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Trial record **1 of 1** for: CSPP100A2255

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A Study to Investigate the Pharmacodynamic and Pharmacokinetic Interaction Between Aliskiren and Furosemide in Patients With Heart Failure

This study has been completed.

Sponsor:
Novartis Pharmaceuticals

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

ClinicalTrials.gov Identifier:
NCT01125514

First received: May 17, 2010
Last updated: August 9, 2012
Last verified: August 2012
History of Changes

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Results First Received: August 9, 2012

Study Type:	Interventional
Study Design:	Allocation: Non-Randomized; Intervention Model: Single Group Assignment; Masking: Single Blind (Subject); Primary Purpose: Treatment
Condition:	Heart Failure
Interventions:	Drug: Aliskiren 150 mg Drug: Furosemide 60 mg Drug: Placebo for Aliskiren Drug: Aliskiren 300 mg

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
Furosemide (Fu) /Fu+Aliskiren(Alis)150mg/fu+Alis 300mg	Treatment period 1 (Day 1 to Day 7): All eligible patients received 60 mg furosemide, 150 mg placebo of aliskiren, and 300 mg placebo aliskiren once daily. Treatment Period 2 (Day 8 to day 17): Patients received 60 mg furosemide, 150 mg aliskiren and 300 mg placebo once daily. Treatment Period 3 (Day 18 to day 27): Patients received 60 mg furosemide, 300 mg aliskiren and 150 mg placebo of aliskiren once daily. Day 28, no study treatment.

Participant Flow for 3 periods

Period 1: Treatment Period 1 (Day 1 - Day 7)

	Furosemide (Fu) /Fu+Aliskiren(Alis)150mg/fu+Alis 300mg
STARTED	37 [1]
COMPLETED	35
NOT COMPLETED	2
Adverse Event	1
Administrative problems	1

[1] Randomized and safety population

Period 2: Treatment Period 2 (Day 8 - Day 17)

	Furosemide (Fu) /Fu+Aliskiren(Alis)150mg/fu+Alis 300mg
STARTED	35
Pharmacokinetic (PK) Analysis Set	33
Pharmacodynamics (PD) Analysis Set	33
COMPLETED	32
NOT COMPLETED	3
Adverse Event	3

Period 3: Treatment Period2(Day9-Day27) and Day 28

	Furosemide (Fu) /Fu+Aliskiren(Alis)150mg/fu+Alis 300mg
STARTED	32
COMPLETED	28
NOT COMPLETED	4
Adverse Event	2
Protocol Deviation	1
Withdrawal by Subject	1

Baseline Characteristics

Hide Baseline Characteristics

Population Description

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

Reporting Groups

	Description
Furosemide (Fu) /Fu+Aliskiren(Alis)150mg/fu+Alis 300mg	Treatment period 1 (Day 1 to Day 7): All eligible patients received 60 mg furosemide, 150 mg placebo of aliskiren, and 300 mg placebo aliskiren once daily. Treatment Period 2 (Day 8 to day 17): Patients received 60 mg furosemide, 150 mg aliskiren and 300 mg placebo once daily. Treatment Period 3 (Day 18 to day 27): Patients received 60 mg furosemide, 300 mg aliskiren and 150 mg placebo of aliskiren once daily.

	Day 28, no study treatment.

Baseline Measures

	Furosemide (Fu) /Fu+Aliskiren(Alis)150mg/fu+Alis 300mg
Number of Participants [units: participants]	**37**
Age [units: years] Mean (Standard Deviation)	**59.6 (11.90)**
Gender [units: participants]	
Female	**3**
Male	**34**

Outcome Measures

Hide All Outcome Measures

1. Primary: Diuretic Efficacy Index 1 for Sodium Excretion [Time Frame: 0 to 4 hours]

Measure Type	Primary
Measure Title	Diuretic Efficacy Index 1 for Sodium Excretion
Measure Description	Efficacy of furosemide for sodium excretion (efficacy index 1) was defined by dividing urinary sodium excretion by the urinary excretion of furosemide. Diuretic index 1 for sodium was calculated for the for the total 0 to 4 hour urine collection.
Time Frame	0 to 4 hours
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.
All patients who received at least one dose of study drug and had evaluable pharmacodynamic (PD) data with no major protocol deviation in at least one period were included in the PD analysis set.

Reporting Groups

	Description
Furosemide 60 mg + Aliskiren Placebo	Patient received 60 mg furosemide at steady state + placebo to aliskiren from day 1 to day 7.
Furosemide 60 mg+ Single Dose Aliskiren 150mg	Patient received 60 mg furosemide at steady state + single dose aliskiren 150mg on day 8.
Furosemide 60 mg + Multiple Dose Aliskiren 150mg	Patient received 60 mg furosemide at steady state + single dose aliskiren 150mg (day 9 - day 17).
Furosemide 60 mg + Multiple Dose Aliskiren 300mg	Patient received 60 mg furosemide at steady state + single dose aliskiren 300mg (day 18 - day 27).

Measured Values

	Furosemide 60 mg + Aliskiren Placebo	Furosemide 60 mg+ Single Dose Aliskiren 150mg	Furosemide 60 mg + Multiple Dose Aliskiren 150mg	Furosemide 60 mg + Multiple Dose Aliskiren 300mg
Number of Participants				

Analyzed [units: participants]	**33**	**32**	**31**	**28**
Diuretic Efficacy Index 1 for Sodium Excretion [units: mmol/mg] Mean (Standard Deviation)	**10.185 (4.4568)**	**12.122 (6.2867)**	**13.453 (8.3524)**	**12.858 (6.1040)**

No statistical analysis provided for Diuretic Efficacy Index 1 for Sodium Excretion

2. Primary: Diuretic Efficacy Index 1 for Sodium Excretion [Time Frame: 0 to 24 hours]

Measure Type	Primary
Measure Title	Diuretic Efficacy Index 1 for Sodium Excretion
Measure Description	Efficacy of furosemide for sodium excretion (efficacy index 1) was defined by dividing urinary sodium excretion by the urinary excretion of furosemide. Diuretic index 1 for sodium was calculated for the for the total 0 to 24 hour urine collection.
Time Frame	0 to 24 hours
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.
All patients who received at least one dose of study drug and had evaluable pharmacodynamic (PD) data with no major protocol deviation in at least one period were included in the PD analysis set.

