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Trial record **1 of 1** for: CSPP100A2404

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A Study Evaluating the Gastrointestinal (GI) Safety and Tolerability of Aliskiren Compared to Ramipril in Essential Hypertension

This study has been completed.

Sponsor:
Novartis

Information provided by:
Novartis

ClinicalTrials.gov Identifier:
NCT00631917

First received: March 3, 2008
Last updated: June 30, 2011
Last verified: June 2011
History of Changes

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Results First Received: January 5, 2011

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Caregiver, Investigator, Outcomes Assessor); Primary Purpose: Treatment
Condition:	Hypertension
Interventions:	Drug: Aliskiren Drug: Ramipril Other: Placebo to Ramipril Other: Placebo to 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	For the first 2 weeks of the study, participants received aliskiren 150 mg once a day and were then forced titrated to aliskiren 300 mg once a day for 52 weeks. Participants also received a placebo capsule to match ramipril once a day for the study duration.
Ramipril	For the first 2 weeks of the study participants received 5 mg ramipril orally once a day and were then forced titrated to ramipril 10 mg once a day for 52 weeks. Participants also received placebo to aliskiren for the duration of the study.

Participant Flow: Overall Study

	Aliskiren	Ramipril
STARTED	375	399
COMPLETED	287	291
NOT COMPLETED	88	108
Adverse Event	34	45
Abnormal laboratory value(s)	2	1
Abnormal test procedure result(s)	3	2
Unsatisfactory therapeutic effect	8	14
No longer required study drug	0	1
Protocol deviation	6	5
Subject withdrew consent	25	33
Lost to Follow-up	7	7
Administrative problems	2	0
Death	1	0

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
Aliskiren	For the first 2 weeks of the study, participants received aliskiren 150 mg once a day and were then forced titrated to aliskiren 300 mg once a day for 52 weeks. Participants also received a placebo capsule to match ramipril once a day for the study duration.
Ramipril	For the first 2 weeks of the study participants received 5 mg ramipril orally once a day and were then forced titrated to ramipril 10 mg once a day for 52 weeks. Participants also received placebo to aliskiren for the duration of the study.
Total	Total of all reporting groups

Baseline Measures

	Aliskiren	Ramipril	Total
Number of Participants [units: participants]	375	399	774
Age [units: years] Mean (Standard Deviation)	59.3 (6.99)	59.3 (6.65)	59.3 (6.81)
Age, Customized [units: Participants]			
< 65 years	299	313	612
65 years and greater	76	86	162
Gender [units: participants]			
Female	194	194	388

Male	**181**	**205**	**386**

Outcome Measures

Hide All Outcome Measures

1. Primary: Percentage of Participants With Colonic Pathology [Time Frame: 54 weeks]

Measure Type	Primary
Measure Title	Percentage of Participants With Colonic Pathology
Measure Description	The primary analysis variable was the occurrence of an abnormal colonoscopy finding (defined as hyper-plastic polyps, inflammatory polyps, adenomatous polyps or carcinoma) at or prior to the planned one year visit. The occurrence of colonic pathology was identified during colonoscopy and histopathologic examination of biopsy. The composite endpoint was evaluated after one year of treatment with an aliskiren-based regimen compared to a ramipril-based regimen.
Time Frame	54 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.
Primary Analysis Set, consisting of all randomized patients that had post-baseline colonoscopy procedure performed.

Reporting Groups

	Description
Aliskiren	For the first 2 weeks of the study, participants received aliskiren 150 mg once a day and were then forced titrated to aliskiren 300 mg once a day for 52 weeks. Participants also received a placebo capsule to match ramipril once a day for the study duration.
Ramipril	For the first 2 weeks of the study participants received 5 mg ramipril orally once a day and were then forced titrated to ramipril 10 mg once a day for 52 weeks. Participants also received placebo to aliskiren for the duration of the study.

