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Trial record **1 of 1** for: CSPP100AES02

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ALiskiren or Losartan Effects on bioMARKers of Myocardial Remodeling (ALLMARK)

This study has been completed.

Sponsor:
Novartis Pharmaceuticals

Information provided by (Responsible Party):
Novartis (Novartis Pharmaceuticals)

ClinicalTrials.gov Identifier:
NCT01176032

First received: August 2, 2010
Last updated: July 22, 2014
Last verified: July 2014
History of Changes

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Results First Received: April 22, 2014

Study Type:	Interventional
Study Design:	Allocation: Randomized; Intervention Model: Parallel Assignment; Masking: Open Label; Primary Purpose: Treatment
Conditions:	Hypertension Left Ventricle Hypertrophy
Interventions:	Drug: Aliskiren Drug: Losartan Drug: Amlodipine Drug: Hydrochlorothiazide (HCTZ)

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
Aliskiren	Aliskiren 150 mg od for 2 weeks and up-titration to aliskiren 300 mg od for 34 weeks
Lostaran	Losartan 50 mg od for 2 weeks and up-titration to losartan 100 mg od for 34 weeks

Participant Flow: Overall Study

	Aliskiren	**Lostaran**
STARTED	**37** [1]	**37**

Intention-to-treat (ITT) Population	**32**	**37**
COMPLETED	**31**	**36**
NOT COMPLETED	**6**	**1**
Adverse Event	**1**	**0**
Unsatisfactory therapeutic effect	**0**	**1**
Protocol Violation	**1**	**0**
Informed consent withdrawn	**3**	**0**
Not available	**1**	**0**

[1] "Started" indicates randomized and safety population

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.
Intention-to-treat (ITT) population

Reporting Groups

	Description
Aliskiren	Aliskiren 150 mg od for 2 weeks and up-titration to aliskiren 300 mg od for 34 weeks
Lostaran	Losartan 50 mg od for 2 weeks and up-titration to losartan 100 mg od for 34 weeks
Total	Total of all reporting groups

Baseline Measures

	Aliskiren	Lostaran	Total
Number of Participants [units: participants]	**32**	**37**	**69**
Age [units: Years] Mean (Standard Deviation)	**60.34 (9.34)**	**58.05 (10.34)**	**59.12 (9.88)**
Gender [units: Participants]			
Female	**9**	**11**	**20**
Male	**23**	**26**	**49**

Outcome Measures

Hide All Outcome Measures

1. Primary: Change From Baseline in C-terminal Propeptide of Procollagen Type I (PICP) [Time Frame: Baseline, Week 36]

Measure Type	Primary
Measure Title	Change From Baseline in C-terminal Propeptide of Procollagen Type I (PICP)
Measure Description	PICP is a measure of blood concentration of procollagen I carboxy-terminal propeptide (PICP), a peptide released from the myocardium when procollagen is converted to type I collagen. This biomarker exhibits good specificity and sensitivity for identifying myocardial fibrosis in hypertension.

Time Frame	Baseline, Week 36
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.
Intention-to-treat (ITT) population included all patients included in the safety population who had a baseline assessment of the primary variable and at least one post-baseline assessment.

Reporting Groups

	Description
Aliskiren	Aliskiren 150 mg od for 2 weeks and up-titration to aliskiren 300 mg od for 34 weeks
Lostaran	Losartan 50 mg od for 2 weeks and up-titration to losartan 100 mg od for 34 weeks

Measured Values

	Aliskiren	**Lostaran**
Number of Participants Analyzed [units: participants]	**32**	**37**
Change From Baseline in C-terminal Propeptide of Procollagen Type I (PICP) [units: ug/l] Mean (Standard Deviation)	**-5.22 (20.37)**	**-4.25 (24.80)**

No statistical analysis provided for Change From Baseline in C-terminal Propeptide of Procollagen Type I (PICP)

2. Secondary: Change From Baseline in Biomarkers in Heart Disease [Time Frame: Baseline, Week 36]

Measure Type	Secondary
Measure Title	Change From Baseline in Biomarkers in Heart Disease
Measure Description	The plasma level of biomarkers parameters used to measure improvement in left ventricular (LV) function or reduction in left ventricular mass index (LVMI). The following biomarkers were analyzed: cardiotrophin-1 (CT-1), matrix metalloproteinase-1 (MMP-1); tissue inhibitor of MMPs (TIMP-1); annexin A5 (AnxA5); N-terminal prohormone of B-type natriuretic peptide (NT-proBNP)
Time Frame	Baseline, Week 36
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.
Intention-to-treat (ITT) population included all patients included in the safety population who had a baseline assessment of the primary variable and at least one post-baseline assessment. Patients with both baseline and week 36 assessment were included in this analysis.

Reporting Groups

	Description
Aliskiren	Aliskiren 150 mg od for 2 weeks and up-titration to aliskiren 300 mg od for 34 weeks
Lostaran	Losartan 50 mg od for 2 weeks and up-titration to losartan 100 mg od for 34 weeks

Measured Values

	Aliskiren	**Lostaran**

Number of Participants Analyzed [units: participants]	**32**	**37**
Change From Baseline in Biomarkers in Heart Disease [units: ng/ml] Mean (Standard Deviation)		
cardiotrophin-1 (CT-1) (n=32,37)	**-169.15 (561.51)**	**-128.23 (568.02)**
matrix metalloproteinase-1 (MMP-1) (n=32,37)	**5.93 (13.33)**	**5.51 (9.58)**
tissue inhibitor of MMPs (TIMP-1) (n=32,37)	**-0.70 (59.18)**	**9.15 (42.58)**
annexin A5 (AnxA5) (n=31,37)	**-0.98 (7.33)**	**-1.21 (4.75)**
NT-proBNP (n=31,34)	**18.66 (165.21)**	**-7.55 (38.11)**