Reporting Groups

	Description
Furosemide 60 mg + Aliskiren Placebo	Patient received 60 mg furosemide at steady state + placebo to aliskiren from day 1 to day 7.
Furosemide 60 mg+ Single Dose Aliskiren 150mg	Patient received 60 mg furosemide at steady state + single dose aliskiren 150mg on day 8.
Furosemide 60 mg + Multiple Dose Aliskiren 150mg	Patient received 60 mg furosemide at steady state + single dose aliskiren 150mg (day 9 - day 17).
Furosemide 60 mg + Multiple Dose Aliskiren 300mg	Patient received 60 mg furosemide at steady state + single dose aliskiren 300mg (day 18 - day 27).

Measured Values

	Furosemide 60 mg + Aliskiren Placebo	**Furosemide 60 mg+ Single Dose Aliskiren 150mg**	**Furosemide 60 mg + Multiple Dose Aliskiren 150mg**	**Furosemide 60 mg + Multiple Dose Aliskiren 300mg**
Number of Participants Analyzed [units: participants]	**31**	**31**	**30**	**28**
Diuretic Efficacy Index 1 for Sodium Excretion [units: mmol/mg] Mean (Standard Deviation)	**10.775 (5.2486)**	**13.264 (6.3535)**	**13.364 (6.1511)**	**14.747 (6.3531)**

No statistical analysis provided for Diuretic Efficacy Index 1 for Sodium Excretion

3. Primary: Diuretic Efficacy Index 2 for Water Excretion [Time Frame: 0 to 4 hours]

Measure Type	Primary
Measure Title	Diuretic Efficacy Index 2 for Water Excretion
Measure Description	Efficacy of furosemide for water excretion (efficacy index 2) was defined by dividing urine volume by the urinary excretion of furosemide.Diuretic index 2 for water was calculated for the 0 to 4 hour fraction urine collection.
Time Frame	0 to 4 hours
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.
All patients who received at least one dose of study drug and had evaluable PD data with no major protocol deviation in at least one period were included in the PD analysis set.

Reporting Groups

	Description
Furosemide 60 mg + Aliskiren Placebo	Patient received 60 mg furosemide at steady state + placebo to aliskiren from day 1 to day 7.
Furosemide 60 mg + Single Dose Aliskiren 150mg	Patient received 60 mg furosemide at steady state + single dose aliskiren 150mg on day 8.
Furosemide 60 mg + Multiple Dose Aliskiren 150mg	Patient received 60 mg furosemide at steady state + single dose aliskiren 150mg (day 9 - day 17).
Furosemide 60 mg + Multiple Dose Aliskiren 300mg	Patient received 60 mg furosemide at steady state + single dose aliskiren 300mg (day 18 - day 27).

Measured Values

	Furosemide 60 mg + Aliskiren Placebo	**Furosemide 60 mg + Single Dose Aliskiren 150mg**	**Furosemide 60 mg + Multiple Dose Aliskiren 150mg**	**Furosemide 60 mg + Multiple Dose Aliskiren 300mg**
Number of Participants Analyzed [units: participants]	**33**	**32**	**31**	**28**
Diuretic Efficacy Index 2 for Water Excretion [units: mL/mg] Mean (Standard Deviation)	**90.402 (34.7866)**	**109.773 (50.2433)**	**119.239 (63.3655)**	**122.157 (58.8815)**

No statistical analysis provided for Diuretic Efficacy Index 2 for Water Excretion

4. Primary: Diuretic Efficacy Index 2 for Water Excretion [Time Frame: 0 to 24 hours]

Measure Type	Primary
Measure Title	Diuretic Efficacy Index 2 for Water Excretion
Measure Description	Efficacy of furosemide for water excretion (efficacy index 2) was defined by dividing urine volume by the urinary excretion of furosemide.Diuretic index 2 for water was calculated for the 0 to 4 hour fraction and for the total 0 to 24 hour urine collection.

Time Frame	0 to 24 hours
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.
All patients who received at least one dose of study drug and had evaluable PD data with no major protocol deviation in at least one period were included in the PD analysis set.

Reporting Groups

	Description
Furosemide 60 mg + Aliskiren Placebo	Patient received 60 mg furosemide at steady state + placebo to aliskiren from day 1 to day 7.
Furosemide 60 mg + Single Dose Aliskiren 150mg	Patient received 60 mg furosemide at steady state + single dose aliskiren 150mg on day 8.
Furosemide 60 mg + Multiple Dose Aliskiren 150mg	Patient received 60 mg furosemide at steady state + single dose aliskiren 150mg (day 9 - day 17).
Furosemide 60 mg + Multiple Dose Aliskiren 300mg	Patient received 60 mg furosemide at steady state + single dose aliskiren 300mg (day 18 - day 27).

