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Trial record **1 of 1** for: CSPP100A2366

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Safety and Efficacy of Aliskiren on the Progression of Atherosclerosis in Coronary Artery Disease Patients (AQUARIUS)

This study has been completed.

Sponsor:
Novartis Pharmaceuticals

Collaborator:
The Cleveland Clinic

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

ClinicalTrials.gov Identifier:
NCT00853827

First received: February 26, 2009
Last updated: May 20, 2014
Last verified: May 2014
History of Changes

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Results First Received: January 23, 2014

Study Type:	Interventional
Study Design:	Allocation: Randomized; Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Investigator); Primary Purpose: Treatment
Conditions:	Coronary Artery Disease (CAD) Coronary Atherosclerosis
Interventions:	Drug: Placebo Drug: Aliskiren

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	Period 1(Screening Period) visit 1(Day -42 to Day -1) eligibility for study participation was assessed. Period 2: Visit 2 to 3, single blind for 1 week: patients received aliskiren 150 mg. Period 3: visit 3 to 15, Double-blind Randomization/Forced Titration and Maintenance Period for 103 weeks: patients received 2 tablets aliskiren 150 mg (force titration)
Placebo	Period 1(Screening Period) visit 1(Day -42 to Day -1) eligibility for study participation was assessed. Period 2: visit 2 to 3, single blind for 1 week: patients received 1 tablet aliskiren 150 mg, 1 tablet placebo 150 mg. Period 3: visit 3 to 15, Double-blind Randomization/Forced Titration and Maintenance Period for 103 weeks: patients received 2 tablets placebo 150 mg

Participant Flow for 2 periods

Period 1: Single Blind Period (1 Week)

	Aliskiren	Placebo
STARTED	652 [1]	0 [2]
COMPLETED	613 [3]	0
NOT COMPLETED	39	0
unknown	4	0
Adverse Event	9	0
Abnormal laboratory value	3	0
Abnormal test procedure result	1	0
Withdrawal by Subject	9	0
Lost to Follow-up	1	0
Protocol Violation	12	0

[1] Enrolled patients in single blind
[2] This arm was only used in double blind period
[3] Completed patients in single blind period

Period 2: Double Blind Period (103 Weeks)

	Aliskiren	Placebo
STARTED	305 [1]	308
Modified Full Analysis Set (mFAS)	225	233
COMPLETED	201	199
NOT COMPLETED	104	109
Adverse Event	25	14
Abnormal laboratory values	0	3
Lack of Efficacy	1	0
Patient's no longer requires study drug	3	1
Protocol Violation	2	1
Withdrawal by Subject	19	18
Lost to Follow-up	8	10
Administrative problems	45	56
Death	1	6

[1] "Started" indicates number of patients in randomized set, full analysis set (FAS) and safety set.

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.
Randomized - All patients who received a randomization number, regardless of whether or not the patient received the trial medication

Reporting Groups

	Description
Aliskiren	Period 1(Screening Period) visit 1(Day -42 to Day -1) eligibility for study participation was assessed. Period 2: Visit 2 to 3, single blind for 1 week: patients received aliskiren 150 mg. Period 3: visit 3 to 15, Double-blind Randomization/Forced Titration and Maintenance Period for 103 weeks: patients received 2 tablets aliskiren 150 mg (force titration)
Placebo	Period 1(Screening Period) visit 1(Day -42 to Day -1) eligibility for study participation was assessed. Period 2: visit 2 to 3, single blind for 1 week: patients received 1 tablet aliskiren 150 mg, 1 tablet placebo 150 mg. Period 3: visit 3 to 15, Double-blind Randomization/Forced Titration and Maintenance Period for 103 weeks: patients received 2 tablets placebo 150 mg
Total	Total of all reporting groups

Baseline Measures

	Aliskiren	Placebo	Total
Number of Participants [units: participants]	**305**	**308**	**613**
Age [units: years] Mean (Standard Deviation)	**60.2 (9.35)**	**59.2 (8.32)**	**59.7 (8.86)**
Gender [units: participants]			
Female	**77**	**69**	**146**
Male	**228**	**239**	**467**

Outcome Measures

Hide All Outcome Measures

1. Primary: Change From Baseline in Percent Atheroma Volume(PAV) After 104 Weeks of Treatment [Time Frame: Baseline, 104 weeks]

Measure Type	Primary
Measure Title	Change From Baseline in Percent Atheroma Volume(PAV) After 104 Weeks of Treatment
Measure Description	Change from baseline in PAV for all matched slices of anatomically comparable segments of the target coronary artery were assessed by intravascular ultrasound (IVUS) evaluation after 104 weeks of treatment . calculation for change is the value at the later time point minus the value at the earlier time point, with positive numbers to represent increases and negative numbers to represent decreases
Time Frame	Baseline, 104 weeks
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.
Full Analysis Set (FAS) - All randomized patients. Patients were analyzed according to the treatment that they were assigned at randomization. All patients who had a valid baseline and post baseline IVUS measurement and post-baseline IVUS measurement and at least ≥72 weeks of treatment were included in this analysis.

