Efficacy and Tolerability of an Aliskiren-based Treatment Algorithm in Patients With Mild to Moderate Hypertension

ClinicalTrials.gov Identifier: NCT00765947

Recruitment Status : Completed
First Posted : October 3, 2008
Results First Posted : January 11, 2011
Last Update Posted : August 6, 2020

Sponsor:
Novartis

Information provided by (Responsible Party):
Novartis

Study Details | Tabular View | Study Results | Disclaimer | How to Read a Study Record

Study Type
Interventional
Study Design

Allocation: N/A; Intervention Model: Single Group Assignment; Masking: None (Open Label); Primary Purpose: Treatment
Condition
Essential Hypertension (Mild to Moderate)
Interventions
Drug: Aliskiren Drug: Hydrochlorothiazide Drug: Amlodipine
Enrollment
256

Participant Flow

Recruitment Details	
Pre-assignment Details	

Arm/Group Title	
▼ Arm/Group Description	Patients initiated treat followed by the additi (up-titrated to 10 mg),

Period Title: **Overall Study**

Started	
Completed	
Not Completed	

Baseline Characteristics

Arm/Group Title	
▼ Arm/Group Description	Patients initiated treat followed by the additi (up-titrated to 10 mg),
Overall Number of Baseline Participants	
▼ Baseline Analysis Population Description	[Not Specified]

Age, Customized Measure Type: Number Unit of measure: Participants	Number Analyzed	

< 65 yrs		
≥ 65 yrs		
Sex: Female, Male Measure Type: Count of Participants Unit of measure: Participants		
	Number Analyzed	
	Female	
	Male	

Outcome Measures

1. Primary Outcome

Title	Percentage of Participants (Defined as Estimated Cumulative Control Rate) Rea based Regimen
▼ Description	For non diabetic patients the Blood Pressure target is defined as mean sitting Sy Diastolic Blood Pressure [msDBP] < 90 mmHg and for diabetic patients the Bloo [msSBP] < 130 mmHg and mean sitting Diastolic Blood Pressure [msDBP] < 80
Time Frame	24 weeks

▼ Outcome Measure Data

▼ Analysis Population Description
Full analysis set

Arm/Group Title	Aliskiren-based Regir
▼ Arm/Group Description:	Patients initiated treatment with aliskiren 150 mg (up-titrated to aliskiren 300 mg) mg) and amlodipine 5 mg (up-titrated to 10 mg), as necessary to achieve the Blo
Overall Number of Participants Analyzed	256
Measure Type: Number Unit of Measure: Percentage of participants	
	86.12

2. Secondary Outcome

Title	Percentage of Patients (Defined as Estimated Cumulative Control Rate) Reachin Regimen by Patient Subgroups of Mild and Moderate Hypertensive Patients, anc
▼ Description	For non diabetic patients the Blood Pressure target is defined as mean sitting Sy Diastolic Blood Pressure [msDBP] < 90 mmHg and for diabetic patients the Bloo [msSBP] < 130 mmHg and mean sitting Diastolic Blood Pressure [msDBP] < 80
Time Frame	24 weeks

▼ Outcome Measure Data

▼ Analysis Population Description
[Not Specified]

Arm/Group Title	Aliskiren-based Regir
▼ Arm/Group Description:	Patients initiated treatment with aliskiren 150 mg (up-titrated to aliskiren 300 mg) mg) and amlodipine 5 mg (up-titrated to 10 mg), as necessary to achieve the Blo
Overall Number of Participants Analyzed	256
Measure Type: Number Unit of Measure: Percentage of Participants	
Mild Hypertensive	91.48
Moderate Hypertensive	79.24
Non-diabetic	92.74
Diabetic	72.58

3. Secondary Outcome

Title	Changes From Baseline to Week 24 in Mean Sitting Systolic Blood Pressure [ms
▼ Description	[Not Specified]
Time Frame	Baseline and Week 24

▼ Outcome Measure Data

▼ Analysis Population Description
Full analysis set

Arm/Group Title	Aliskiren-based Regir

▼ Arm/Group Description:	Patients initiated treatment with aliskiren 150 mg (up-titrated to aliskiren 300 mg) mg) and amlodipine 5 mg (up-titrated to 10 mg), as necessary to achieve the Blo
Overall Number of Participants Analyzed	251
Mean (Standard Deviation) Unit of Measure: mm Hg	
msSBP	-25.33 (13.942)
msDBP	-12.40 (9.371)

4. Secondary Outcome

Title	Percent of Responders for Mean Sitting Systolic Blood Pressure [msSBP] and fo
▼ Description	Response for mean sitting Systolic Blood Pressure [msSBP] is defined as a redu Blood Pressure [msSBP] < 140 mmHg (non diabetics) or < 130 mmHg (diabetics [msDBP] is defined as a reduction of ≥10 mmHg from baseline or mean sitting Di < 80 mmHg (diabetics).
Time Frame	24 weeks

▼ Outcome Measure Data

▼ Analysis Population Description
[Not Specified]

Arm/Group Title	Aliskiren-based Regir
▼ Arm/Group Description:	Patients initiated treatment with aliskiren 150 mg (up-titrated to aliskiren 300 mg) mg) and amlodipine 5 mg (up-titrated to 10 mg), as necessary to achieve the Blo
Overall Number of Participants Analyzed	256
Measure Type: Number Unit of Measure: Percentage of Participants	
msSBP	96.80
msDBP	97.78

Adverse Events

Time Frame	[Not Specified]
Adverse Event Reporting Description	[Not Specified]

Arm/Group Title	Aliskiren	Aliskiren
▼ Arm/Group Description	Aliskiren treatment step	Aliskiren and HCTZ t

All-Cause Mortality

	Aliskiren	Aliskiren
	Affected / at Risk (%)	Affected / a
Total	--/--	--/

▼ Serious Adverse Events

	Aliskiren	Aliskiren
	Affected / at Risk (%)	Affected / a
Total	3/256 (1.17%)	0/197 (0
Cardiac disorders		
Myocardial infarction † 1	1/256 (0.39%)	0/197 (0
General disorders		
Non-cardiac chest pain † 1	1/256 (0.39%)	0/197 (0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		
Renal neoplasm † 1	1/256 (0.39%)	0/197 (0
Vascular disorders		
Hypertension † 1	1/256 (0.39%)	0/197 (0

† Indicates events were collected by systematic assessment

1 Term from vocabulary, MedDRA

▼ Other (Not Including Serious) Adverse Events

Frequency Threshold for Reporting Other Adverse Events	5%

	Aliskiren	Aliskiren
	Affected / at Risk (%)	Affected / a
Total	0/256 (0.00%)	0/197 (0

Limitations and Caveats

Go to

[Not Specified]

More Information

Go to

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 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

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Responsible Party:
Novartis

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