No statistical analysis provided for Change From Baseline in Biomarkers in Heart Disease

3. Secondary: Change From Baseline in Biomarker Such as Aldosterone (Aldo) in Heart Disease [Time Frame: Baseline, Week 36]

Measure Type	Secondary
Measure Title	Change From Baseline in Biomarker Such as Aldosterone (Aldo) in Heart Disease
Measure Description	The plasma level of biomarker parameter (aldosterone (Aldo)) used to measure improvement in left ventricular (LV) function or reduction in left ventricular mass index (LVMI)
Time Frame	Baseline, Week 36
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.
Intention-to-treat (ITT) population included all patients included in the safety population who had a baseline assessment of the primary variable and at least one post-baseline assessment. Patients with both baseline and week 36 assessment were included in this analysis.

Reporting Groups

	Description
Aliskiren	Aliskiren 150 mg od for 2 weeks and up-titration to aliskiren 300 mg od for 34 weeks
Lostaran	Losartan 50 mg od for 2 weeks and up-titration to losartan 100 mg od for 34 weeks

Measured Values

	Aliskiren	**Lostaran**
Number of Participants Analyzed [units: participants]	**32**	**37**
Change From Baseline in Biomarker Such as Aldosterone (Aldo) in Heart Disease [units: ng/dl] Mean (Standard Deviation)	**-1.81 (27.78)**	**-7.90 (76.35)**

No statistical analysis provided for Change From Baseline in Biomarker Such as Aldosterone (Aldo) in Heart Disease

4. Secondary: Change From Baseline in Left Ventricular (LV) Function, LV End-diastolic Volume by Simpson's Rule, and LV End-systolic Volume by Simpson's Rule [Time Frame: Baseline, Week 36]

Measure Type	Secondary

Measure Title	Change From Baseline in Left Ventricular (LV) Function, LV End-diastolic Volume by Simpson's Rule, and LV End-systolic Volume by Simpson's Rule
Measure Description	Reductions in the following measurements were analysed between the baseline visit and the final visit: LV end-diastolic volume by Simpson's rule, and LV end-systolic volume by Simpson's rule
Time Frame	Baseline, Week 36
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.
Intention-to-treat (ITT) population included all patients included in the safety population who had a baseline assessment of the primary variable and at least one post-baseline assessment. Patients with both baseline and week 36 assessment were included in this analysis.

Reporting Groups

	Description
Aliskiren	Aliskiren 150 mg od for 2 weeks and up-titration to aliskiren 300 mg od for 34 weeks
Lostaran	Losartan 50 mg od for 2 weeks and up-titration to losartan 100 mg od for 34 weeks

Measured Values

	Aliskiren	Lostaran
Number of Participants Analyzed [units: participants]	**32**	**37**
Change From Baseline in Left Ventricular (LV) Function, LV End-diastolic Volume by Simpson's Rule, and LV End-systolic Volume by Simpson's Rule [units: ml] Mean (Standard Deviation)		
LV end-diastolic volume (n=22,34)	**2.30 (35.65)**	**0.54 (33.19)**
LV end-systolic volume (n=22,34)	**-0.92 (12.24)**	**0.64 (21.01)**

No statistical analysis provided for Change From Baseline in Left Ventricular (LV) Function, LV End-diastolic Volume by Simpson's Rule, and LV End-systolic Volume by Simpson's Rule

5. Secondary: Change From Baseline in Left Ventricular (LV) Function, LV Ejection Fraction (Teicholz), and LV Ejection Fraction (Simpson) [Time Frame: Baseline, Week 36]

Measure Type	Secondary
Measure Title	Change From Baseline in Left Ventricular (LV) Function, LV Ejection Fraction (Teicholz), and LV Ejection Fraction (Simpson)
Measure Description	Reductions in the following measurements were analysed between the baseline visit and the final visit: LV ejection fraction (Teicholz), and LV ejection fraction (Simpson)
Time Frame	Baseline, Week 36
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.
Intention-to-treat (ITT) population included all patients included in the safety population who had a baseline assessment of the primary

variable and at least one post-baseline assessment. Patients with both baseline and week 36 assessment were included in this analysis.

Reporting Groups

	Description
Aliskiren	Aliskiren 150 mg od for 2 weeks and up-titration to aliskiren 300 mg od for 34 weeks
Lostaran	Losartan 50 mg od for 2 weeks and up-titration to losartan 100 mg od for 34 weeks

Measured Values

	Aliskiren	Lostaran
Number of Participants Analyzed [units: participants]	**32**	**37**
Change From Baseline in Left Ventricular (LV) Function, LV Ejection Fraction (Teicholz), and LV Ejection Fraction (Simpson) [units: Percent] Mean (Standard Deviation)		
LV ejection fraction Teicholz(n=29,36)	**0.00 (0.11)**	**0.01 (0.08)**
LV ejection fraction Simpson(n=22,34)	**0.02 (0.14)**	**0.00 (0.11)**

No statistical analysis provided for Change From Baseline in Left Ventricular (LV) Function, LV Ejection Fraction (Teicholz), and LV Ejection Fraction (Simpson)

6. Secondary: Change From Baseline in Left Ventricular (LV) Function, LA (Left Atrium) Diameter [Time Frame: Baseline, Week 36]

Measure Type	Secondary
Measure Title	Change From Baseline in Left Ventricular (LV) Function, LA (Left Atrium) Diameter
Measure Description	Reductions in the following measurements were analysed between the baseline visit and the final visit: LA diameter
Time Frame	Baseline, Week 36
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.
Intention-to-treat (ITT) population included all patients included in the safety population who had a baseline assessment of the primary variable and at least one post-baseline assessment. Patients with both baseline and week 36 assessment were included in this analysis.