Reporting Groups

	Description
Aliskiren	Period 1(Screening Period) visit 1(Day -42 to Day -1) eligibility for study participation was assessed. Period 2: Visit 2 to 3, single blind for 1 week: patients received aliskiren 150 mg. Period 3: visit 3 to 15, Double-blind Randomization/Forced Titration and Maintenance Period for 103 weeks: patients received 2 tablets aliskiren 150 mg (force titration)
Placebo	Period 1(Screening Period) visit 1(Day -42 to Day -1) eligibility for study participation was assessed. Period 2: visit 2 to 3, single blind for 1 week: patients received 1 tablet aliskiren 150 mg, 1 tablet placebo 150 mg. Period 3: visit 3 to 15, Double-blind

	Randomization/Forced Titration and Maintenance Period for 103 weeks: patients received 2 tablets placebo 150 mg

Measured Values

	Aliskiren	Placebo
Number of Participants Analyzed [units: participants]	**225**	**233**
Change From Baseline in Percent Atheroma Volume(PAV) After 104 Weeks of Treatment [units: percentage of baseline] Least Squares Mean (Standard Error)	**-0.33 (0.18)**	**0.11 (0.18)**

No statistical analysis provided for Change From Baseline in Percent Atheroma Volume(PAV) After 104 Weeks of Treatment

2. Secondary: Change in Normalized Total Atheroma Volume (TAV) as Assessed by IVUS [Time Frame: Baseline, 104 weeks]

Measure Type	Secondary
Measure Title	Change in Normalized Total Atheroma Volume (TAV) as Assessed by IVUS
Measure Description	Change from baseline in normalized total atheroma volume (TAV) (mm^3) for all matched slices of anatomically comparable segments of the target coronary artery were assess by IVUS after 104 weeks of treatment. calculation for change is the value at the later time point minus the value at the earlier time point, with positive numbers to represent increases and negative numbers to represent decreases
Time Frame	Baseline, 104 weeks
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.
Full Analysis Set (FAS) - All randomized patients. Patients were analyzed according to the treatment that they were assigned at randomization. All patients who had a valid baseline and post baseline IVUS measurement and post-baseline IVUS measurement and at least ≥72 weeks of treatment were included in this analysis.

Reporting Groups

	Description
Aliskiren	Period 1(Screening Period) visit 1(Day -42 to Day -1) eligibility for study participation was assessed. Period 2: Visit 2 to 3, single blind for 1 week: patients received aliskiren 150 mg. Period 3: visit 3 to 15, Double-blind Randomization/Forced Titration and Maintenance Period for 103 weeks: patients received 2 tablets aliskiren 150 mg (force titration)
Placebo	Period 1(Screening Period) visit 1(Day -42 to Day -1) eligibility for study participation was assessed. Period 2: visit 2 to 3, single blind for 1 week: patients received 1 tablet aliskiren 150 mg, 1 tablet placebo 150 mg. Period 3: visit 3 to 15, Double-blind Randomization/Forced Titration and Maintenance Period for 103 weeks: patients received 2 tablets placebo 150 mg

Measured Values

	Aliskiren	Placebo
Number of Participants Analyzed [units: participants]	**225**	**233**
Change in Normalized Total Atheroma Volume (TAV) as Assessed by IVUS [units: mm^3] Least Squares Mean (Standard Error)	**-4.11 (1.10)**	**-2.07 (1.09)**

No statistical analysis provided for Change in Normalized Total Atheroma Volume (TAV) as Assessed by IVUS

3. Secondary: Patients That Demonstrated Evidence of Atheroma Regression [Time Frame: Baseline to endpoint (104 weeks)]

Measure Type	Secondary
Measure Title	Patients That Demonstrated Evidence of Atheroma Regression
Measure Description	Atheroma regression is defined as change from baseline to endpoint in PAV <0 .
Time Frame	Baseline to endpoint (104 weeks)
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.
Full Analysis Set (FAS) - All randomized patients. Patients were analyzed according to the treatment that they were assigned at randomization

Reporting Groups

	Description
Aliskiren	Period 1(Screening Period) visit 1(Day -42 to Day -1) eligibility for study participation was assessed. Period 2: Visit 2 to 3, single blind for 1 week: patients received aliskiren 150 mg. Period 3: visit 3 to 15, Double-blind Randomization/Forced Titration and Maintenance Period for 103 weeks: patients received 2 tablets aliskiren 150 mg (force titration)
Placebo	Period 1(Screening Period) visit 1(Day -42 to Day -1) eligibility for study participation was assessed. Period 2: visit 2 to 3, single blind for 1 week: patients received 1 tablet aliskiren 150 mg, 1 tablet placebo 150 mg. Period 3: visit 3 to 15, Double-blind Randomization/Forced Titration and Maintenance Period for 103 weeks: patients received 2 tablets placebo 150 mg

Measured Values

	Aliskiren	Placebo
Number of Participants Analyzed [units: participants]	**225**	**233**
Patients That Demonstrated Evidence of Atheroma Regression [units: Participants]	**128**	**114**

No statistical analysis provided for Patients That Demonstrated Evidence of Atheroma Regression

