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Trial record **1 of 1** for: CSPA100A2201

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Assessment of Aliskiren/Amlodipine and Amlodipine on Ankle Foot Volume (AFV) in Patients With Hypertension

This study has been terminated.

(Publication of data from a similar study made the current study redundant.)

Sponsor:
Novartis Pharmaceuticals

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

ClinicalTrials.gov Identifier:
NCT01080768

First received: March 3, 2010
Last updated: November 22, 2011
Last verified: November 2011
History of Changes

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Results First Received: November 22, 2011

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Investigator); Primary Purpose: Treatment
Conditions:	Hypertension Ankle Edema
Interventions:	Drug: Aliskiren/amlodipine Drug: Amlodipine Drug: Placebo to Aliskiren/amlodipine Drug: Placebo to Amlodipine

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/Amlodipine + Placebo to Amlodipine	During the first week of active treatment, patients were instructed to take one tablet of aliskiren/amlodipine 150/5 mg and one capsule of placebo to amlodipine daily. For the 2nd to 4th week of active treatment, the patients were up-titrated to take 2 tablets of aliskiren/amlodipine 150/5 mg/day and 1 capsule of placebo to amlodipine. The patients were instructed to administer daily dose between 8:00 and 10:00 am preferably

	at the same time of the day.
Amlodipine+ Placebo to Aliskiren/Amlodipine	During the first week of active treatment, patients were instructed to take one capsule of amlodipine 5 mg and one tablet of placebo to aliskiren/amlodipine 150/5 mg daily. For the 2nd to 4th week of active treatment, the patients were up-titrated to take 1 capsule of amlodipine 10 mg/day and 2 tablets of placebo to aliskiren/amlodipine 150/5 mg/day. The patients were instructed to administer daily dose between 8:00 and 10:00 am preferably at the same time of the day.

Participant Flow: Overall Study

	Aliskiren/Amlodipine + Placebo to Amlodipine	Amlodipine+ Placebo to Aliskiren/Amlodipine
STARTED	**14**	**17**
COMPLETED	**12**	**16**
NOT COMPLETED	**2**	**1**
Protocol Deviation	**2**	**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
Aliskiren/Amlodipine + Placebo to Amlodipine	During the first week of active treatment, patients were instructed to take one tablet of aliskiren/amlodipine 150/5 mg and one capsule of placebo to amlodipine daily. For the 2nd to 4th week of active treatment, the patients were up-titrated to take 2 tablets of aliskiren/amlodipine 150/5 mg/day and 1 capsule of placebo to amlodipine. The patients were instructed to administer daily dose between 8:00 and 10:00 am preferably at the same time of the day.
Amlodipine+ Placebo to Aliskiren/Amlodipine	During the first week of active treatment, patients were instructed to take one capsule of amlodipine 5 mg and one tablet of placebo to aliskiren/amlodipine 150/5 mg daily. For the 2nd to 4th week of active treatment, the patients were up-titrated to take 1 capsule of amlodipine 10 mg/day and 2 tablets of placebo to aliskiren/amlodipine 150/5 mg/day. The patients were instructed to administer daily dose between 8:00 and 10:00 am preferably at the same time of the day.
Total	Total of all reporting groups

Baseline Measures

	Aliskiren/Amlodipine + Placebo to Amlodipine	Amlodipine+ Placebo to Aliskiren/Amlodipine	Total
Number of Participants [units: participants]	**14**	**17**	**31**
Age [units: years] Mean (Standard Deviation)	**55.4 (6.21)**	**58.0 (4.49)**	**56.8 (5.40)**
Gender [units: participants]			

Female	**5**	**4**	**9**
Male	**9**	**13**	**22**

Outcome Measures

1. Primary: Change in the Ankle Foot Volume (AFV) as Measured by Displacement Method [Time Frame: Baseline, 4 weeks]

Hide Outcome Measure 1

Measure Type	Primary
Measure Title	Change in the Ankle Foot Volume (AFV) as Measured by Displacement Method
Measure Description	AFV (mL) was measured using the principle of water displacement using a commercially available foot volumeter. The amount of water displaced in milliliters (mL) equals the volume of the foot/ankle. The study was terminated due to the publication of the results of a near identical study by Fogari et al. Hence, for the current study, no analysis was performed.
Time Frame	Baseline, 4 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.
The study was terminated due to the publication of the results of a near identical study by Fogari et al. Hence, for the current study, no analysis was performed.

Reporting Groups

	Description
Aliskiren/Amlodipine + Placebo to Amlodipine	During the first week of active treatment, patients were instructed to take one tablet of aliskiren/amlodipine 150/5 mg and one capsule of placebo to amlodipine daily. For the 2nd to 4th week of active treatment, the patients were up-titrated to take 2 tablets of aliskiren/amlodipine 150/5 mg/day and 1 capsule of placebo to amlodipine. The patients were instructed to administer daily dose between 8:00 and 10:00 am preferably at the same time of the day.
Amlodipine+ Placebo to Aliskiren/Amlodipine	During the first week of active treatment, patients were instructed to take one capsule of amlodipine 5 mg and one tablet of placebo to aliskiren/amlodipine 150/5 mg daily. For the 2nd to 4th week of active treatment, the patients were up-titrated to take 1 capsule of amlodipine 10 mg/day and 2 tablets of placebo to aliskiren/amlodipine 150/5 mg/day. The patients were instructed to administer daily dose between 8:00 and 10:00 am preferably at the same time of the day.