Reporting Groups

	Description
Aliskiren	Aliskiren 150 mg od for 2 weeks and up-titration to aliskiren 300 mg od for 34 weeks
Lostaran	Losartan 50 mg od for 2 weeks and up-titration to losartan 100 mg od for 34 weeks

Measured Values

	Aliskiren	Lostaran
Number of Participants Analyzed [units: participants]	**24**	**30**
Change From Baseline in Left Ventricular (LV) Function, LA (Left Atrium) Diameter [units: mm/m^2] Mean (Standard Deviation)	**-0.13 (1.17)**	**-0.22 (0.98)**

No statistical analysis provided for Change From Baseline in Left Ventricular (LV) Function, LA (Left Atrium) Diameter

7. Secondary: Change From Baseline in Left Ventricular (LV) Function, Left Atrial Volume (Biplane Simpson's Method) [Time Frame: Baseline, Week 36]

Measure Type	Secondary
Measure Title	Change From Baseline in Left Ventricular (LV) Function, Left Atrial Volume (Biplane Simpson's Method)
Measure Description	Reductions in the following measurements were analysed between the baseline visit and the final visit: left atrial volume (biplane Simpson's method)
Time Frame	Baseline, Week 36
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.
Intention-to-treat (ITT) population included all patients included in the safety population who had a baseline assessment of the primary variable and at least one post-baseline assessment. Patients with both baseline and week 36 assessment were included in this analysis.

Reporting Groups

	Description
Aliskiren	Aliskiren 150 mg od for 2 weeks and up-titration to aliskiren 300 mg od for 34 weeks
Lostaran	Losartan 50 mg od for 2 weeks and up-titration to losartan 100 mg od for 34 weeks

Measured Values

	Aliskiren	**Lostaran**
Number of Participants Analyzed [units: participants]	**12**	**22**
Change From Baseline in Left Ventricular (LV) Function, Left Atrial Volume (Biplane Simpson's Method) [units: cm3/m^2] Mean (Standard Deviation)	**-0.55 (17.94)**	**-2.27 (26.46)**

No statistical analysis provided for Change From Baseline in Left Ventricular (LV) Function, Left Atrial Volume (Biplane Simpson's Method)

8. Secondary: Change From Baseline in Reduction of Left Ventricular Mass Index (LVMI) [Time Frame: Baseline, Week 36]

Measure Type	Secondary
Measure Title	Change From Baseline in Reduction of Left Ventricular Mass Index (LVMI)
Measure Description	Echocardiogram was performed at week 1 and at week 36. Reduction in LVMI is defined as the difference between the LVMI at the final visit and the baseline LVMI
Time Frame	Baseline, Week 36
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.
Intention-to-treat (ITT) population included all patients included in the safety population who had a baseline assessment of the primary

variable and at least one post-baseline assessment

Reporting Groups

	Description
Aliskiren	Aliskiren 150 mg od for 2 weeks and up-titration to aliskiren 300 mg od for 34 weeks
Lostaran	Losartan 50 mg od for 2 weeks and up-titration to losartan 100 mg od for 34 weeks

Measured Values

	Aliskiren	Lostaran
Number of Participants Analyzed [units: participants]	**32**	**37**
Change From Baseline in Reduction of Left Ventricular Mass Index (LVMI) [units: g/m^2] Mean (Standard Deviation)	**-8.05 (18.98)**	**-7.96 (18.69)**

No statistical analysis provided for Change From Baseline in Reduction of Left Ventricular Mass Index (LVMI)

9. Secondary: Change From Baseline in Combination of Aliskiren With Amlodipine in Biomarkers of Heart Disease. [Time Frame: Baseline, Week 36]

Measure Type	Secondary
Measure Title	Change From Baseline in Combination of Aliskiren With Amlodipine in Biomarkers of Heart Disease.
Measure Description	The plasma level of biomarkers parameters used to measure improvement in left ventricular (LV) function or reduction in left ventricular mass index (LVMI). The following biomarkers were analyzed: cardiotrophin-1 (CT-1), matrix metalloproteinase-1 (MMP-1); tissue inhibitor of MMPs (TIMP-1); annexin A5 (AnxA5); N-terminal prohormone of B-type natriuretic peptide (NT-proBNP)
Time Frame	Baseline, Week 36
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.
Intention-to-treat (ITT) population included all patients included in the safety population who had a baseline assessment of the primary variable and at least one post-baseline assessment. Patients with both baseline and week 36 assessment were included in this analysis.

Reporting Groups

	Description
Aliskiren	Aliskiren 150 mg od for 2 weeks and up-titration to aliskiren 300 mg od for 34 weeks
Aliskiren + Amlodipine	5 mg of amlodipine in addition to the study medication in order to reach the required BP (<140/90 mmHg). At week 18 the dose of amlodipine can be increased to 10mg if the required level (<140/90 mmHg) was still not achieved.
Losartan	Losartan 50 mg od for 2 weeks and up-titration to losartan 100 mg od for 34 weeks
Losartan + Amlodipine	5 mg of amlodipine in addition to the study medication in order to reach the required BP (<140/90 mmHg). At week 18 the dose of amlodipine can be increased to 10mg if the required level (<140/90 mmHg) was still not achieved.