4. Secondary: Number of Patients With Adverse Events, Serious Adverse Events, and Death [Time Frame: 104 weeks]

Measure Type	Secondary
Measure Title	Number of Patients With Adverse Events, Serious Adverse Events, and Death
Measure Description	overall safety and tolerability of aliskiren 300 mg compared to placebo in patients with CAD and BP in the pre-hypertensive (high normal) range with or without treatment for hypertension following 104 weeks of treatment. Any Adverse Event was defined as occurrence of any symptom regardless of intensity grade, Serious Adverse Event (SAEs) assessed as medical occurrences that result in death, are life threatening, require hospitalization or prolongation of hospitalization or result in persistent or significant disability/incapacity.
Time Frame	104 weeks
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Safety - All patients who received at least one dose of double-blind trial medication. Patients were analyzed according to the treatment that they received

Reporting Groups

	Description
Aliskiren	Period 1(Screening Period) visit 1(Day -42 to Day -1) eligibility for study participation was assessed. Period 2: Visit 2 to 3, single blind for 1 week: patients received aliskiren 150 mg. Period 3: visit 3 to 15, Double-blind Randomization/Forced Titration and Maintenance Period for 103 weeks: patients received 2 tablets aliskiren 150 mg (force titration)
Placebo	Period 1(Screening Period) visit 1(Day -42 to Day -1) eligibility for study participation was assessed. Period 2: visit 2 to 3, single blind for 1 week: patients received 1 tablet aliskiren 150 mg, 1 tablet placebo 150 mg. Period 3: visit 3 to 15, Double-blind Randomization/Forced Titration and Maintenance Period for 103 weeks: patients received 2 tablets placebo 150 mg

Measured Values

	Aliskiren	Placebo
Number of Participants Analyzed [units: participants]	**305**	**308**
Number of Patients With Adverse Events, Serious Adverse Events, and Death [units: Number of patients]		
SAEs	**76**	**97**
AE	**228**	**227**
Death	**1**	**6**

No statistical analysis provided for Number of Patients With Adverse Events, Serious Adverse Events, and Death

Serious Adverse Events

Hide Serious Adverse Events

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

Reporting Groups

	Description
Aliskiren 300 mg	Visit 2 to 3, single blind for 1 week: patients received aliskiren 150 mg. visit 3 to 15, Double-blind Randomization/Forced Titration and Maintenance Period for 103 weeks: patients received 2 tablets aliskiren 150 mg (force titration)
Placebo	Period 1(Screening Period) visit 1(Day -42 to Day -1) eligibility for study participation was assessed. Period 2: visit 2 to 3, single blind for 1 week: patients received 1 tablet aliskiren 150 mg, 1 tablet placebo 150 mg. Period 3: visit 3 to 15, Double-blind Randomization/Forced Titration and Maintenance Period for 103 weeks: patients received 2 tablets placebo 150 mg

Serious Adverse Events

	Aliskiren 300 mg	Placebo
Total, serious adverse events		
# participants affected / at risk	**76/305 (24.92%)**	**97/308 (31.49%)**
Blood and lymphatic system disorders		
Anaemia † 1		
# participants affected / at risk	**1/305 (0.33%)**	**1/308 (0.32%)**
Spontaneous haematoma † 1		
# participants affected / at risk	**1/305 (0.33%)**	**0/308 (0.00%)**
Thrombocytopenia † 1		

# participants affected / at risk	1/305 (0.33%)	0/308 (0.00%)
Cardiac disorders		
Acute coronary syndrome † [1]		
# participants affected / at risk	1/305 (0.33%)	3/308 (0.97%)
Acute myocardial infarction † [1]		
# participants affected / at risk	0/305 (0.00%)	2/308 (0.65%)
Angina pectoris † [1]		
# participants affected / at risk	6/305 (1.97%)	12/308 (3.90%)
Angina unstable † [1]		
# participants affected / at risk	6/305 (1.97%)	6/308 (1.95%)
Arteriosclerosis coronary artery † [1]		
# participants affected / at risk	1/305 (0.33%)	2/308 (0.65%)
Atrial fibrillation † [1]		
# participants affected / at risk	2/305 (0.66%)	2/308 (0.65%)
Atrial flutter † [1]		
# participants affected / at risk	0/305 (0.00%)	1/308 (0.32%)
Cardiac arrest † [1]		
# participants affected / at risk	0/305 (0.00%)	1/308 (0.32%)
Cardiac failure † [1]		
# participants affected / at risk	0/305 (0.00%)	1/308 (0.32%)
Cardiac failure acute † [1]		
# participants affected / at risk	0/305 (0.00%)	1/308 (0.32%)
Coronary artery disease † [1]		
# participants affected / at risk	2/305 (0.66%)	5/308 (1.62%)
Coronary artery occlusion † [1]		
# participants affected / at risk	1/305 (0.33%)	2/308 (0.65%)
Coronary artery stenosis † [1]		
# participants affected / at risk	2/305 (0.66%)	5/308 (1.62%)
Myocardial infarction † [1]		
# participants affected / at risk	1/305 (0.33%)	2/308 (0.65%)
Myocardial ischaemia † [1]		
# participants affected / at risk	2/305 (0.66%)	2/308 (0.65%)
Sick sinus syndrome † [1]		
# participants affected / at risk	0/305 (0.00%)	1/308 (0.32%)
Tachycardia † [1]		
# participants affected / at risk	1/305 (0.33%)	1/308 (0.32%)
Ventricular fibrillation † [1]		
# participants affected / at risk	1/305 (0.33%)	0/308 (0.00%)
Congenital, familial and genetic disorders		
Atrial septal defect † [1]		
# participants affected / at risk	1/305 (0.33%)	0/308 (0.00%)
Ear and labyrinth disorders		
Deafness † [1]		
# participants affected / at risk	1/305 (0.33%)	0/308 (0.00%)