Measured Values

	Furosemide 60 mg + Aliskiren Placebo	**Furosemide 60 mg + Single Dose Aliskiren 150mg**	**Furosemide 60 mg + Multiple Dose Aliskiren 150mg**	**Furosemide 60 mg + Multiple Dose Aliskiren 300mg**
Number of Participants Analyzed [units: participants]	**31**	**32**	**30**	**28**
Diuretic Efficacy Index 2 for Water Excretion [units: mL/mg] Mean (Standard Deviation)	**119.439 (46.2607)**	**151.859 (53.6734)**	**154.116 (40.5598)**	**175.112 (59.4236)**

No statistical analysis provided for Diuretic Efficacy Index 2 for Water Excretion

5. Secondary: Plasma Pharmacokinetics (PK) of Furosemide: Area Under the Plasma Concentration-time Curve (AUC) [Time Frame: pre-dose, 0.5, 1, 1.5, 2, 3, 4, 6, 8, 10 and 24 hours post dose]

Measure Type	Secondary
Measure Title	Plasma Pharmacokinetics (PK) of Furosemide: Area Under the Plasma Concentration-time Curve (AUC)
Measure Description	Pharmacokinetic (PK) parameters were determined from the plasma concentration time profile of furosemide using a non-compartmental method: AUCtau: Area under the plasma concentration-time curve from time zero to the end of the dosing interval AUC (0-24): Area under the plasma concentration-time curve from time zero to 24 hours AUClast: Area under the plasma concentration-time curve from time zero to the time of the last quantifiable concentration. AUClast was calculated as the sum of linear trapezoids using non-compartmental analysis. AUCinf: Area under the plasma concentration-time curve from time zero to infinity. AUCinf was calculated by adding AUClast and the value obtained from dividing the last measurable plasma concentration by λz, where λz was determined from automated linear regression of the last three time points with non-zero concentrations in the terminal phase of the log-transformed concentration-time profile
Time Frame	pre-dose, 0.5, 1, 1.5, 2, 3, 4, 6, 8, 10 and 24 hours post dose

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.
All patients who received at least one dose of study drug and had evaluable Pharmacokinetic (PK) data with no major protocol deviation in at least one period were included in the PK analysis set.

Reporting Groups

	Description
Furosemide 60 mg + Aliskiren Placebo	Patient received 60 mg furosemide at steady state + placebo to aliskiren from day 1 to day 7.
Furosemide 60 mg + Single Dose Aliskiren 150mg	Patient received 60 mg furosemide at steady state + single dose aliskiren 150mg on day 8.
Furosemide 60 mg + Multiple Dose Aliskiren 150mg	Patient received 60 mg furosemide at steady state + single dose aliskiren 150mg (day 9 - day 17).
Furosemide 60 mg + Multiple Dose Aliskiren 300mg	Patient received 60 mg furosemide at steady state + single dose aliskiren 300mg (day 18 - day 27).

Measured Values

	Furosemide 60 mg + Aliskiren Placebo	**Furosemide 60 mg + Single Dose Aliskiren 150mg**	**Furosemide 60 mg + Multiple Dose Aliskiren 150mg**	**Furosemide 60 mg + Multiple Dose Aliskiren 300mg**
Number of Participants Analyzed [units: participants]	**33**	**31**	**31**	**28**
Plasma Pharmacokinetics (PK) of Furosemide: Area Under the Plasma Concentration-time Curve (AUC) [units: h*ng/mL] Mean (Standard Deviation)				
AUCtau	**5217 (1996.7)**	**4255 (1390.6)**	**4638 (1532.9)**	**4218 (1469.3)**
AUC	**5217 (1996.7)**	**4255 (1390.6)**	**4638 (1532.9)**	**4218 (1469.3)**
AUClast	**5154 (1999.2)**	**4207 (1387.5)**	**4535 (1531.6)**	**4130 (1525.4)**
AUCinf	**5420 (2005.2)**	**4559 (1387.4)**	**4783 (1611.7)**	**4381 (1578.3)**

No statistical analysis provided for Plasma Pharmacokinetics (PK) of Furosemide: Area Under the Plasma Concentration-time Curve (AUC)

6. Secondary: Plasma Pharmacokinetics (PK) of Furosemide: Observed Maximum Plasma Concentration Following Drug Administration at Steady State (Cmax, ss) [Time Frame: pre-dose, 0.5, 1, 1.5, 2, 3, 4, 6, 8, 10 and 24 hours post dose]

Measure Type	Secondary
Measure Title	Plasma Pharmacokinetics (PK) of Furosemide: Observed Maximum Plasma Concentration Following Drug Administration at Steady State (Cmax, ss)
Measure Description	Cmax,ss was directly determined from the raw plasma concentration-time data.
Time Frame	pre-dose, 0.5, 1, 1.5, 2, 3, 4, 6, 8, 10 and 24 hours post dose
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.
All patients who received at least one dose of study drug and had evaluable pharmacokinetic (PK) data with no major protocol deviation in at least one period were included in the PK analysis set

Reporting Groups

	Description
Furosemide 60 mg + Aliskiren Placebo	Patient received 60 mg furosemide at steady state + placebo to aliskiren from day 1 to day 7.
Furosemide 60 mg + Single Dose Aliskiren 150mg	Patient received 60 mg furosemide at steady state + single dose aliskiren 150mg on day 8.
Furosemide 60 mg + Multiple Dose Aliskiren 150mg	Patient received 60 mg furosemide at steady state + single dose aliskiren 150mg (day 9 - day 17).
Furosemide 60 mg + Multiple Dose Aliskiren 300mg	Patient received 60 mg furosemide at steady state + single dose aliskiren 300mg (day 18 - day 27).

Measured Values

	Furosemide 60 mg + Aliskiren Placebo	**Furosemide 60 mg + Single Dose Aliskiren 150mg**	**Furosemide 60 mg + Multiple Dose Aliskiren 150mg**	**Furosemide 60 mg + Multiple Dose Aliskiren 300mg**
Number of Participants Analyzed [units: participants]	**33**	**31**	**31**	**28**
Plasma Pharmacokinetics (PK) of Furosemide: Observed Maximum Plasma Concentration Following Drug Administration at Steady State (Cmax, ss) [units: ng/mL] Mean (Standard Deviation)	**1702 (708.66)**	**1326 (518.15)**	**1317 (542.73)**	**1180 (404.92)**

No statistical analysis provided for Plasma Pharmacokinetics (PK) of Furosemide: Observed Maximum Plasma Concentration Following Drug Administration at Steady State (Cmax, ss)

7. Secondary: Plasma Pharmacokinetics (PK) of Furosemide: Time to Reach the Maximum Concentration After Drug Administration (Tmax) [Time Frame: pre-dose, 0.5, 1, 1.5, 2, 3, 4, 6, 8, 10 and 24 hours post dose]

Measure Type	Secondary
Measure Title	Plasma Pharmacokinetics (PK) of Furosemide: Time to Reach the Maximum Concentration After Drug Administration (Tmax)
Measure Description	Tmax was directly determined from the raw plasma concentration-time data.
Time Frame	pre-dose, 0.5, 1, 1.5, 2, 3, 4, 6, 8, 10 and 24 hours post dose
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.
All patients who received at least one dose of study drug and had evaluable PK data with no major protocol deviation in at least one period were included in the PK analysis set

Reporting Groups

	Description
Furosemide 60 mg + Aliskiren Placebo	Patient received 60 mg furosemide at steady state + placebo to aliskiren from day 1 to day 7.