Measured Values

	Aliskiren	Aliskiren + Amlodipine	Losartan	Losartan + Amlodipine
Number of Participants Analyzed [units: participants]	**15**	**17**	**16**	**21**

Change From Baseline in Combination of Aliskiren With Amlodipine in Biomarkers of Heart Disease. [units: ng/ml] Mean (Standard Deviation)				
CT-1(n=15,17,16,21)	-289.18 (608.91)	-63.23 (510.91)	156.89 (599.29)	-345.47 (443.63)
ANXA5 (n=15,16,16,21)	-1.24 (3.70)	-0.74 (9.73)	-1.73 (4.21)	-0.81 (5.20)
MMP-1(n=15,17,16,21)	7.00 (10.28)	4.99 (15.80)	5.47 (7.88)	5.54 (10.89)
TIMP-1 (n=15,17,16,21)	-10.01 (73.00)	7.51 (44.38)	21.38 (38.40)	-0.16 (44.13)
NT-proBNP (n=15,16,15,19)	21.00 (214.06)	16.46 (108.69)	-3.68 (23.78)	-10.60 (46.91)

No statistical analysis provided for Change From Baseline in Combination of Aliskiren With Amlodipine in Biomarkers of Heart Disease.

10. Secondary: Change From Baseline in Biomarker Such as Aldosterone (Aldo) in Heart Disease in Combination of Aliskiren With Amlodipine [Time Frame: Baseline, Week 36]

Measure Type	Secondary
Measure Title	Change From Baseline in Biomarker Such as Aldosterone (Aldo) in Heart Disease in Combination of Aliskiren With Amlodipine
Measure Description	The plasma level of biomarker parameter plasma aldosterone used to measure improvement in left ventricular (LV) function or reduction in left ventricular mass index (LVMI).
Time Frame	Baseline, Week 36
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.
Intention-to-treat (ITT) population included all patients included in the safety population who had a baseline assessment of the primary variable and at least one post-baseline assessment. Patients with both baseline and week 36 assessment were included in this analysis.

Reporting Groups

	Description
Aliskiren	Aliskiren 150 mg od for 2 weeks and up-titration to aliskiren 300 mg od for 34 weeks
Aliskiren + Amlodipine	5 mg of amlodipine in addition to the study medication in order to reach the required BP (<140/90 mmHg). At week 18 the dose of amlodipine can be increased to 10mg if the required level (<140/90 mmHg) was still not achieved.
Losartan	Losartan 50 mg od for 2 weeks and up-titration to losartan 100 mg od for 34 weeks
Losartan + Amlodipine	5 mg of amlodipine in addition to the study medication in order to reach the required BP (<140/90 mmHg). At week 18 the dose of amlodipine can be increased to 10mg if the required level (<140/90 mmHg) was still not achieved.

Measured Values

	Aliskiren	**Aliskiren + Amlodipine**	**Losartan**	**Losartan + Amlodipine**
Number of Participants Analyzed [units: participants]	**15**	**17**	**16**	**21**
Change From Baseline in Biomarker Such as Aldosterone (Aldo) in Heart Disease				

in Combination of Aliskiren With Amlodipine [units: ng/dl] Mean (Standard Deviation)	**2.81 (21.36)**	**-5.89 (32.54)**	**-3.12 (32.45)**	**-11.55 (98.35)**

No statistical analysis provided for Change From Baseline in Biomarker Such as Aldosterone (Aldo) in Heart Disease in Combination of Aliskiren With Amlodipine

11. Secondary: Change From Baseline in Left Ventricular (LV) Function, LV End-diastolic Volume by Simpson's Rule, and LV End-systolic Volume by Simpson's Rule in Combination of Aliskiren With Amlodipine [Time Frame: Baseline, Week 36]

Measure Type	Secondary
Measure Title	Change From Baseline in Left Ventricular (LV) Function, LV End-diastolic Volume by Simpson's Rule, and LV End-systolic Volume by Simpson's Rule in Combination of Aliskiren With Amlodipine
Measure Description	Reductions in the following measurements were analysed between the baseline visit and the final visit: LV end-diastolic volume by Simpson's rule, and LV end-systolic volume by Simpson's rule
Time Frame	Baseline, Week 36
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.
Intention-to-treat (ITT) population included all patients included in the safety population who had a baseline assessment of the primary variable and at least one post-baseline assessment. Patients with both baseline and week 36 assessment were included in this analysis.

Reporting Groups

	Description
Aliskiren	Aliskiren 150 mg od for 2 weeks and up-titration to aliskiren 300 mg od for 34 weeks
Aliskiren + Amlodipinet	5 mg of amlodipine in addition to the study medication in order to reach the required BP (<140/90 mmHg). At week 18 the dose of amlodipine can be increased to 10mg if the required level (<140/90 mmHg) was still not achieved.
Losartan	Losartan 50 mg od for 2 weeks and up-titration to losartan 100 mg od for 34 weeks
Losartan + Amlodipine	5 mg of amlodipine in addition to the study medication in order to reach the required BP (<140/90 mmHg). At week 18 the dose of amlodipine can be increased to 10mg if the required level (<140/90 mmHg) was still not achieved.