Tinnitus † 1		
# participants affected / at risk	**1/305 (0.33%)**	**0/308 (0.00%)**
Endocrine disorders		
Hyperparathyroidism † 1		
# participants affected / at risk	**1/305 (0.33%)**	**0/308 (0.00%)**
Eye disorders		
Amaurosis fugax † 1		
# participants affected / at risk	**0/305 (0.00%)**	**1/308 (0.32%)**
Cataract † 1		
# participants affected / at risk	**1/305 (0.33%)**	**0/308 (0.00%)**
Retinal degeneration † 1		
# participants affected / at risk	**0/305 (0.00%)**	**1/308 (0.32%)**
Visual impairment † 1		
# participants affected / at risk	**1/305 (0.33%)**	**0/308 (0.00%)**
Gastrointestinal disorders		
Abdominal hernia † 1		
# participants affected / at risk	**0/305 (0.00%)**	**1/308 (0.32%)**
Abdominal pain † 1		
# participants affected / at risk	**2/305 (0.66%)**	**0/308 (0.00%)**
Diarrhoea † 1		
# participants affected / at risk	**1/305 (0.33%)**	**0/308 (0.00%)**
Dyspepsia † 1		
# participants affected / at risk	**1/305 (0.33%)**	**0/308 (0.00%)**
Enterocolitis † 1		
# participants affected / at risk	**0/305 (0.00%)**	**1/308 (0.32%)**
Gastric ulcer † 1		
# participants affected / at risk	**0/305 (0.00%)**	**1/308 (0.32%)**
Gastritis † 1		
# participants affected / at risk	**0/305 (0.00%)**	**1/308 (0.32%)**
Gastrointestinal haemorrhage † 1		
# participants affected / at risk	**1/305 (0.33%)**	**2/308 (0.65%)**
Gastrointestinal inflammation † 1		
# participants affected / at risk	**1/305 (0.33%)**	**0/308 (0.00%)**
Gastrooesophageal reflux disease † 1		
# participants affected / at risk	**1/305 (0.33%)**	**0/308 (0.00%)**
Inguinal hernia † 1		
# participants affected / at risk	**0/305 (0.00%)**	**1/308 (0.32%)**
Intestinal obstruction † 1		
# participants affected / at risk	**0/305 (0.00%)**	**1/308 (0.32%)**
Large intestine perforation † 1		
# participants affected / at risk	**0/305 (0.00%)**	**1/308 (0.32%)**
Melaena † 1		
# participants affected / at risk	**1/305 (0.33%)**	**0/308 (0.00%)**
Nausea † 1		

# participants affected / at risk	1/305 (0.33%)	0/308 (0.00%)
Pancreatitis acute † 1		
# participants affected / at risk	1/305 (0.33%)	0/308 (0.00%)
Peptic ulcer † 1		
# participants affected / at risk	0/305 (0.00%)	1/308 (0.32%)
Rectal haemorrhage † 1		
# participants affected / at risk	1/305 (0.33%)	0/308 (0.00%)
Small intestinal obstruction † 1		
# participants affected / at risk	0/305 (0.00%)	1/308 (0.32%)
Vomiting † 1		
# participants affected / at risk	2/305 (0.66%)	0/308 (0.00%)
General disorders		
Asthenia † 1		
# participants affected / at risk	0/305 (0.00%)	1/308 (0.32%)
Catheter site haemorrhage † 1		
# participants affected / at risk	1/305 (0.33%)	0/308 (0.00%)
Chest discomfort † 1		
# participants affected / at risk	1/305 (0.33%)	0/308 (0.00%)
Chest pain † 1		
# participants affected / at risk	1/305 (0.33%)	2/308 (0.65%)
Fatigue † 1		
# participants affected / at risk	2/305 (0.66%)	1/308 (0.32%)
Multi-organ failure † 1		
# participants affected / at risk	0/305 (0.00%)	1/308 (0.32%)
Non-cardiac chest pain † 1		
# participants affected / at risk	4/305 (1.31%)	4/308 (1.30%)
Oedema peripheral † 1		
# participants affected / at risk	2/305 (0.66%)	0/308 (0.00%)
Pyrexia † 1		
# participants affected / at risk	0/305 (0.00%)	1/308 (0.32%)
Sudden cardiac death † 1		
# participants affected / at risk	0/305 (0.00%)	1/308 (0.32%)
Sudden death † 1		
# participants affected / at risk	0/305 (0.00%)	1/308 (0.32%)
Hepatobiliary disorders		
Cholecystitis † 1		
# participants affected / at risk	1/305 (0.33%)	1/308 (0.32%)
Cholelithiasis † 1		
# participants affected / at risk	1/305 (0.33%)	0/308 (0.00%)
Hydrocholecystis † 1		
# participants affected / at risk	0/305 (0.00%)	1/308 (0.32%)
Infections and infestations		
Abscess intestinal † 1		
# participants affected / at risk	0/305 (0.00%)	1/308 (0.32%)