Measured Values

	Aliskiren	**Ramipril**
Number of Participants Analyzed [units: participants]	**314**	**325**
Percentage of Participants With Colonic Pathology [units: Percentage of participants]	**25.5**	**25.1**

No statistical analysis provided for Percentage of Participants With Colonic Pathology

2. Primary: Summary of the End of Study Colonoscopy Results [Time Frame: 54 weeks]

Measure Type	Primary
Measure Title	Summary of the End of Study Colonoscopy Results
Measure Description	During each colonoscopy procedure, random biopsy samples were taken from normal appearing mucosa in both the cecum and rectum in addition to obvious endoscopically atypical areas. The mucosal biopsy samples were evaluated for mucosal hyperplasia, dysplasia, and inflammation. Anything noted as a distinct visual abnormality from cecum to rectum such as ulcers, erythematous mucosa, or polyps, was photographed and biopsied for histopathology evaluation. Colonic lesions were categorized according to location in the colon, size, number, and morphology.
Time Frame	54 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.
Primary Analysis Set, consisting of all randomized patients that had post-baseline colonoscopy procedure performed.

Reporting Groups

	Description
Aliskiren	For the first 2 weeks of the study, participants received aliskiren 150 mg once a day and were then forced titrated to aliskiren 300 mg once a day for 52 weeks. Participants also received a placebo capsule to match ramipril once a day for the study duration.
Ramipril	For the first 2 weeks of the study participants received 5 mg ramipril orally once a day and were then forced titrated to ramipril 10 mg once a day for 52 weeks. Participants also received placebo to aliskiren for the duration of the study.

Measured Values

	Aliskiren	Ramipril
Number of Participants Analyzed [units: participants]	**314**	**325**
Summary of the End of Study Colonoscopy Results [units: Percentage of Participants]		
Complete colonoscopy performed	**100**	**100**
Was cecum reached in procedure	**99.7**	**100**
Photos obtained	**99.4**	**99.7**
Took drug affecting bowel function	**0.0**	**0.6**
Took low dose aspirin during wk prior to procedure	**4.8**	**5.2**
Adequacy of bowel preparation - Optimal	**72.3**	**73.5**
Adequacy of bowel preparation - Suboptimal	**27.4**	**25.5**
Adequacy of bowel preparation - Inadequate	**0.3**	**0.9**
Colonoscopy prep given- PEG containing solution	**96.8**	**97.2**
Colonoscopy prep given - Other	**3.2**	**2.8**
Occurrence of colon polyps	**29.6**	**26.5**
Patients with polyps-Cecum/ascending	**11.8**	**11.4**
Patients with polyps-Transverse	**6.1**	**5.2**
Patients with polyps-Descending/sigmoid	**12.1**	**11.7**
Patients with polyps-Rectum	**8.0**	**6.5**
Mean number of polyps-Cecum/ascending	**1.3**	**1.2**
Mean number of polyps-Transverse	**1.2**	**1.4**
Mean number of polyps-Descending/sigmoid	**1.5**	**1.5**
Mean number of polyps-Rectum	**1.6**	**1.3**
Polyps were completely resected-Cecum/ascending	**11.8**	**11.1**
Polyps were completely resected-Transverse	**6.1**	**4.9**
Polyps were completely resected-Descending/sigmoid	**12.1**	**11.7**
Polyps were completely resected-Rectum	**7.6**	**6.5**
Photo taken for polyps-Cecum/ascending	**11.8**	**11.1**