Furosemide 60 mg + Single Dose Aliskiren 150mg	Patient received 60 mg furosemide at steady state + single dose aliskiren 150mg on day 8.
Furosemide 60 mg + Multiple Dose Aliskiren 150mg	Patient received 60 mg furosemide at steady state + single dose aliskiren 150mg (day 9 - day 17).
Furosemide 60 mg + Multiple Dose Aliskiren 300mg	Patient received 60 mg furosemide at steady state + single dose aliskiren 300mg (day 18 - day 27).

Measured Values

	Furosemide 60 mg + Aliskiren Placebo	**Furosemide 60 mg + Single Dose Aliskiren 150mg**	**Furosemide 60 mg + Multiple Dose Aliskiren 150mg**	**Furosemide 60 mg + Multiple Dose Aliskiren 300mg**
Number of Participants Analyzed [units: participants]	**33**	**31**	**31**	**28**
Plasma Pharmacokinetics (PK) of Furosemide: Time to Reach the Maximum Concentration After Drug Administration (Tmax) [units: Hours] Median (Full Range)	**1.500 (1.00 to 3.00)**	**1.500 (0.500 to 3.00)**	**1.500 (1.00 to 4.00)**	**2.00 (0.500 to 3.00)**

No statistical analysis provided for Plasma Pharmacokinetics (PK) of Furosemide: Time to Reach the Maximum Concentration After Drug Administration (Tmax)

8. Secondary: Plasma Pharmacokinetics (PK) of Furosemide: Average Steady State Plasma Concentration During Multiple Dosing (Cav,ss) [Time Frame: pre-dose, 0.5, 1, 1.5, 2, 3, 4, 6, 8, 10 and 24 hours post dose]

Measure Type	Secondary
Measure Title	Plasma Pharmacokinetics (PK) of Furosemide: Average Steady State Plasma Concentration During Multiple Dosing (Cav,ss)
Measure Description	The average steady-state drug concentration in the plasma, blood, serum, or other body fluids during multiple dosing [amount x volume-1]. This was estimated as AUC_{τ}/τ
Time Frame	pre-dose, 0.5, 1, 1.5, 2, 3, 4, 6, 8, 10 and 24 hours post dose
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.
All subjects with evaluable pharmacokinetic parameter data with no exclusion flags and no major protocol deviations.

Reporting Groups

	Description
Furosemide 60 mg + Aliskiren Placebo	Patient received 60 mg furosemide at steady state + placebo to aliskiren from day 1 to day 7.
Furosemide 60 mg + Single Dose Aliskiren 150mg	Patient received 60 mg furosemide at steady state + single dose aliskiren 150mg on day 8.
Furosemide 60 mg + Multiple Dose Aliskiren 150mg	Patient received 60 mg furosemide at steady state + single dose aliskiren 150mg (day 9 - day 17).
Furosemide 60 mg + Multiple Dose Aliskiren 300mg	Patient received 60 mg furosemide at steady state + single dose aliskiren 300mg (day 18 - day 27).

Measured Values

	Furosemide 60 mg + Aliskiren Placebo	Furosemide 60 mg + Single Dose Aliskiren 150mg	Furosemide 60 mg + Multiple Dose Aliskiren 150mg	Furosemide 60 mg + Multiple Dose Aliskiren 300mg
Number of Participants Analyzed [units: participants]	**33**	**31**	**31**	**28**
Plasma Pharmacokinetics (PK) of Furosemide: Average Steady State Plasma Concentration During Multiple Dosing (Cav,ss) [units: ng/mL] Mean (Standard Deviation)	**217.4 (83.196)**	**177.3 (57.942)**	**193.2 (63.872)**	**175.8 (61.219)**

No statistical analysis provided for Plasma Pharmacokinetics (PK) of Furosemide: Average Steady State Plasma Concentration During Multiple Dosing (Cav,ss)

9. Secondary: Plasma Pharmacokinetics (PK) of Furosemide: Lowest Plasma Concentration Observed During a Dosing Interval at Steady State (Cmin, ss) [Time Frame: pre-dose, 0.5, 1, 1.5, 2, 3, 4, 6, 8, 10, 24 hours post dose]

Measure Type	Secondary
Measure Title	Plasma Pharmacokinetics (PK) of Furosemide: Lowest Plasma Concentration Observed During a Dosing Interval at Steady State (Cmin, ss)
Measure Description	The minimum observed steady-state drug concentration in the plasma, blood, serum, or other body fluids at the end of the dosing interval during multiple dosing [amount x volume-1]
Time Frame	pre-dose, 0.5, 1, 1.5, 2, 3, 4, 6, 8, 10, 24 hours post dose
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.
All patients who received at least one dose of study drug and had evaluable PK data with no major protocol deviation in at least one period were included in the PK analysis set

Reporting Groups

	Description
Furosemide 60 mg + Aliskiren Placebo	Patient received 60 mg furosemide at steady state + placebo to aliskiren from day 1 to day 7.
Furosemide 60 mg + Single Dose Aliskiren 150mg	Patient received 60 mg furosemide at steady state + single dose aliskiren 150mg on day 8.
Furosemide 60 mg+ Multiple Dose Aliskiren 150mg	Patient received 60 mg furosemide at steady state + single dose aliskiren 150mg (day 9 - day 17).
Furosemide 60 mg + Multiple Dose Aliskiren 300mg	Patient received 60 mg furosemide at steady state + single dose aliskiren 300mg (day 18 - day 27).