Cellulitis † 1		
# participants affected / at risk	**2/305 (0.66%)**	**0/308 (0.00%)**
Diverticulitis † 1		
# participants affected / at risk	**0/305 (0.00%)**	**2/308 (0.65%)**
Enterocolitis infectious † 1		
# participants affected / at risk	**1/305 (0.33%)**	**0/308 (0.00%)**
Gastroenteritis † 1		
# participants affected / at risk	**0/305 (0.00%)**	**2/308 (0.65%)**
Liver abscess † 1		
# participants affected / at risk	**0/305 (0.00%)**	**1/308 (0.32%)**
Lobar pneumonia † 1		
# participants affected / at risk	**1/305 (0.33%)**	**0/308 (0.00%)**
Meningitis aseptic † 1		
# participants affected / at risk	**1/305 (0.33%)**	**0/308 (0.00%)**
Osteomyelitis † 1		
# participants affected / at risk	**0/305 (0.00%)**	**1/308 (0.32%)**
Pneumonia † 1		
# participants affected / at risk	**2/305 (0.66%)**	**3/308 (0.97%)**
Pneumonia bacterial † 1		
# participants affected / at risk	**0/305 (0.00%)**	**1/308 (0.32%)**
Pneumonia klebsiella † 1		
# participants affected / at risk	**0/305 (0.00%)**	**1/308 (0.32%)**
Pyelonephritis acute † 1		
# participants affected / at risk	**1/305 (0.33%)**	**0/308 (0.00%)**
Sepsis † 1		
# participants affected / at risk	**1/305 (0.33%)**	**2/308 (0.65%)**
Staphylococcal sepsis † 1		
# participants affected / at risk	**0/305 (0.00%)**	**1/308 (0.32%)**
Sweat gland infection † 1		
# participants affected / at risk	**0/305 (0.00%)**	**1/308 (0.32%)**
Urinary tract infection † 1		
# participants affected / at risk	**0/305 (0.00%)**	**1/308 (0.32%)**
Injury, poisoning and procedural complications		
Arterial restenosis † 1		
# participants affected / at risk	**2/305 (0.66%)**	**1/308 (0.32%)**
Coronary artery restenosis † 1		
# participants affected / at risk	**1/305 (0.33%)**	**4/308 (1.30%)**
Femur fracture † 1		
# participants affected / at risk	**1/305 (0.33%)**	**0/308 (0.00%)**
Fibula fracture † 1		
# participants affected / at risk	**0/305 (0.00%)**	**1/308 (0.32%)**
Humerus fracture † 1		
# participants affected / at risk	**0/305 (0.00%)**	**1/308 (0.32%)**
Joint dislocation † 1		

# participants affected / at risk	1/305 (0.33%)	0/308 (0.00%)
Joint injury † 1		
# participants affected / at risk	0/305 (0.00%)	1/308 (0.32%)
Ligament rupture † 1		
# participants affected / at risk	0/305 (0.00%)	1/308 (0.32%)
Overdose † 1		
# participants affected / at risk	2/305 (0.66%)	1/308 (0.32%)
Road traffic accident † 1		
# participants affected / at risk	0/305 (0.00%)	1/308 (0.32%)
Spinal compression fracture † 1		
# participants affected / at risk	0/305 (0.00%)	1/308 (0.32%)
Toxicity to various agents † 1		
# participants affected / at risk	1/305 (0.33%)	0/308 (0.00%)
Vascular pseudoaneurysm † 1		
# participants affected / at risk	0/305 (0.00%)	1/308 (0.32%)
Wound dehiscence † 1		
# participants affected / at risk	0/305 (0.00%)	1/308 (0.32%)
Investigations		
Electrocardiogram ST segment depression † 1		
# participants affected / at risk	0/305 (0.00%)	2/308 (0.65%)
Electrocardiogram T wave inversion † 1		
# participants affected / at risk	0/305 (0.00%)	1/308 (0.32%)
Metabolism and nutrition disorders		
Dehydration † 1		
# participants affected / at risk	1/305 (0.33%)	0/308 (0.00%)
Diabetes mellitus † 1		
# participants affected / at risk	2/305 (0.66%)	1/308 (0.32%)
Diabetes mellitus inadequate control † 1		
# participants affected / at risk	0/305 (0.00%)	1/308 (0.32%)
Musculoskeletal and connective tissue disorders		
Back pain † 1		
# participants affected / at risk	0/305 (0.00%)	1/308 (0.32%)
Haemarthrosis † 1		
# participants affected / at risk	1/305 (0.33%)	0/308 (0.00%)
Intervertebral disc protrusion † 1		
# participants affected / at risk	0/305 (0.00%)	1/308 (0.32%)
Lumbar spinal stenosis † 1		
# participants affected / at risk	0/305 (0.00%)	1/308 (0.32%)
Neck pain † 1		
# participants affected / at risk	1/305 (0.33%)	0/308 (0.00%)
Osteoarthritis † 1		
# participants affected / at risk	1/305 (0.33%)	1/308 (0.32%)
Spinal column stenosis † 1		
# participants affected / at risk	0/305 (0.00%)	1/308 (0.32%)