Photo taken for polyps-Transverse	**5.7**	**4.6**
Photo taken for polyps-Descending/sigmoid	**10.8**	**10.5**
Photo taken for polyps-Rectum	**7.6**	**6.2**
Mucosal abnormalities for colitis	**1.3**	**1.5**
Patients with colitis-Cecum/ascending	**0.6**	**0.9**
Patients with colitis-Transverse	**0.0**	**0.0**
Patients with colitis-Descending/sigmoid	**0.0**	**0.0**
Patients with colitis-Rectum	**0.6**	**0.6**
Area of colitis biopsied-Cecum/ascending	**0.6**	**0.9**
Area of colitis biopsied-Transverse	**0.0**	**0.0**
Area of colitis biopsied-Descending/sigmoid	**0.0**	**0.0**
Area of colitis biopsied-Rectum	**0.6**	**0.6**
Area of colitis photographed-Cecum/ascending	**0.6**	**0.9**
Area of colitis photographed-Transverse	**0.0**	**0.0**
Area of colitis photographed-Descending/sigmoid	**0.0**	**0.0**
Area of colitis photographed-Rectum	**0.6**	**0.6**
Normal mucosal biopsies collected-Cecum	**99.4**	**99.7**
Normal mucosal biopsies collected-Rectum	**99.7**	**99.7**
Mean number of normal mucosal biopsies-Cecum	**3.0**	**3.0**
Mean number of normal mucosal biopsies-Rectum	**3.0**	**3.0**
Malignance for any biopsy samples-Yes	**0.0**	**0.0**
Malignance for any biopsy samples-No	**99.4**	**98.8**
Malignance for any biopsy samples-Missing	**0.6**	**0.9**
Inflammation for any biopsy samples-Yes	**1.0**	**0.6**
Inflammation for any biopsy samples-No	**98.4**	**98.8**
Inflammation for any biopsy samples-Missing	**0.6**	**0.6**

No statistical analysis provided for Summary of the End of Study Colonoscopy Results

3. Secondary: Percentage of Participants With Each of the Individual Components of Colonic Pathology [Time Frame: 54 weeks]

Measure Type	Secondary
Measure Title	Percentage of Participants With Each of the Individual Components of Colonic Pathology
Measure Description	Assessment of the occurrence of the individual components (hyperplastic polyps, inflammatory polyps, adenomatous polyps or carcinomas) of the composite endpoint (colonic pathology) following one-year of treatment with an aliskiren-based regimen compared to a ramipril-based regimen.
Time Frame	54 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.
Primary analysis set

Reporting Groups

	Description
Aliskiren	For the first 2 weeks of the study, participants received aliskiren 150 mg once a day and were then forced titrated to aliskiren 300 mg once a day for 52 weeks. Participants also received a placebo capsule to match ramipril once a day for the study duration.
Ramipril	For the first 2 weeks of the study participants received 5 mg ramipril orally once a day and were then forced titrated to ramipril 10 mg once a day for 52 weeks. Participants also received placebo to aliskiren for the duration of the study.

Measured Values

	Aliskiren	Ramipril
Number of Participants Analyzed [units: participants]	**314**	**325**
Percentage of Participants With Each of the Individual Components of Colonic Pathology [units: Percentage of Participants]		
Hyperplastic polyps	**13.1**	**10.2**
Inflammatory polyps	**0.0**	**0.3**
Adenomatous polyps	**15.0**	**17.3**
Carcinoma	**0.0**	**0.0**

No statistical analysis provided for Percentage of Participants With Each of the Individual Components of Colonic Pathology

4. Secondary: Mucosal Hyperplasia Score in Rectal and Cecal Mucosal Biopsy Specimens After One Year of Treatment [Time Frame: 54 weeks]

Measure Type	Secondary
Measure Title	Mucosal Hyperplasia Score in Rectal and Cecal Mucosal Biopsy Specimens After One Year of Treatment
Measure Description	Maximum hyperplasia score at end of study across rectal and cecal mucosa biopsy specimens. Score of 0 is no change from baseline, the minimum possible score. Score > 0 is worsening from baseline in which the maximum possible score is 3.
Time Frame	54 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.
Primary analysis set

Reporting Groups

	Description
Aliskiren	For the first 2 weeks of the study, participants received aliskiren 150 mg once a day and were then forced titrated to aliskiren 300 mg once a day for 52 weeks. Participants also received a placebo capsule to match ramipril once a day for the study duration.
Ramipril	For the first 2 weeks of the study participants received 5 mg ramipril orally once a day and were then forced titrated to ramipril 10 mg once a day for 52 weeks. Participants also received placebo to aliskiren for the duration of the study.