Measured Values

	Aliskiren	**Aliskiren + Amlodipinet**	**Losartan**	**Losartan + Amlodipine**
Number of Participants Analyzed [units: participants]	**15**	**17**	**16**	**21**
Change From Baseline in Left Ventricular (LV) Function, LV End-diastolic Volume by Simpson's Rule, and LV End-systolic Volume by Simpson's Rule in Combination of Aliskiren With Amlodipine [units: ml] Mean (Standard Deviation)				
LV end-diastolic volume (n=11,11,15,19)	**6.60 (40.43)**	**-2.00 (31.51)**	**5.01 (38.15)**	**-2.98 (29.30)**
LV end-systolic volume (n=11,11, 15,19)	**-2.93 (13.24)**	**1.09 (11.44)**	**6.11 (23.82)**	**-3.69 (17.97)**

No statistical analysis provided for Change From Baseline in Left Ventricular (LV) Function, LV End-diastolic Volume by Simpson's Rule, and LV

End-systolic Volume by Simpson's Rule in Combination of Aliskiren With Amlodipine

12. Secondary: Change From Baseline in Left Ventricular (LV) Function, LV Ejection Fraction (Teicholz), and LV Ejection Fraction (Simpson) in Combination of Aliskiren With Amlodipine [Time Frame: Baseline, Week 36]

Measure Type	Secondary
Measure Title	Change From Baseline in Left Ventricular (LV) Function, LV Ejection Fraction (Teicholz), and LV Ejection Fraction (Simpson) in Combination of Aliskiren With Amlodipine
Measure Description	Reductions in the following measurements were analysed between the baseline visit and the final visit: LV ejection fraction (Teicholz), and LV ejection fraction (Simpson)
Time Frame	Baseline, Week 36
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.
Intention-to-treat (ITT) population included all patients included in the safety population who had a baseline assessment of the primary variable and at least one post-baseline assessment. Patients with both baseline and week 36 assessment were included in this analysis.

Reporting Groups

	Description
Aliskiren	Aliskiren 150 mg od for 2 weeks and up-titration to aliskiren 300 mg od for 34 weeks
Aliskiren + Amlodipinet	5 mg of amlodipine in addition to the study medication in order to reach the required BP (<140/90 mmHg). At week 18 the dose of amlodipine can be increased to 10mg if the required level (<140/90 mmHg) was still not achieved.
Losartan	Losartan 50 mg od for 2 weeks and up-titration to losartan 100 mg od for 34 weeks
Losartan + Amlodipine	5 mg of amlodipine in addition to the study medication in order to reach the required BP (<140/90 mmHg). At week 18 the dose of amlodipine can be increased to 10mg if the required level (<140/90 mmHg) was still not achieved.

Measured Values

	Aliskiren	**Aliskiren + Amlodipinet**	**Losartan**	**Losartan + Amlodipine**
Number of Participants Analyzed [units: participants]	**15**	**17**	**16**	**21**
Change From Baseline in Left Ventricular (LV) Function, LV Ejection Fraction (Teicholz), and LV Ejection Fraction (Simpson) in Combination of Aliskiren With Amlodipine [units: Percent] Mean (Standard Deviation)				
LV ejection fraction Teicholz (n=14,15,16,20)	**0.00 (0.09)**	**-0.00 (0.13)**	**-0.00 (0.07)**	**0.01 (0.09)**
LV ejection fraction Simpson(n=11,11,15,19)	**0.05 (0.10)**	**-0.01 (0.17)**	**-0.02 (0.12)**	**0.02 (0.11)**

No statistical analysis provided for Change From Baseline in Left Ventricular (LV) Function, LV Ejection Fraction (Teicholz), and LV Ejection Fraction (Simpson) in Combination of Aliskiren With Amlodipine

13. Secondary: Change From Baseline in Left Ventricular (LV) Function, LA (Left Atrium) Diameter in Combination of Aliskiren With Amlodipine [Time Frame: Baseline, Week 36]

Measure Type	Secondary
Measure Title	Change From Baseline in Left Ventricular (LV) Function, LA (Left Atrium) Diameter in Combination of Aliskiren With Amlodipine
Measure Description	Reductions in the following measurements were analysed between the baseline visit and the final visit: LA diameter
Time Frame	Baseline, Week 36
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.
Intention-to-treat (ITT) population included all patients included in the safety population who had a baseline assessment of the primary variable and at least one post-baseline assessment. Patients with both baseline and week 36 assessment were included in this analysis.

Reporting Groups

	Description
Aliskiren	Aliskiren 150 mg od for 2 weeks and up-titration to aliskiren 300 mg od for 34 weeks
Aliskiren + Amlodipinet	5 mg of amlodipine in addition to the study medication in order to reach the required BP (<140/90 mmHg). At week 18 the dose of amlodipine can be increased to 10mg if the required level (<140/90 mmHg) was still not achieved.
Losartan	Losartan 50 mg od for 2 weeks and up-titration to losartan 100 mg od for 34 weeks
Losartan + Amlodipine	5 mg of amlodipine in addition to the study medication in order to reach the required BP (<140/90 mmHg). At week 18 the dose of amlodipine can be increased to 10mg if the required level (<140/90 mmHg) was still not achieved.

Measured Values

	Aliskiren	**Aliskiren + Amlodipinet**	**Losartan**	**Losartan + Amlodipine**
Number of Participants Analyzed [units: participants]	**12**	**12**	**13**	**17**
Change From Baseline in Left Ventricular (LV) Function, LA (Left Atrium) Diameter in Combination of Aliskiren With Amlodipine [units: mm/m^2] Mean (Standard Deviation)	**-0.18 (1.12)**	**-0.07 (1.27)**	**-0.19 (0.96)**	**-0.24 (1.03)**

No statistical analysis provided for Change From Baseline in Left Ventricular (LV) Function, LA (Left Atrium) Diameter in Combination of Aliskiren With Amlodipine

14. Secondary: Change From Baseline in Left Ventricular (LV) Function, Left Atrial Volume (Biplane Simpson's Method) in Combination of Aliskiren With Amlodipine [Time Frame: Baseline, Week 36]

Measure Type	Secondary
Measure Title	Change From Baseline in Left Ventricular (LV) Function, Left Atrial Volume (Biplane Simpson's Method) in Combination of Aliskiren With Amlodipine
Measure Description	Reductions in the following measurements were analysed between the baseline visit and the final visit: left atrial volume (biplane Simpson's method)
Time Frame	Baseline, Week 36
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.
Intention-to-treat (ITT) population included all patients included in the safety population who had a baseline assessment of the primary variable and at least one post-baseline assessment. Patients with both baseline and week 36 assessment were included in this analysis.