Neoplasms benign, malignant and unspecified (incl cysts and polyps)		
Basal cell carcinoma † 1		
# participants affected / at risk	**0/305 (0.00%)**	**1/308 (0.32%)**
Bladder cancer † 1		
# participants affected / at risk	**2/305 (0.66%)**	**0/308 (0.00%)**
Bladder papilloma † 1		
# participants affected / at risk	**1/305 (0.33%)**	**0/308 (0.00%)**
Breast cancer † 1		
# participants affected / at risk	**1/305 (0.33%)**	**0/308 (0.00%)**
Colon cancer † 1		
# participants affected / at risk	**0/305 (0.00%)**	**1/308 (0.32%)**
Mesothelioma † 1		
# participants affected / at risk	**1/305 (0.33%)**	**0/308 (0.00%)**
Pancreatic carcinoma metastatic † 1		
# participants affected / at risk	**0/305 (0.00%)**	**1/308 (0.32%)**
Prostate cancer † 1		
# participants affected / at risk	**2/305 (0.66%)**	**0/308 (0.00%)**
Prostatic adenoma † 1		
# participants affected / at risk	**0/305 (0.00%)**	**1/308 (0.32%)**
Rectal adenoma † 1		
# participants affected / at risk	**1/305 (0.33%)**	**0/308 (0.00%)**
Squamous cell carcinoma † 1		
# participants affected / at risk	**0/305 (0.00%)**	**1/308 (0.32%)**
Nervous system disorders		
Cerebral ischaemia † 1		
# participants affected / at risk	**1/305 (0.33%)**	**0/308 (0.00%)**
Cerebral microangiopathy † 1		
# participants affected / at risk	**1/305 (0.33%)**	**0/308 (0.00%)**
Cerebrovascular accident † 1		
# participants affected / at risk	**1/305 (0.33%)**	**2/308 (0.65%)**
Convulsion † 1		
# participants affected / at risk	**2/305 (0.66%)**	**0/308 (0.00%)**
Headache † 1		
# participants affected / at risk	**1/305 (0.33%)**	**2/308 (0.65%)**
Ischaemic stroke † 1		
# participants affected / at risk	**0/305 (0.00%)**	**1/308 (0.32%)**
Paraesthesia † 1		
# participants affected / at risk	**2/305 (0.66%)**	**0/308 (0.00%)**
Syncope † 1		
# participants affected / at risk	**3/305 (0.98%)**	**1/308 (0.32%)**
Transient ischaemic attack † 1		
# participants affected / at risk	**0/305 (0.00%)**	**1/308 (0.32%)**
Vertebrobasilar insufficiency † 1		
# participants affected / at risk	**0/305 (0.00%)**	**1/308 (0.32%)**

Psychiatric disorders		
Conversion disorder † 1		
# participants affected / at risk	**0/305 (0.00%)**	**1/308 (0.32%)**
Depression † 1		
# participants affected / at risk	**1/305 (0.33%)**	**1/308 (0.32%)**
Depression suicidal † 1		
# participants affected / at risk	**1/305 (0.33%)**	**0/308 (0.00%)**
Suicidal ideation † 1		
# participants affected / at risk	**1/305 (0.33%)**	**0/308 (0.00%)**
Suicide attempt † 1		
# participants affected / at risk	**1/305 (0.33%)**	**0/308 (0.00%)**
Renal and urinary disorders		
Haematuria † 1		
# participants affected / at risk	**0/305 (0.00%)**	**2/308 (0.65%)**
Nephrolithiasis † 1		
# participants affected / at risk	**1/305 (0.33%)**	**0/308 (0.00%)**
Renal failure † 1		
# participants affected / at risk	**1/305 (0.33%)**	**0/308 (0.00%)**
Renal failure acute † 1		
# participants affected / at risk	**1/305 (0.33%)**	**1/308 (0.32%)**
Urethral stenosis † 1		
# participants affected / at risk	**1/305 (0.33%)**	**0/308 (0.00%)**
Urinary retention † 1		
# participants affected / at risk	**0/305 (0.00%)**	**1/308 (0.32%)**
Reproductive system and breast disorders		
Benign prostatic hyperplasia † 1		
# participants affected / at risk	**0/305 (0.00%)**	**1/308 (0.32%)**
Uterine haemorrhage † 1		
# participants affected / at risk	**1/305 (0.33%)**	**0/308 (0.00%)**
Uterine polyp † 1		
# participants affected / at risk	**0/305 (0.00%)**	**1/308 (0.32%)**
Respiratory, thoracic and mediastinal disorders		
Asthma † 1		
# participants affected / at risk	**1/305 (0.33%)**	**0/308 (0.00%)**
Chronic obstructive pulmonary disease † 1		
# participants affected / at risk	**2/305 (0.66%)**	**0/308 (0.00%)**
Diaphragmatic disorder † 1		
# participants affected / at risk	**0/305 (0.00%)**	**1/308 (0.32%)**
Dyspnoea † 1		
# participants affected / at risk	**1/305 (0.33%)**	**1/308 (0.32%)**
Dyspnoea exertional † 1		
# participants affected / at risk	**0/305 (0.00%)**	**1/308 (0.32%)**
Epistaxis † 1		
# participants affected / at risk	**1/305 (0.33%)**	**0/308 (0.00%)**