Measured Values

	Furosemide 60 mg + Aliskiren Placebo	Furosemide 60 mg + Single Dose Aliskiren 150mg	Furosemide 60 mg+ Multiple Dose Aliskiren 150mg	Furosemide 60 mg + Multiple Dose Aliskiren 300mg
Number of Participants Analyzed [units: participants]	**33**	**31**	**31**	**28**
Plasma Pharmacokinetics (PK) of Furosemide: Lowest				

Plasma Concentration Observed During a Dosing Interval at Steady State (Cmin, ss) [units: ng/mL] Mean (Standard Deviation)	**20.42 (25.558)**	**20.03 (23.780)**	**19.80 (29.258)**	**16.70 (20.868)**

No statistical analysis provided for Plasma Pharmacokinetics (PK) of Furosemide: Lowest Plasma Concentration Observed During a Dosing Interval at Steady State (Cmin, ss)

10. Secondary: Urine Pharmacokinetics (PK) of Furosemide: Amount of Drug Excreted Into the Urine From Time Zero to 24 Hours After Administration (Ae0-24) [Time Frame: 0 to 4, 4 to 8, 8 to 12 and 12 to 24 hours post dose]

Measure Type	Secondary
Measure Title	Urine Pharmacokinetics (PK) of Furosemide: Amount of Drug Excreted Into the Urine From Time Zero to 24 Hours After Administration (Ae0-24)
Measure Description	The area under the plasma (or serum or blood) concentration-time curve from time zero to 24 h [mass × time × volume-1]
Time Frame	0 to 4, 4 to 8, 8 to 12 and 12 to 24 hours post dose
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.
All patients who received at least one dose of study drug and had evaluable PK data with no major protocol deviation in at least one period were included in the PK analysis set

Reporting Groups

	Description
Furosemide 60 mg + Aliskiren Placebo	Patient received 60 mg furosemide at steady state + placebo to aliskiren from day 1 to day 7.
Furosemide 60 mg + Single Dose Aliskiren 150mg	Patient received 60 mg furosemide at steady state + single dose aliskiren 150mg on day 8.
Furosemide 60 mg + Multiple Dose Aliskiren 150mg	Patient received 60 mg furosemide at steady state + single dose aliskiren 150mg (day 9 - day 17).
Furosemide 60 mg+ Multiple Dose Aliskiren 300mg	Patient received 60 mg furosemide at steady state + single dose aliskiren 300mg (day 18 - day 27).

Measured Values

	Furosemide 60 mg + Aliskiren Placebo	**Furosemide 60 mg + Single Dose Aliskiren 150mg**	**Furosemide 60 mg + Multiple Dose Aliskiren 150mg**	**Furosemide 60 mg+ Multiple Dose Aliskiren 300mg**
Number of Participants Analyzed [units: participants]	**31**	**31**	**30**	**28**
Urine Pharmacokinetics (PK) of Furosemide: Amount of Drug Excreted Into the Urine From Time Zero to 24 Hours After Administration (Ae0-24) [units: mg] Mean (Standard Deviation)	**18.61 (5.9012)**	**15.08 (3.9613)**	**14.98 (4.5264)**	**13.63 (4.5134)**

No statistical analysis provided for Urine Pharmacokinetics (PK) of Furosemide: Amount of Drug Excreted Into the Urine From Time Zero to 24 Hours After Administration (Ae0-24)

11. Secondary: Urine Pharmacokinetics (PK) of Furosemide: Renal Clearance (CLR) [Time Frame: 0 to 4, 4 to 8, 8 to 12 and 12 to 24 hours post dose]

Measure Type	Secondary
Measure Title	Urine Pharmacokinetics (PK) of Furosemide: Renal Clearance (CLR)
Measure Description	The renal clearance of drug [volume x time-1]
Time Frame	0 to 4, 4 to 8, 8 to 12 and 12 to 24 hours post dose
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.
All patients who received at least one dose of study drug and had evaluable pharmacodynamic (PD) data with no major protocol deviation in at least one period were included in the PD analysis set.

Reporting Groups

	Description
Furosemide 60 mg + Aliskiren Placebo	Patient received 60 mg furosemide at steady state + placebo to aliskiren from day 1 to day 7.
Furosemide 60 mg + Single Dose Aliskiren 150mg	Patient received 60 mg furosemide at steady state + single dose aliskiren 150mg on day 8.
Furosemide 60 mg + Multiple Dose Aliskiren 150mg	Patient received 60 mg furosemide at steady state + single dose aliskiren 150mg (day 9 - day 17).
Furosemide 60 mg + Multiple Dose Aliskiren 300mg	Patient received 60 mg furosemide at steady state + single dose aliskiren 300mg (day 18 - day 27).

Measured Values

	Furosemide 60 mg + Aliskiren Placebo	**Furosemide 60 mg + Single Dose Aliskiren 150mg**	**Furosemide 60 mg + Multiple Dose Aliskiren 150mg**	**Furosemide 60 mg + Multiple Dose Aliskiren 300mg**
Number of Participants Analyzed [units: participants]	**31**	**31**	**30**	**28**
Urine Pharmacokinetics (PK) of Furosemide: Renal Clearance (CLR) [units: L/h] Mean (Standard Deviation)	**3.808 (1.3567)**	**3.841 (1.4321)**	**3.519 (1.3592)**	**3.561 (1.4458)**

No statistical analysis provided for Urine Pharmacokinetics (PK) of Furosemide: Renal Clearance (CLR)

12. Secondary: Creatinine Clearance [Time Frame: 0 to 4, 4 to 8, 8 to 12 and 12 to 24 hours post dose]

Measure Type	Secondary
Measure Title	Creatinine Clearance
Measure Description	Creatinine clearance= (Urine creatinine/Serum creatinine) x (Urine volume/(24*60)).
Time Frame	0 to 4, 4 to 8, 8 to 12 and 12 to 24 hours post dose
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.
All patients who received at least one dose of study drug and had evaluable PD data with no major protocol deviation in at least one period were included in the PD analysis set.