Reporting Groups

	Description
Aliskiren	Aliskiren 150 mg od for 2 weeks and up-titration to aliskiren 300 mg od for 34 weeks
Aliskiren + Amlodipinet	5 mg of amlodipine in addition to the study medication in order to reach the required BP (<140/90 mmHg). At week 18 the dose of amlodipine can be increased to 10mg if the required level (<140/90 mmHg) was still not achieved.
Losartan	Losartan 50 mg od for 2 weeks and up-titration to losartan 100 mg od for 34 weeks
Losartan + Amlodipine	5 mg of amlodipine in addition to the study medication in order to reach the required BP (<140/90 mmHg). At week 18 the dose of amlodipine can be increased to 10mg if the required level (<140/90 mmHg) was still not achieved.

Measured Values

	Aliskiren	**Aliskiren + Amlodipinet**	**Losartan**	**Losartan + Amlodipine**
Number of Participants Analyzed [units: participants]	**6**	**6**	**9**	**13**
Change From Baseline in Left Ventricular (LV) Function, Left Atrial Volume (Biplane Simpson's Method) in Combination of Aliskiren With Amlodipine [units: cm3/m^2] Mean (Standard Deviation)	**-8.88 (15.74)**	**7.78 (17.14)**	**-7.42 (24.37)**	**1.30 (28.21)**

No statistical analysis provided for Change From Baseline in Left Ventricular (LV) Function, Left Atrial Volume (Biplane Simpson's Method) in Combination of Aliskiren With Amlodipine

15. Secondary: Change From Baseline of LVMI in Combination of Aliskiren With Amlodipine [Time Frame: Baseline, Week 36]

Measure Type	Secondary
Measure Title	Change From Baseline of LVMI in Combination of Aliskiren With Amlodipine
Measure Description	Echocardiogram was performed at week 1 and at week 36. Reduction in LVMI is defined as the difference between the LVMI at the final visit and the baseline LVMI
Time Frame	Baseline, Week 36
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.
Intention-to-treat (ITT) population included all patients included in the safety population who had a baseline assessment of the primary variable and at least one post-baseline assessment

Reporting Groups

	Description
Aliskiren	Aliskiren 150 mg od for 2 weeks and up-titration to aliskiren 300 mg od for 34 weeks
Aliskiren + Amlodipinet	5 mg of amlodipine in addition to the study medication in order to reach the required BP (<140/90 mmHg). At week 18 the dose of amlodipine can be increased to 10mg if the required level (<140/90 mmHg) was still not achieved.
Losartan	losartan 50 mg od for 2 weeks and up-titration to losartan 100 mg od for 34 weeks

Losartan + Amlodipine	5 mg of amlodipine in addition to the study medication in order to reach the required BP (<140/90 mmHg). At week 18 the dose of amlodipine can be increased to 10mg if the required level (<140/90 mmHg) was still not achieved.

Measured Values

	Aliskiren	Aliskiren + Amlodipinet	Losartan	Losartan + Amlodipine
Number of Participants Analyzed [units: participants]	**14**	**15**	**16**	**20**
Change From Baseline of LVMI in Combination of Aliskiren With Amlodipine [units: g/m2] Mean (Standard Deviation)	**-5.68 (18.95)**	**-10.26 (19.40)**	**-3.59 (13.46)**	**-11.46 (21.71)**

No statistical analysis provided for Change From Baseline of LVMI in Combination of Aliskiren With Amlodipine

16. Secondary: Effectivness of Aliskiren in Controlling Blood Pressure Compare to Losartan in Terms of Reduction in Systolic Blood Pressure (SBP) [Time Frame: Baseline, Week 10,18,26,36]

Measure Type	Secondary
Measure Title	Effectivness of Aliskiren in Controlling Blood Pressure Compare to Losartan in Terms of Reduction in Systolic Blood Pressure (SBP)
Measure Description	The mean systolic BP (SBP) and diastolic BP (DBP) readings for the aliskiren and losartan treatment groups, the difference in these values between the two groups and the comparison of post-baseline vs. baseline values
Time Frame	Baseline, Week 10,18,26,36
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.
Intention-to-treat (ITT) population included all patients included in the safety population who had a baseline assessment of the primary variable and at least one post-baseline assessment

Reporting Groups

	Description
Aliskiren	Aliskiren 150 mg od for 2 weeks and up-titration to aliskiren 300 mg od for 34 weeks
Lostaran	Losartan 50 mg od for 2 weeks and up-titration to losartan 100 mg od for 34 weeks

Measured Values

	Aliskiren	Lostaran
Number of Participants Analyzed [units: participants]	**32**	**37**
Effectivness of Aliskiren in Controlling Blood Pressure Compare to Losartan in Terms of Reduction in Systolic Blood Pressure (SBP) [units: mmHg] Mean (Standard Deviation)		
Baseline, Week 10 (n=30,37)	**-5.56 (12.89)**	**-4.03 (16.93)**
Baseline, Week 18 (n=29,36)	**-9.77 (12.25)**	**-8.44 (17.30)**
	-12.69	**-10.40**