Pleural effusion † 1		
# participants affected / at risk	**1/305 (0.33%)**	**0/308 (0.00%)**
Pneumothorax † 1		
# participants affected / at risk	**0/305 (0.00%)**	**1/308 (0.32%)**
Pulmonary embolism † 1		
# participants affected / at risk	**2/305 (0.66%)**	**0/308 (0.00%)**
Pulmonary oedema † 1		
# participants affected / at risk	**0/305 (0.00%)**	**1/308 (0.32%)**
Respiratory arrest † 1		
# participants affected / at risk	**0/305 (0.00%)**	**1/308 (0.32%)**
Skin and subcutaneous tissue disorders		
Dermal cyst † 1		
# participants affected / at risk	**0/305 (0.00%)**	**1/308 (0.32%)**
Diabetic ulcer † 1		
# participants affected / at risk	**0/305 (0.00%)**	**1/308 (0.32%)**
Psoriasis † 1		
# participants affected / at risk	**1/305 (0.33%)**	**0/308 (0.00%)**
Vascular disorders		
Aortic aneurysm † 1		
# participants affected / at risk	**0/305 (0.00%)**	**1/308 (0.32%)**
Aortic stenosis † 1		
# participants affected / at risk	**3/305 (0.98%)**	**0/308 (0.00%)**
Arterial stenosis † 1		
# participants affected / at risk	**0/305 (0.00%)**	**1/308 (0.32%)**
Arteriosclerosis † 1		
# participants affected / at risk	**1/305 (0.33%)**	**0/308 (0.00%)**
Hypertensive crisis † 1		
# participants affected / at risk	**0/305 (0.00%)**	**1/308 (0.32%)**
Hypotension † 1		
# participants affected / at risk	**1/305 (0.33%)**	**0/308 (0.00%)**
Hypovolaemic shock † 1		
# participants affected / at risk	**0/305 (0.00%)**	**1/308 (0.32%)**
Peripheral arterial occlusive disease † 1		
# participants affected / at risk	**0/305 (0.00%)**	**1/308 (0.32%)**
Peripheral artery aneurysm † 1		
# participants affected / at risk	**0/305 (0.00%)**	**1/308 (0.32%)**
Peripheral embolism † 1		
# participants affected / at risk	**0/305 (0.00%)**	**1/308 (0.32%)**
Reperfusion injury † 1		
# participants affected / at risk	**1/305 (0.33%)**	**0/308 (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	2%

Reporting Groups

	Description
Aliskiren 300 mg	Visit 2 to 3, single blind for 1 week: patients received aliskiren 150 mg. visit 3 to 15, Double-blind Randomization/Forced Titration and Maintenance Period for 103 weeks: patients received 2 tablets aliskiren 150 mg (force titration)
Placebo	Period 1(Screening Period) visit 1(Day -42 to Day -1) eligibility for study participation was assessed. Period 2: visit 2 to 3, single blind for 1 week: patients received 1 tablet aliskiren 150 mg, 1 tablet placebo 150 mg. Period 3: visit 3 to 15, Double-blind Randomization/Forced Titration and Maintenance Period for 103 weeks: patients received 2 tablets placebo 150 mg

Other Adverse Events

	Aliskiren 300 mg	Placebo
Total, other (not including serious) adverse events		
# participants affected / at risk	**186/305 (60.98%)**	**175/308 (56.82%)**
Cardiac disorders		
Angina pectoris † 1		
# participants affected / at risk	**21/305 (6.89%)**	**24/308 (7.79%)**
Palpitations † 1		
# participants affected / at risk	**4/305 (1.31%)**	**8/308 (2.60%)**
Gastrointestinal disorders		
Constipation † 1		
# participants affected / at risk	**8/305 (2.62%)**	**10/308 (3.25%)**
Diarrhoea † 1		
# participants affected / at risk	**20/305 (6.56%)**	**15/308 (4.87%)**
Dyspepsia † 1		
# participants affected / at risk	**5/305 (1.64%)**	**8/308 (2.60%)**
Gastrooesophageal reflux disease † 1		
# participants affected / at risk	**9/305 (2.95%)**	**5/308 (1.62%)**
Nausea † 1		
# participants affected / at risk	**15/305 (4.92%)**	**13/308 (4.22%)**
General disorders		
Asthenia † 1		
# participants affected / at risk	**7/305 (2.30%)**	**8/308 (2.60%)**
Chest pain † 1		
# participants affected / at risk	**5/305 (1.64%)**	**9/308 (2.92%)**
Fatigue † 1		
# participants affected / at risk	**32/305 (10.49%)**	**21/308 (6.82%)**
Non-cardiac chest pain † 1		