Reporting Groups

	Description
Furosemide 60 mg + Aliskiren Placebo	Patient received 60 mg furosemide at steady state + placebo to aliskiren from day 1 to day 7.
Furosemide 60 mg + Single Dose Aliskiren 150mg	Patient received 60 mg furosemide at steady state + single dose aliskiren 150mg on day 8.
Furosemide 60 mg + Multiple Dose Aliskiren 150mg	Patient received 60 mg furosemide at steady state + single dose aliskiren 150mg (day 9 - day 17).
Furosemide 60 mg + Multiple Dose Aliskiren 300mg	Patient received 60 mg furosemide at steady state + single dose aliskiren 300mg (day 18 - day 27).

Measured Values

	Furosemide 60 mg + Aliskiren Placebo	**Furosemide 60 mg + Single Dose Aliskiren 150mg**	**Furosemide 60 mg + Multiple Dose Aliskiren 150mg**	**Furosemide 60 mg + Multiple Dose Aliskiren 300mg**
Number of Participants Analyzed [units: participants]	**32**	**32**	**29**	**28**
Creatinine Clearance [units: mL/min] Mean (Standard Deviation)	**104.745 (38.2884)**	**109.657 (30.0667)**	**103.841 (28.2845)**	**105.304 (25.4076)**

No statistical analysis provided for Creatinine Clearance

13. Secondary: Urine Sodium and Potassium Excretion Per Treatment at 4 Hours Postdose [Time Frame: 4 hours postdose]

Measure Type	Secondary
Measure Title	Urine Sodium and Potassium Excretion Per Treatment at 4 Hours Postdose
Measure Description	Urine was collected 4 hours postdose in all treatment groups for sodium and potassium analysis. Each patient was required to void their bladder before drug administration and at the end 4 hours.
Time Frame	4 hours postdose
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.
All patients who received at least one dose of study drug and had evaluable pharmacodynamics (PD)data with no major protocol deviation in at least one period were included in the PD analysis set.

Reporting Groups

	Description

Furosemide 60 mg + Aliskiren Placebo	Patient received 60 mg furosemide at steady state + placebo to aliskiren from day 1 to day 7.
Furosemide 60 mg + Single Dose Aliskiren 150mg	Patient received 60 mg furosemide at steady state + single dose aliskiren 150mg on day 8.
Furosemide 60 mg + Multiple Dose Aliskiren 150mg	Patient received 60 mg furosemide at steady state + single dose aliskiren 150mg (day 9 - day 17).
Furosemide 60 mg + Multiple Dose Aliskiren 300mg	Patient received 60 mg furosemide at steady state + single dose aliskiren 300mg (day 18 - day 27).

Measured Values

	Furosemide 60 mg + Aliskiren Placebo	**Furosemide 60 mg + Single Dose Aliskiren 150mg**	**Furosemide 60 mg + Multiple Dose Aliskiren 150mg**	**Furosemide 60 mg + Multiple Dose Aliskiren 300mg**
Number of Participants Analyzed [units: participants]	**33**	**32**	**31**	**28**
Urine Sodium and Potassium Excretion Per Treatment at 4 Hours Postdose [units: mmol] Mean (Standard Deviation)				
Sodium excretion	**113.992 (47.5976)**	**104.031 (49.5036)**	**98.691 (55.0495)**	**93.341 (43.9419)**
Potassium excretion	**24.555 (11.9749)**	**19.403 (10.5975)**	**23.046 (8.6829)**	**21.037 (7.9355)**

No statistical analysis provided for Urine Sodium and Potassium Excretion Per Treatment at 4 Hours Postdose

14. Secondary: Urine Sodium and Potassium Excretion Per Treatment at 8 Hours Postdose [Time Frame: 8 hours postdose]

Measure Type	Secondary
Measure Title	Urine Sodium and Potassium Excretion Per Treatment at 8 Hours Postdose
Measure Description	Urine was collected 8 hours postdose in all treatment groups for sodium and potassium analysis. Each patient was required to void their bladder before drug administration and at the end 8 hours.
Time Frame	8 hours postdose
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.
All patients who received at least one dose of study drug and had evaluable pharmacodynamics (PD)data with no major protocol deviation in at least one period were included in the PD analysis set.

Reporting Groups

	Description
Furosemide 60 mg + Aliskiren Placebo	Patient received 60 mg furosemide at steady state + placebo to aliskiren from day 1 to day 7.
Furosemide 60 mg + Single Dose Aliskiren 150mg	Patient received 60 mg furosemide at steady state + single dose aliskiren 150mg on day 8.
Furosemide 60 mg + Multiple Dose Aliskiren 150mg	Patient received 60 mg furosemide at steady state + single dose aliskiren 150mg (day 9 - day 17).

Furosemide 60 mg + Multiple Dose Aliskiren 300mg	Patient received 60 mg furosemide at steady state + single dose aliskiren 300mg (day 18 - day 27).