Measured Values

	Aliskiren	Ramipril
Number of Participants Analyzed [units: participants]	**314**	**325**

Mucosal Hyperplasia Score in Rectal and Cecal Mucosal Biopsy Specimens After One Year of Treatment [units: participants]		
Score = 0	295	304
Score = 1	17	19
Score = 2	0	0
Score = 3	0	0
Score is Missing	2	2

No statistical analysis provided for Mucosal Hyperplasia Score in Rectal and Cecal Mucosal Biopsy Specimens After One Year of Treatment

5. Secondary: Percentage of Participants Achieving the Mean Sitting Blood Pressure Control Target [Time Frame: Weeks 8, 30 and End of Study (54 weeks)]

Measure Type	Secondary
Measure Title	Percentage of Participants Achieving the Mean Sitting Blood Pressure Control Target
Measure Description	The mean sitting blood pressure control target is defined as less than 140/90 mmHg (or 130/80 mmHg for diabetic patients)
Time Frame	Weeks 8, 30 and End of Study (54 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

Reporting Groups

	Description
Aliskiren	For the first 2 weeks of the study, participants received aliskiren 150 mg once a day and were then forced titrated to aliskiren 300 mg once a day for 52 weeks. Participants also received a placebo capsule to match ramipril once a day for the study duration.
Ramipril	For the first 2 weeks of the study participants received 5 mg ramipril orally once a day and were then forced titrated to ramipril 10 mg once a day for 52 weeks. Participants also received placebo to aliskiren for the duration of the study.

Measured Values

	Aliskiren	Ramipril
Number of Participants Analyzed [units: participants]	374	394
Percentage of Participants Achieving the Mean Sitting Blood Pressure Control Target [units: Percentage of Participants]		
Week 8	50.8	44.9
Week 30	60.2	54.1
End of Study	65.0	56.1

No statistical analysis provided for Percentage of Participants Achieving the Mean Sitting Blood Pressure Control Target

Serious Adverse Events

Hide Serious Adverse Events

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

Reporting Groups

	Description
Aliskiren	For the first 2 weeks of the study, participants received aliskiren 150 mg once a day and were then forced titrated to aliskiren 300 mg once a day for 52 weeks. Participants also received a placebo capsule to match ramipril once a day for the study duration.
Ramipril	For the first 2 weeks of the study participants received 5 mg ramipril orally once a day and were then forced titrated to ramipril 10 mg once a day for 52 weeks. Participants also received placebo to aliskiren for the duration of the study.

Serious Adverse Events

	Aliskiren	Ramipril
Total, serious adverse events		
# participants affected / at risk	**28/375 (7.47%)**	**22/399 (5.51%)**
Cardiac disorders		
Atrioventricular block complete † 1		
# participants affected / at risk	**1/375 (0.27%)**	**0/399 (0.00%)**
Coronary artery disease † 1		
# participants affected / at risk	**3/375 (0.80%)**	**1/399 (0.25%)**
Myocardial infarction † 1		
# participants affected / at risk	**3/375 (0.80%)**	**2/399 (0.50%)**
Tachycardia † 1		
# participants affected / at risk	**1/375 (0.27%)**	**0/399 (0.00%)**
Endocrine disorders		
Hyperparathyroidism primary † 1		
# participants affected / at risk	**1/375 (0.27%)**	**0/399 (0.00%)**
Gastrointestinal disorders		
Abdominal pain upper † 1		
# participants affected / at risk	**0/375 (0.00%)**	**1/399 (0.25%)**
Diarrhoea haemorrhagic † 1		
# participants affected / at risk	**0/375 (0.00%)**	**1/399 (0.25%)**
Inguinal hernia † 1		
# participants affected / at risk	**0/375 (0.00%)**	**2/399 (0.50%)**
Lower gastrointestinal haemorrhage † 1		
# participants affected / at risk	**1/375 (0.27%)**	**0/399 (0.00%)**
General disorders		
Non-cardiac chest pain † 1		
# participants affected / at risk	**2/375 (0.53%)**	**0/399 (0.00%)**
Hepatobiliary disorders		
Bile duct stone † 1		
# participants affected / at risk	**0/375 (0.00%)**	**1/399 (0.25%)**
Cholecystitis acute † 1		
# participants affected / at risk	**1/375 (0.27%)**	**0/399 (0.00%)**

