg valsartan free combination therapy, taken in the morning between 6-10 am. At week 4, uncontrolled patients (msSBP >= 140 mmHg and/or msDBP >= 90 mmHg or msSBP >= 130 mmHg and/or msDBP >= 80 mmHg in the case of diabetes or renal insufficiency measured by using conventional methods) received amlodipine/valsartan 10/160 mg for 4 additional weeks. Patients who were controlled at Week 4 (msSBP < 140 mmHg and msDBP < 90 mmHg or msSBP < 130 mmHg and msDBP < 80 mmHg in the case of diabetes or renal insufficiency) continued their amlodipine/valsartan 5/160 mg treatment for the remaining 4 weeks of the study.
Evening Intake	After randomization participants received a single daily oral dose of 5 mg amlodipine and 160 mg valsartan free combination therapy, taken in the evening between 6-10 pm. At week 4, uncontrolled patients (msSBP >= 140 mmHg and/or msDBP >= 90 mmHg or msSBP >= 130 mmHg and/or msDBP >= 80 mmHg in the case of diabetes or renal insufficiency measured by using conventional methods) received amlodipine/valsartan 10/160 mg for 4 additional weeks. Patients who were controlled at Week 4 (msSBP < 140 mmHg and msDBP < 90 mmHg or msSBP < 130 mmHg and msDBP < 80 mmHg in the case of diabetes or renal insufficiency) continued their amlodipine/valsartan 5/160 mg treatment for the remaining 4 weeks of the study.

Serious Adverse Events

	Morning Intake	Evening Intake
Total, serious adverse events		
# participants affected / at risk	**2/278 (0.72%)**	**2/268 (0.75%)**
Cardiac disorders		
Atrial fibrillation † 1		
# participants affected / at risk	**1/278 (0.36%)**	**0/268 (0.00%)**
Atrioventricular block † 1		
# participants affected / at risk	**0/278 (0.00%)**	**1/268 (0.37%)**
Bradycardia † 1		
# participants affected / at risk	**0/278 (0.00%)**	**1/268 (0.37%)**
Palpitations † 1		
# participants affected / at risk	**1/278 (0.36%)**	**1/268 (0.37%)**
Sinus tachycardia † 1		
# participants affected / at risk	**0/278 (0.00%)**	**1/268 (0.37%)**
Metabolism and nutrition disorders		
Hyperglycaemia † 1		
# participants affected / at risk	**1/278 (0.36%)**	**0/268 (0.00%)**
Nervous system disorders		
Syncope † 1		
# participants affected / at risk	**1/278 (0.36%)**	**0/268 (0.00%)**
Psychiatric disorders		
Stress † 1		
# participants affected / at risk	**1/278 (0.36%)**	**0/268 (0.00%)**
Renal and urinary disorders		
Renal impairment † 1		
# participants affected / at risk	**0/278 (0.00%)**	**1/268 (0.37%)**

† 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
Morning Intake	After randomization, participants received a single daily oral dose of 5 mg amlodipine and 160 mg valsartan free combination therapy, taken in the morning between 6-10 am. At week 4, uncontrolled patients (msSBP >= 140 mmHg and/or msDBP >= 90 mmHg or msSBP >= 130 mmHg and/or msDBP >= 80 mmHg in the case of diabetes or renal insufficiency measured by using conventional methods) received amlodipine/valsartan 10/160 mg for 4 additional weeks. Patients who were controlled at Week 4 (msSBP < 140 mmHg and msDBP < 90 mmHg or msSBP < 130 mmHg and msDBP < 80 mmHg in the case of diabetes or renal insufficiency) continued their amlodipine/valsartan 5/160 mg treatment for the remaining 4 weeks of the study.
Evening Intake	After randomization participants received a single daily oral dose of 5 mg amlodipine and 160 mg valsartan free combination therapy, taken in the evening between 6-10 pm. At week 4, uncontrolled patients (msSBP >= 140 mmHg and/or msDBP >= 90 mmHg or msSBP >= 130 mmHg and/or msDBP >= 80 mmHg in the case of diabetes or renal insufficiency measured by using conventional methods) received amlodipine/valsartan 10/160 mg for 4 additional weeks. Patients who were controlled at Week 4 (msSBP < 140 mmHg and msDBP < 90 mmHg or msSBP < 130 mmHg and msDBP < 80 mmHg in the case of diabetes or renal insufficiency) continued their amlodipine/valsartan 5/160 mg treatment for the remaining 4 weeks of the study.

Other Adverse Events

	Morning Intake	Evening Intake
Total, other (not including serious) adverse events		
# participants affected / at risk	**0/278 (0.00%)**	**0/268 (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; or publication of the trial results in their entirety.

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:	NCT00700271 History of Changes
Other Study ID Numbers:	**CVAA489AFR01**
Study First Received:	December 11, 2007
Results First Received:	December 15, 2010
Last Updated:	May 16, 2011
Health Authority:	France: Afssaps - Agence française de sécurité sanitaire des produits de santé (Saint-Denis)