Measured Values

	Furosemide 60 mg + Aliskiren Placebo	Furosemide 60 mg + Single Dose Aliskiren 150mg	Furosemide 60 mg + Multiple Dose Aliskiren 150mg	Furosemide 60 mg + Multiple Dose Aliskiren 300mg
Number of Participants Analyzed [units: participants]	**33**	**31**	**31**	**28**
Urine Sodium and Potassium Excretion Per Treatment at 8 Hours Postdose [units: mmol] Mean (Standard Deviation)				
Sodium excretion	**129.990 (49.2835)**	**123.835 (56.2734)**	**125.677 (58.6125)**	**119.776 (59.0523)**
Potassium excretion	**33.474 (12.2417)**	**28.068 (12.5292)**	**36.120 (14.4509)**	**32.498 (9.6174)**

No statistical analysis provided for Urine Sodium and Potassium Excretion Per Treatment at 8 Hours Postdose

15. Secondary: Urine Sodium and Potassium Excretion Per Treatment at 12 Hours Postdose [Time Frame: 12 hours postdose]

Measure Type	Secondary
Measure Title	Urine Sodium and Potassium Excretion Per Treatment at 12 Hours Postdose
Measure Description	Urine was collected 12 hours postdose in all treatment groups for sodium and potassium analysis. Each patient was required to void their bladder before drug administration and at the end 12 hours.
Time Frame	12 hours postdose
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.
All patients who received at least one dose of study drug and had evaluable pharmacodynamics (PD)data with no major protocol deviation in at least one period were included in the PD analysis set.

Reporting Groups

	Description
Furosemide 60 mg + Aliskiren Placebo	Patient received 60 mg furosemide at steady state + placebo to aliskiren from day 1 to day 7.
Furosemide 60 mg + Single Dose Aliskiren 150mg	Patient received 60 mg furosemide at steady state + single dose aliskiren 150mg on day 8.
Furosemide 60 mg + Multiple Dose Aliskiren 150mg	Patient received 60 mg furosemide at steady state + single dose aliskiren 150mg (day 9 - day 17).
Furosemide 60 mg + Multiple Dose Aliskiren 300mg	Patient received 60 mg furosemide at steady state + single dose aliskiren 300mg (day 18 - day 27).

Measured Values

	Furosemide 60 mg + Aliskiren Placebo	Furosemide 60 mg + Single Dose Aliskiren 150mg	Furosemide 60 mg + Multiple Dose Aliskiren 150mg	Furosemide 60 mg + Multiple Dose Aliskiren 300mg

Number of Participants Analyzed [units: participants]	**32**	**32**	**31**	**27**
Urine Sodium and Potassium Excretion Per Treatment at 12 Hours Postdose [units: mmol] Mean (Standard Deviation)				
Sodium excretion	**151.254 (57.6190)**	**142.476 (59.1617)**	**144.839 (63.6708)**	**140.887 (68.4341)**
Potassium excretion	**45.013 (17.3416)**	**37.827 (16.0087)**	**46.770 (17.4395)**	**44.137 (11.0631)**

No statistical analysis provided for Urine Sodium and Potassium Excretion Per Treatment at 12 Hours Postdose

16. Secondary: Urine Sodium and Potassium Excretion Per Treatment at 24 Hours Postdose [Time Frame: 24 hours postdose]

Measure Type	Secondary
Measure Title	Urine Sodium and Potassium Excretion Per Treatment at 24 Hours Postdose
Measure Description	Urine was collected 24 hours postdose in all treatment groups for sodium and potassium analysis. Each patient was required to void their bladder before drug administration and at the end 24 hours.
Time Frame	24 hours postdose
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.
All patients who received at least one dose of study drug and had evaluable pharmacodynamics (PD)data with no major protocol deviation in at least one period were included in the PD analysis set.

Reporting Groups

	Description
Furosemide 60 mg + Aliskiren Placebo	Patient received 60 mg furosemide at steady state + placebo to aliskiren from day 1 to day 7.
Furosemide 60 mg + Single Dose Aliskiren 150mg	Patient received 60 mg furosemide at steady state + single dose aliskiren 150mg on day 8.
Furosemide 60 mg + Multiple Dose Aliskiren 150mg	Patient received 60 mg furosemide at steady state + single dose aliskiren 150mg (day 9 - day 17).
Furosemide 60 mg + Multiple Dose Aliskiren 300mg	Patient received 60 mg furosemide at steady state + single dose aliskiren 300mg (day 18 - day 27).

Measured Values

	Furosemide 60 mg + Aliskiren Placebo	**Furosemide 60 mg + Single Dose Aliskiren 150mg**	**Furosemide 60 mg + Multiple Dose Aliskiren 150mg**	**Furosemide 60 mg + Multiple Dose Aliskiren 300mg**
Number of Participants Analyzed [units: participants]	**31**	**31**	**30**	**28**
Urine Sodium and Potassium Excretion Per Treatment at 24 Hours Postdose [units: mmol] Mean (Standard Deviation)				

Sodium excretion	**185.426 (69.9537)**	**187.256 (69.1028)**	**188.886 (73.8708)**	**192.176 (76.0983)**
Potassium excretion	**57.323 (20.0607)**	**53.107 (21.3416)**	**62.715 (20.4014)**	**61.012 (13.6072)**

No statistical analysis provided for Urine Sodium and Potassium Excretion Per Treatment at 24 Hours Postdose

17. Secondary: Mean Sitting Systolic Blood Pressure (msSBP)and Mean Sitting Diastolic Blood Pressure (msDBP) [Time Frame: 0.5 hour pre-dose, 0.5, 1, 2, 4, 8, 12 and 24 hours post dose.]

Measure Type	Secondary
Measure Title	Mean Sitting Systolic Blood Pressure (msSBP)and Mean Sitting Diastolic Blood Pressure (msDBP)
Measure Description	Sitting blood pressure was measured three times at 1 to 2-minute intervals. The mean of the three sitting blood pressure measurements was used as the average of the sitting office blood pressure. The msSBP and msDBP data were analyzed using a mixed effect model with fixed effects from treatment and treatment*time; random effect from patients and predose as covariate.
Time Frame	0.5 hour pre-dose, 0.5, 1, 2, 4, 8, 12 and 24 hours post dose.
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.
Safety analysis set include subjects that received study drug.