Cholelithiasis † [1]		
# participants affected / at risk	0/375 (0.00%)	1/399 (0.25%)
Immune system disorders		
Type III immune complex mediated reaction † [1]		
# participants affected / at risk	1/375 (0.27%)	0/399 (0.00%)
Infections and infestations		
Appendicitis † [1]		
# participants affected / at risk	1/375 (0.27%)	0/399 (0.00%)
Arthritis bacterial † [1]		
# participants affected / at risk	1/375 (0.27%)	0/399 (0.00%)
Bronchitis † [1]		
# participants affected / at risk	0/375 (0.00%)	1/399 (0.25%)
Staphylococcal infection † [1]		
# participants affected / at risk	1/375 (0.27%)	0/399 (0.00%)
Injury, poisoning and procedural complications		
Femur fracture † [1]		
# participants affected / at risk	0/375 (0.00%)	1/399 (0.25%)
In-stent arterial restenosis † [1]		
# participants affected / at risk	1/375 (0.27%)	0/399 (0.00%)
Meniscus lesion † [1]		
# participants affected / at risk	0/375 (0.00%)	1/399 (0.25%)
Post procedural haemorrhage † [1]		
# participants affected / at risk	1/375 (0.27%)	0/399 (0.00%)
Musculoskeletal and connective tissue disorders		
Costochondritis † [1]		
# participants affected / at risk	1/375 (0.27%)	0/399 (0.00%)
Spinal osteoarthritis † [1]		
# participants affected / at risk	0/375 (0.00%)	1/399 (0.25%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		
Basal cell carcinoma † [1]		
# participants affected / at risk	0/375 (0.00%)	1/399 (0.25%)
Prostate cancer † [1]		
# participants affected / at risk	2/375 (0.53%)	0/399 (0.00%)
Nervous system disorders		
Cerebrovascular accident † [1]		
# participants affected / at risk	0/375 (0.00%)	1/399 (0.25%)
Facial palsy † [1]		
# participants affected / at risk	1/375 (0.27%)	0/399 (0.00%)
Occipital neuralgia † [1]		
# participants affected / at risk	0/375 (0.00%)	1/399 (0.25%)
Subarachnoid haemorrhage † [1]		
# participants affected / at risk	0/375 (0.00%)	1/399 (0.25%)
Syncope † [1]		
# participants affected / at risk	2/375 (0.53%)	0/399 (0.00%)

Transient ischaemic attack † 1		
# participants affected / at risk	**1/375 (0.27%)**	**2/399 (0.50%)**
Renal and urinary disorders		
Calculus ureteric † 1		
# participants affected / at risk	**0/375 (0.00%)**	**1/399 (0.25%)**
Cystitis haemorrhagic † 1		
# participants affected / at risk	**0/375 (0.00%)**	**1/399 (0.25%)**
Nephrolithiasis † 1		
# participants affected / at risk	**0/375 (0.00%)**	**1/399 (0.25%)**
Renal failure acute † 1		
# participants affected / at risk	**1/375 (0.27%)**	**0/399 (0.00%)**
Respiratory, thoracic and mediastinal disorders		
Chronic obstructive pulmonary disease † 1		
# participants affected / at risk	**1/375 (0.27%)**	**0/399 (0.00%)**
Laryngeal oedema † 1		
# participants affected / at risk	**1/375 (0.27%)**	**0/399 (0.00%)**
Pulmonary embolism † 1		
# participants affected / at risk	**0/375 (0.00%)**	**1/399 (0.25%)**
Vascular disorders		
Aortic dissection † 1		
# participants affected / at risk	**1/375 (0.27%)**	**0/399 (0.00%)**
Arteritis † 1		
# participants affected / at risk	**0/375 (0.00%)**	**1/399 (0.25%)**
Hypertension † 1		
# participants affected / at risk	**3/375 (0.80%)**	**0/399 (0.00%)**
Hypertensive crisis † 1		
# participants affected / at risk	**2/375 (0.53%)**	**0/399 (0.00%)**
Hypertensive emergency † 1		
# participants affected / at risk	**1/375 (0.27%)**	**0/399 (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	For the first 2 weeks of the study, participants received aliskiren 150 mg once a day and were then forced titrated to aliskiren 300