Measured Values

	Aliskiren/Amlodipine + Placebo to Amlodipine	**Amlodipine+ Placebo to Aliskiren/Amlodipine**
Number of Participants Analyzed [units: participants]	**0**	**0**
Change in the Ankle Foot Volume (AFV) as Measured by Displacement Method [units: mL] Least Squares Mean (Standard Error)		

No statistical analysis provided for Change in the Ankle Foot Volume (AFV) as Measured by Displacement Method

Serious Adverse Events

Hide Serious Adverse Events

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

Reporting Groups

	Description
Aliskiren/Amlodipine and Placebo to Amlodipine	During the first week of active treatment, patients were instructed to take one tablet of aliskiren/amlodipine 150/5 mg and one capsule of placebo to amlodipine daily. For the 2nd to 4th week of active treatment, the patient up-titrated to take 2 tablets of aliskiren/amlodipine 150/5 mg/day and 1 capsule of placebo to amlodipine. The patients were instructed to administer daily dose between 8:00 and 10:00 am preferably at the same time of the day.
Amlodipine and Placebo to Aliskiren/Amlodipine	During the first week of active treatment, patients were instructed to take one capsule of amlodipine 5 mg and one tablet of placebo to aliskiren/amlodipine 150/5 mg daily. For the 2nd to 4th week of active treatment, the patient up-titrated to take 1 capsule of amlodipine 10 mg/day and 2 tablets of placebo to aliskiren/amlodipine 150/5 mg/day. The patients were instructed to administer daily dose between 8:00 and 10:00 am preferably at the same time of the day.

Serious Adverse Events

	Aliskiren/Amlodipine and Placebo to Amlodipine	Amlodipine and Placebo to Aliskiren/Amlodipine
Total, serious adverse events		
# participants affected / at risk	**0/14 (0.00%)**	**0/17 (0.00%)**

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/Amlodipine and Placebo to Amlodipine	During the first week of active treatment, patients were instructed to take one tablet of aliskiren/amlodipine 150/5 mg and one capsule of placebo to amlodipine daily. For the 2nd to 4th week of active treatment, the patient up-titrated to take 2 tablets of aliskiren/amlodipine 150/5 mg/day and 1 capsule of placebo to amlodipine. The patients were instructed to administer daily dose between 8:00 and 10:00 am preferably at the same time of the day.
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	preferably at the same time of the day.

Other Adverse Events

	Aliskiren/Amlodipine and Placebo to Amlodipine	Amlodipine and Placebo to Aliskiren/Amlodipine
Total, other (not including serious) adverse events		
# participants affected / at risk	**2/14 (14.29%)**	**2/17 (11.76%)**
Cardiac disorders		
Palpitations † 1		
# participants affected / at risk	**1/14 (7.14%)**	**0/17 (0.00%)**
Gastrointestinal disorders		
Abdominal pain † 1		
# participants affected / at risk	**1/14 (7.14%)**	**0/17 (0.00%)**
Gastrooesophageal reflux disease † 1		
# participants affected / at risk	**0/14 (0.00%)**	**1/17 (5.88%)**
General disorders		
Chest discomfort † 1		
# participants affected / at risk	**0/14 (0.00%)**	**1/17 (5.88%)**
Oedema peripheral † 1		
# participants affected / at risk	**0/14 (0.00%)**	**1/17 (5.88%)**
Infections and infestations		
Otitis externa † 1		
# participants affected / at risk	**1/14 (7.14%)**	**0/17 (0.00%)**
Musculoskeletal and connective tissue disorders		
Back pain † 1		
# participants affected / at risk	**1/14 (7.14%)**	**1/17 (5.88%)**
Joint swelling † 1		
# participants affected / at risk	**0/14 (0.00%)**	**1/17 (5.88%)**
Musculoskeletal pain † 1		
# participants affected / at risk	**1/14 (7.14%)**	**0/17 (0.00%)**
Pain in extremity † 1		
# participants affected / at risk	**1/14 (7.14%)**	**0/17 (0.00%)**
Nervous system disorders		
Dizziness † 1		
# participants affected / at risk	**2/14 (14.29%)**	**0/17 (0.00%)**
Headache † 1		
# participants affected / at risk	**1/14 (7.14%)**	**0/17 (0.00%)**
Respiratory, thoracic and mediastinal disorders		
Dyspnoea † 1		
# participants affected / at risk	**1/14 (7.14%)**	**0/17 (0.00%)**

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

Limitations and Caveats

Hide Limitations and Caveats

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

More Information

Hide More Information

Certain Agreements:

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

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:	NCT01080768 History of Changes
Other Study ID Numbers:	**CSPA100A2201** 2009-014359-63 (EudraCT Number)
Study First Received:	March 3, 2010
Results First Received:	November 22, 2011
Last Updated:	November 22, 2011
Health Authority:	Netherlands: The Central Committee on Research Involving Human Subjects (CCMO)