Baseline, Week 26 (n=29,36)	**(15.05)**	**(15.74)**
Baseline, Week 36 (n=32,37)	**-8.87 (19.26)**	**-8.88 (15.91)**

No statistical analysis provided for Effectivness of Aliskiren in Controlling Blood Pressure Compare to Losartan in Terms of Reduction in Systolic Blood Pressure (SBP)

17. Secondary: Effectivness of Aliskiren in Controlling Blood Pressure Compare to Losartan in Terms of Reduction in Diastolic Blood Pressure (DBP) [Time Frame: Baseline, Week 10,18,26,36]

Measure Type	Secondary
Measure Title	Effectivness of Aliskiren in Controlling Blood Pressure Compare to Losartan in Terms of Reduction in Diastolic Blood Pressure (DBP)
Measure Description	The mean systolic BP (SBP) and diastolic BP (DBP) readings for the aliskiren and losartan treatment groups, the difference in these values between the two groups and the comparison of post-baseline vs. baseline values
Time Frame	Baseline, Week 10,18,26,36
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.
Intention-to-treat (ITT) population included all patients included in the safety population who had a baseline assessment of the primary variable and at least one post-baseline assessment

Reporting Groups

	Description
Aliskiren	Aliskiren 150 mg od for 2 weeks and up-titration to aliskiren 300 mg od for 34 weeks
Lostaran	Losartan 50 mg od for 2 weeks and up-titration to losartan 100 mg od for 34 weeks

Measured Values

	Aliskiren	**Lostaran**
Number of Participants Analyzed [units: participants]	**32**	**37**
Effectivness of Aliskiren in Controlling Blood Pressure Compare to Losartan in Terms of Reduction in Diastolic Blood Pressure (DBP) [units: mmHg] Mean (Standard Deviation)		
Baseline, Week 10 (n=30,37)	**-1.77 (10.22)**	**-3.15 (10.97)**
Baseline, Week 18 (n=29,36)	**-5.34 (10.66)**	**-7.07 (9.98)**
Baseline, Week 26 (n=29,36)	**-5.34 (11.37)**	**-6.94 (10.10)**
Baseline, Week 36 (n=32,37)	**-4.19 (10.32)**	**-6.68 (9.66)**

No statistical analysis provided for Effectivness of Aliskiren in Controlling Blood Pressure Compare to Losartan in Terms of Reduction in Diastolic Blood Pressure (DBP)

18. Secondary: Effectivness of Aliskiren in Controlling Blood Pressure Compare to Losartan in Terms of Patients With Satisfactory Response Rate [Time Frame: Baseline, Week10,18,26,36]

Measure Type	Secondary
Measure Title	Effectivness of Aliskiren in Controlling Blood Pressure Compare to Losartan in Terms of Patients With Satisfactory Response Rate
Measure Description	Response rate was defined as the proportion of patients with a satisfactory systolic BP response (SBP < 140 mmHg or reduction of ≥ 10 mmHg compared to baseline) and a satisfactory diastolic BP response (DBP < 90 mmHg or reduction of ≥ 5 mmHg compared to baseline)
Time Frame	Baseline, Week10,18,26,36
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.
Intention-to-treat (ITT) population included all patients included in the safety population who had a baseline assessment of the primary variable and at least one post-baseline assessment

Reporting Groups

	Description
Aliskiren	Aliskiren 150 mg od for 2 weeks and up-titration to aliskiren 300 mg od for 34 weeks
Lostaran	Losartan 50 mg od for 2 weeks and up-titration to losartan 100 mg od for 34 weeks

Measured Values

	Aliskiren	Lostaran
Number of Participants Analyzed [units: participants]	**32**	**37**
Effectivness of Aliskiren in Controlling Blood Pressure Compare to Losartan in Terms of Patients With Satisfactory Response Rate [units: Patients]		
Baseline, Week 10	**16**	**15**
Baseline, Week 18	**24**	**21**
Baseline, Week 26	**24**	**27**
Baseline, Week 36	**22**	**25**

No statistical analysis provided for Effectivness of Aliskiren in Controlling Blood Pressure Compare to Losartan in Terms of Patients With Satisfactory Response Rate

19. Secondary: Effectivness of Aliskiren in Controlling Blood Pressure Compare to Losartan in Terms of Patients With SBP < 140 mmHg and DBP < 90 mmHg Compared to Baseline [Time Frame: Week10,18,26,36]

Measure Type	Secondary
Measure Title	Effectivness of Aliskiren in Controlling Blood Pressure Compare to Losartan in Terms of Patients With SBP < 140 mmHg and DBP < 90 mmHg Compared to Baseline
Measure Description	The control rate was defined as the proportion of patients with SBP < 140 mmHg and DBP < 90 mmHg compared to baseline
Time Frame	Week10,18,26,36

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.
Intention-to-treat (ITT) population included all patients included in the safety population who had a baseline assessment of the primary variable and at least one post-baseline assessment

Reporting Groups

	Description
Aliskiren	Aliskiren 150 mg od for 2 weeks and up-titration to aliskiren 300 mg od for 34 weeks
Lostaran	Losartan 50 mg od for 2 weeks and up-titration to losartan 100 mg od for 34 weeks

Measured Values

	Aliskiren	Lostaran
Number of Participants Analyzed [units: participants]	**32**	**37**
Effectivness of Aliskiren in Controlling Blood Pressure Compare to Losartan in Terms of Patients With SBP < 140 mmHg and DBP < 90 mmHg Compared to Baseline [units: Patients]		
Control rate at Week 10	**15**	**13**
Control rate at Week 18	**20**	**19**
Control rate at Week 26	**22**	**23**
Control rate at Week 36	**21**	**20**