	mg once a day for 52 weeks. Participants also received a placebo capsule to match ramipril once a day for the study duration.
Ramipril	For the first 2 weeks of the study participants received 5 mg ramipril orally once a day and were then forced titrated to ramipril 10 mg once a day for 52 weeks. Participants also received placebo to aliskiren for the duration of the study.

Other Adverse Events

	Aliskiren	Ramipril
Total, other (not including serious) adverse events		
# participants affected / at risk	**163/375 (43.47%)**	**176/399 (44.11%)**
Gastrointestinal disorders		
Diarrhoea † 1		
# participants affected / at risk	**28/375 (7.47%)**	**24/399 (6.02%)**
Nausea † 1		
# participants affected / at risk	**19/375 (5.07%)**	**15/399 (3.76%)**
General disorders		
Oedema peripheral † 1		
# participants affected / at risk	**28/375 (7.47%)**	**20/399 (5.01%)**
Infections and infestations		
Nasopharyngitis † 1		
# participants affected / at risk	**19/375 (5.07%)**	**21/399 (5.26%)**
Upper respiratory tract infection † 1		
# participants affected / at risk	**27/375 (7.20%)**	**26/399 (6.52%)**
Urinary tract infection † 1		
# participants affected / at risk	**21/375 (5.60%)**	**10/399 (2.51%)**
Musculoskeletal and connective tissue disorders		
Back pain † 1		
# participants affected / at risk	**17/375 (4.53%)**	**22/399 (5.51%)**
Nervous system disorders		
Dizziness † 1		
# participants affected / at risk	**23/375 (6.13%)**	**29/399 (7.27%)**
Headache † 1		
# participants affected / at risk	**41/375 (10.93%)**	**54/399 (13.53%)**
Respiratory, thoracic and mediastinal disorders		
Cough † 1		
# participants affected / at risk	**14/375 (3.73%)**	**48/399 (12.03%)**

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

Limitations and Caveats

Hide Limitations and Caveats

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

More Information

Hide More Information

Certain Agreements:

Principal Investigators are **NOT** employed by the organization sponsoring the study.
There **IS** an agreement between Principal Investigators and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.
The agreement is: ☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **less than or equal to 60 days**. The sponsor cannot require changes to the communication and cannot extend the embargo. ☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **more than 60 days but less than or equal to 180 days**. The sponsor cannot require changes to the communication and cannot extend the embargo. Other disclosure agreement that restricts the right of the PI to discuss or publish trial results after the trial is completed. ☑ **Restriction Description:** The terms and conditions of Novartis' agreements with its investigators may vary. However, Novartis does not prohibit any investigator from publishing. Any publications from a single-site are postponed until the publication of the pooled data (i.e., data from all sites) in the clinical trial.

Results Point of Contact:

Name/Title: Study Director
Organization: Novartis Pharmaceuticals
phone: 862-778-8300

No publications provided

Responsible Party:	Study Director, Novartis Pharmaceuticals
ClinicalTrials.gov Identifier:	NCT00631917 History of Changes
Other Study ID Numbers:	**CSPP100A2404**
Study First Received:	March 3, 2008
Results First Received:	January 5, 2011
Last Updated:	June 30, 2011
Health Authority:	United States: Food and Drug Administration