# participants affected / at risk	23/305 (7.54%)	21/308 (6.82%)
Oedema peripheral † 1		
# participants affected / at risk	19/305 (6.23%)	18/308 (5.84%)
Infections and infestations		
Bronchitis † 1		
# participants affected / at risk	10/305 (3.28%)	14/308 (4.55%)
Influenza † 1		
# participants affected / at risk	16/305 (5.25%)	10/308 (3.25%)
Nasopharyngitis † 1		
# participants affected / at risk	23/305 (7.54%)	13/308 (4.22%)
Sinusitis † 1		
# participants affected / at risk	6/305 (1.97%)	10/308 (3.25%)
Upper respiratory tract infection † 1		
# participants affected / at risk	7/305 (2.30%)	8/308 (2.60%)
Urinary tract infection † 1		
# participants affected / at risk	8/305 (2.62%)	10/308 (3.25%)
Injury, poisoning and procedural complications		
Fall † 1		
# participants affected / at risk	7/305 (2.30%)	6/308 (1.95%)
Musculoskeletal and connective tissue disorders		
Arthralgia † 1		
# participants affected / at risk	16/305 (5.25%)	9/308 (2.92%)
Back pain † 1		
# participants affected / at risk	21/305 (6.89%)	13/308 (4.22%)
Muscle spasms † 1		
# participants affected / at risk	3/305 (0.98%)	9/308 (2.92%)
Musculoskeletal pain † 1		
# participants affected / at risk	8/305 (2.62%)	14/308 (4.55%)
Myalgia † 1		
# participants affected / at risk	10/305 (3.28%)	7/308 (2.27%)
Pain in extremity † 1		
# participants affected / at risk	14/305 (4.59%)	15/308 (4.87%)
Nervous system disorders		
Dizziness † 1		
# participants affected / at risk	35/305 (11.48%)	28/308 (9.09%)
Headache † 1		
# participants affected / at risk	18/305 (5.90%)	22/308 (7.14%)
Hypoaesthesia † 1		
# participants affected / at risk	9/305 (2.95%)	7/308 (2.27%)
Syncope † 1		
# participants affected / at risk	9/305 (2.95%)	4/308 (1.30%)
Psychiatric disorders		
Anxiety † 1		
# participants affected / at risk	3/305 (0.98%)	9/308 (2.92%)

Depression † 1		
# participants affected / at risk	**6/305 (1.97%)**	**12/308 (3.90%)**
Reproductive system and breast disorders		
Benign prostatic hyperplasia † 1		
# participants affected / at risk	**3/305 (0.98%)**	**9/308 (2.92%)**
Respiratory, thoracic and mediastinal disorders		
Cough † 1		
# participants affected / at risk	**14/305 (4.59%)**	**12/308 (3.90%)**
Dyspnoea † 1		
# participants affected / at risk	**12/305 (3.93%)**	**17/308 (5.52%)**
Epistaxis † 1		
# participants affected / at risk	**9/305 (2.95%)**	**1/308 (0.32%)**
Sinus congestion † 1		
# participants affected / at risk	**7/305 (2.30%)**	**4/308 (1.30%)**
Vascular disorders		
Hypertension † 1		
# participants affected / at risk	**16/305 (5.25%)**	**22/308 (7.14%)**
Hypotension † 1		
# participants affected / at risk	**21/305 (6.89%)**	**12/308 (3.90%)**

† 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:

Name/Title: Study Director
Organization: Novartis Pharmaceuticals
phone: 862-778-8300
e-mail: trialandresults.registries@novartis.com

No publications provided by Novartis

Publications automatically indexed to this study:

Puri R, Nissen SE, Menon V, Shao M, Hsu A, Bakris GL, Kastelein JJ, Williams B, Armbrecht J, Brunel P, Kataoka Y, Nicholls SJ. Effects of aliskiren in diabetic and non-diabetic patients with coronary artery disease: Insights from AQUARIUS. Atherosclerosis. 2015 Dec;243(2):553-9. doi: 10.1016/j.atherosclerosis.2015.10.019. Epub 2015 Oct 20.

Nicholls SJ, Bakris GL, Kastelein JJ, Menon V, Williams B, Armbrecht J, Brunel P, Nicolaides M, Hsu A, Hu B, Fang H, Puri R, Uno K, Kataoka Y, Bash D, Nissen SE. Effect of aliskiren on progression of coronary disease in patients with prehypertension: the AQUARIUS randomized clinical trial. JAMA. 2013 Sep 18;310(11):1135-44. doi: 10.1001/jama.2013.277169.

Responsible Party:	Novartis (Novartis Pharmaceuticals)
ClinicalTrials.gov Identifier:	NCT00853827 History of Changes
Other Study ID Numbers:	**CSPP100A2366** 2008-006447-40
Study First Received:	February 26, 2009
Results First Received:	January 23, 2014
Last Updated:	May 20, 2014
Health Authority:	United States: Food and Drug Administration Argentina: Ministry of Health Australia: Human Research Ethics Committee Belgium: Federal Agency for Medicinal Products and Health Products Canada: Health Canada France: Afssaps - Agence française de sécurité sanitaire des produits de santé (Saint-Denis) Germany: Federal Institute for Drugs and Medical Devices Hungary: Research Ethics Medical Committee Italy: National Institute of Health Poland: Ministry of Health Spain: Spanish Agency of Medicines