No statistical analysis provided for Effectivness of Aliskiren in Controlling Blood Pressure Compare to Losartan in Terms of Patients With SBP < 140 mmHg and DBP < 90 mmHg Compared to Baseline

20. Secondary: Effectivness of Aliskiren in Controlling Blood Pressure Compare to Losartan in Terms of Rate of Use of Added Antihypertensive Rescue Drugs [Time Frame: Baseline, Week 10,18,26]

Measure Type	Secondary
Measure Title	Effectivness of Aliskiren in Controlling Blood Pressure Compare to Losartan in Terms of Rate of Use of Added Antihypertensive Rescue Drugs
Measure Description	The rate of use of first and second antihypertensive rescue drugs added was also assessed at all visits after week 2. The rescue drug at week 10 and 18 for those patients not achieving the required BP was amlodipine, Patients who did not achieve the required BP at week 26 were treated with hydrochlorothiazide
Time Frame	Baseline, Week 10,18,26
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.
Intention-to-treat (ITT) population included all patients included in the safety population who had a baseline assessment of the primary variable and at least one post-baseline assessment

Reporting Groups

	Description
Aliskiren	Aliskiren 150 mg od for 2 weeks and up-titration to aliskiren 300 mg od for 34 weeks
Lostaran	Losartan 50 mg od for 2 weeks and up-titration to losartan 100 mg od for 34 weeks

Measured Values

	Aliskiren	Lostaran
Number of Participants Analyzed [units: participants]	**32**	**37**
Effectivness of Aliskiren in Controlling Blood Pressure Compare to Losartan in Terms of Rate of Use of Added Antihypertensive Rescue Drugs [units: Patients]		
Baseline, Week 10 (amlodipine)	**11**	**15**
Baseline, Week 18 (amlodipine)	**2**	**9**
Baseline, Week 26 (hydrochlorothiazide)	**2**	**4**

No statistical analysis provided for Effectivness of Aliskiren in Controlling Blood Pressure Compare to Losartan in Terms of Rate of Use of Added Antihypertensive Rescue Drugs

Serious Adverse Events

Hide Serious Adverse Events

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

Reporting Groups

	Description
Aliskiren	Aliskiren 150 mg od for 2 weeks and up-titration to aliskiren 300 mg od for 34 weeks
Losartan	Losartan 50 mg od for 2 weeks and up-titration to losartan 100 mg od for 34 weeks

Serious Adverse Events

	Aliskiren	Losartan
Total, serious adverse events		
# participants affected / at risk	**2/37 (5.41%)**	**0/37 (0.00%)**
Infections and infestations		
Bronchopneumonia † 1		
# participants affected / at risk	**1/37 (2.70%)**	**0/37 (0.00%)**
Surgical and medical procedures		
Coronary artery bypass † 1		
# participants affected / at risk	**1/37 (2.70%)**	**0/37 (0.00%)**

† 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
Aliskiren	Aliskiren 150 mg od for 2 weeks and up-titration to aliskiren 300 mg od for 34 weeks
Losartan	Losartan 50 mg od for 2 weeks and up-titration to losartan 100 mg od for 34 weeks

Other Adverse Events

	Aliskiren	Losartan
Total, other (not including serious) adverse events		
# participants affected / at risk	**12/37 (32.43%)**	**16/37 (43.24%)**
Cardiac disorders		
Palpitations † 1		
# participants affected / at risk	**2/37 (5.41%)**	**5/37 (13.51%)**
Gastrointestinal disorders		
Abdominal pain † 1		
# participants affected / at risk	**2/37 (5.41%)**	**0/37 (0.00%)**
Diarrhoea † 1		
# participants affected / at risk	**1/37 (2.70%)**	**2/37 (5.41%)**
Vomiting † 1		
# participants affected / at risk	**0/37 (0.00%)**	**2/37 (5.41%)**
General disorders		
Oedema peripheral † 1		
# participants affected / at risk	**3/37 (8.11%)**	**0/37 (0.00%)**
Infections and infestations		
Bronchitis † 1		
# participants affected / at risk	**0/37 (0.00%)**	**2/37 (5.41%)**
Gastroenteritis † 1		
# participants affected / at risk	**1/37 (2.70%)**	**3/37 (8.11%)**
Influenza † 1		
# participants affected / at risk	**1/37 (2.70%)**	**4/37 (10.81%)**
Nasopharyngitis † 1		
# participants affected / at risk	**1/37 (2.70%)**	**3/37 (8.11%)**
Musculoskeletal and connective tissue disorders		
Arthralgia † 1		
# participants affected / at risk	**1/37 (2.70%)**	**2/37 (5.41%)**
Back pain † 1		
# participants affected / at risk	**2/37 (5.41%)**	**2/37 (5.41%)**
Nervous system disorders		

Dizziness † 1		
# participants affected / at risk	**4/37 (10.81%)**	**3/37 (8.11%)**
Headache † 1		
# participants affected / at risk	**4/37 (10.81%)**	**6/37 (16.22%)**
Renal and urinary disorders		
Renal colic † 1		
# participants affected / at risk	**2/37 (5.41%)**	**1/37 (2.70%)**
Vascular disorders		
Hypertension † 1		
# participants affected / at risk	**2/37 (5.41%)**	**0/37 (0.00%)**

† 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 or disclosure of trial results in their entirety

Results Point of Contact:

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No publications provided

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