Reporting Groups

	Description
Furosemide 60 mg + Aliskiren Placebo	Patient received 60 mg furosemide at steady state + placebo to aliskiren from day 1 to day 7.
Furosemide 60 mg + Multiple Dose Aliskiren 150mg	Patient received 60 mg furosemide at steady state + single dose aliskiren 150mg (day 9 - day 17).
Furosemide go mg + Multiple Dose Aliskiren 300mg	Patient received 60 mg furosemide at steady state + single dose aliskiren 300mg (day 18 - day 27).

Measured Values

	Furosemide 60 mg + Aliskiren Placebo	**Furosemide 60 mg + Multiple Dose Aliskiren 150mg**	**Furosemide go mg + Multiple Dose Aliskiren 300mg**
Number of Participants Analyzed [units: participants]	**37**	**35**	**32**
Mean Sitting Systolic Blood Pressure (msSBP)and Mean Sitting Diastolic Blood Pressure (msDBP) [units: mmHg] Least Squares Mean (Standard Error)			
0.5 predose (msSBP)	**118.26 (1.62)**	**117.09 (1.70)**	**116.63 (1.80)**
0.5 hour predose (msDBP)	**71.70 (0.98)**	**71.41 (1.04)**	**71.39 (1.10)**
0.5 hour Postdose (msSBP)	**114.78 (1.64)**	**113.19 (1.70)**	**114.31 (1.80)**
0.5 hour Postdose (msDBP)	**70.94 (1.00)**	**69.04 (1.04)**	**69.86 (1.10)**
1 hour Postdose (msSBP)	**115.15 (1.64)**	**112.22 (1.70)**	**112.16 (1.80)**
1 hour Postdose (msDBP)	**71.22 (1.00)**	**69.04 (1.04)**	**68.96 (1.10)**
2 hour Postdose (msSBP)	**113.61 (1.64)**	**109.22 (1.70)**	**109.63 (1.80)**

2 hour Postdose (msDBP)	68.39 (1.10)	67.50 (1.04)	68.39 (1.10)
4 hour Postdose (msSBP)	106.50 (1.64)	101.84 (1.70)	101.06 (1.80)
4 hour Postdose (msDBP)	63.85 (1.00)	62.32 (1.04)	59.07 (1.10)
8 hour Postdose (msSBP)	110.75 (1.66)	112.09 (1.70)	109.95 (1.80)
8 hour Postdose (msDBP)	66.33 (1.01)	66.94 (1.04)	66.46 (1.10)
12 hour Postdose (msSBP)	116.99 (1.66)	116.90 (1.70)	115.16 (1.80)
12 hour Postdose (msdBP)	67.86 (1.01)	68.79 (1.04)	68.50 (1.10)
24 hour Postdose (msSBP)	115.49 (1.66)	116.69 (1.72)	118.41 (1.80)
24 hour Postdose (msDBP)	71.24 (1.01)	71.66 (1.05)	72.32 (1.10)

No statistical analysis provided for Mean Sitting Systolic Blood Pressure (msSBP)and Mean Sitting Diastolic Blood Pressure (msDBP)

Serious Adverse Events

Hide Serious Adverse Events

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

Reporting Groups

	Description
60 mg Furosemide + 150 mg Placebo + 300 mg Placebo	60 mg furosemide + 150 mg placebo + 300 mg placebo
60 mg Furosemide + 150 mg Aliskiren + 300 mg Placebo	60 mg furosemide + 150 mg aliskiren + 300 mg placebo
60 mg Furosemide + 300 mg Aliskiren + 150 mg Placebo	60 mg furosemide + 300 mg aliskiren + 150 mg placebo

Serious Adverse Events

	60 mg Furosemide + 150 mg Placebo + 300 mg Placebo	60 mg Furosemide + 150 mg Aliskiren + 300 mg Placebo	60 mg Furosemide + 300 mg Aliskiren + 150 mg Placebo
Total, serious adverse events			
# participants affected / at risk	**2/37 (5.41%)**	**0/33 (0.00%)**	**0/31 (0.00%)**
Injury, poisoning and procedural complications			
Rib fracture † 1			
# participants affected / at risk	**1/37 (2.70%)**	**0/33 (0.00%)**	**0/31 (0.00%)**
Metabolism and nutrition disorders			
Gout † 1			
# participants affected / at risk	**1/37 (2.70%)**	**0/33 (0.00%)**	**0/31 (0.00%)**
Respiratory, thoracic and mediastinal disorders			
Haemothorax † 1			
# participants affected / at risk	**1/37 (2.70%)**	**0/33 (0.00%)**	**0/31 (0.00%)**

Pneumothorax † 1			
# participants affected / at risk	**1/37 (2.70%)**	**0/33 (0.00%)**	**0/31 (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
60 mg Furosemide + 150 mg Placebo + 300 mg Placebo	60 mg furosemide + 150 mg placebo + 300 mg placebo
60 mg Furosemide + 150 mg Aliskiren + 300 mg Placebo	60 mg furosemide + 150 mg aliskiren + 300 mg placebo
60 mg Furosemide + 300 mg Aliskiren + 150 mg Placebo	60 mg furosemide + 300 mg aliskiren + 150 mg placebo

Other Adverse Events

	60 mg Furosemide + 150 mg Placebo + 300 mg Placebo	**60 mg Furosemide + 150 mg Aliskiren + 300 mg Placebo**	**60 mg Furosemide + 300 mg Aliskiren + 150 mg Placebo**
Total, other (not including serious) adverse events			
# participants affected / at risk	**0/37 (0.00%)**	**0/33 (0.00%)**	**0/31 (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 disclosure of 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:	Novartis (Novartis Pharmaceuticals)
ClinicalTrials.gov Identifier:	NCT01125514 History of Changes
Other Study ID Numbers:	**CSPP100A2255**
Study First Received:	May 17, 2010
Results First Received:	August 9, 2012
Last Updated:	August 9, 2012
Health Authority:	Germany: Ministry of Health Lithuania: State Medicine Control Agency - Ministry of Health