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Effects of Ventavis in Patients With Pulmonary Hypertension (PH) Secondary to Chronic Obstructive Pulmonary Disease (COPD)

This study has been terminated.

(low recruitment)

Sponsor:
Actelion

Information provided by (Responsible Party):
Actelion

ClinicalTrials.gov Identifier:
NCT01437878

First received: September 20, 2011
Last updated: October 16, 2015
Last verified: October 2015
History of Changes

Results First Received: December 12, 2014

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Caregiver, Investigator); Primary Purpose: Treatment
Conditions:	Chronic Obstructive Pulmonary Disease Pulmonary Hypertension

Interventions:	Drug: Iloprost Drug: Placebo

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
Patients were screened at 4 centres in the US, one centre in France, and one site in Spain. First patient, first visit was 1 March 2012 and last patient, last visit was 30 November 2012.

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment
A total of 22 patients were screened for the study, of these 20 were not randomized because they did not meet the selection criteria.

Reporting Groups

	Description
Iloprost	single dose inhalation using the power disc-6 with I-neb Adaptive Aerosol Delivery (AAD) system Iloprost: 5ug dose of inhaled iloprost (20ug/mL solution) administered 6 to 9 times per day for 4 weeks
Placebo	matching placebo using the power disc-6 with I-neb AAD system Placebo: matching placebo

Participant Flow: Overall Study

	Iloprost	**Placebo**
STARTED	**1** [1]	**1**
COMPLETED	**0**	**1**

NOT COMPLETED	**1**	**0**
Withdrawal by Subject	**1**	**0**

[1] Patient discontinued the study prior to initiation of study treatment

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
Iloprost	single dose inhalation using the power disc-6 with I-neb AAD system Iloprost: 5ug dose of inhaled iloprost (20ug/mL solution) administered 6 to 9 times per day for 4 weeks
Placebo	matching placebo using the power disc-6 with I-neb AAD system Placebo: matching placebo
Total	Total of all reporting groups

Baseline Measures

	Iloprost	**Placebo**	**Total**
Number of Participants [units: participants]	**1**	**1**	**2**
Age, Customized [units: participants]			

Age 64 years	**1**	**0**	**1**
Age 74 years	**0**	**1**	**1**
Gender [units: participants]			
Female	**0**	**1**	**1**
Male	**1**	**0**	**1**
Region of Enrollment [units: participants]			
France	**1**	**0**	**1**
United States	**0**	**1**	**1**

Outcome Measures

Hide All Outcome Measures

1. Primary: Change in Endurance Time [Time Frame: Baseline to week 4]

Measure Type	Primary
Measure Title	Change in Endurance Time
Measure Description	Change from baseline to week 4 in endurance time during constant work rate exercise testing
Time Frame	Baseline to week 4
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 prematurely terminated as after 1 year it was not possible to identify a suitable number of patients who satisfied the selection criteria. Only 2 patients were randomized prior to the termination of the study, and 1 patient received a single dose of active treatment. Therefore, there are inadequate data to evaluate efficacy.

Reporting Groups

	Description
Iloprost	single dose inhalation using the power disc-6 with I-neb AAD system Iloprost: 5ug dose of inhaled iloprost (20ug/mL solution) administered 6 to 9 times per day for 4 weeks
Placebo	matching placebo using the power disc-6 with I-neb AAD system Placebo: matching placebo

Measured Values

	Iloprost	Placebo
Number of Participants Analyzed [units: participants]	**0**	**0**
Change in Endurance Time		

No statistical analysis provided for Change in Endurance Time

2. Secondary: Participants With Treatment-emergent Adverse Events [Time Frame: Baseline up to 24 hours post-EOT, approximately 4 weeks]

Measure Type	Secondary
Measure Title	Participants With Treatment-emergent Adverse Events
Measure Description	Treatment-emergent adverse events up to 24 hours post-end of treatment (EOT), approximately 4 weeks
Time Frame	Baseline up to 24 hours post-EOT, approximately 4 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.
Total population

Reporting Groups

	Description
Iloprost	single dose inhalation using the power disc-6 with I-neb AAD system Iloprost: 5ug dose of inhaled iloprost (20ug/mL solution) administered 6 to 9 times per day for 4 weeks
Placebo	matching placebo using the power disc-6 with I-neb AAD system Placebo: matching placebo

Measured Values

	Iloprost	**Placebo**
Number of Participants Analyzed [units: participants]	**1**	**1**
Participants With Treatment-emergent Adverse Events [units: participants]	**0**	**0**

No statistical analysis provided for Participants With Treatment-emergent Adverse Events

3. Secondary: Change in Systolic Pulmonary Arterial Pressure [Time Frame: 15 minutes]

Measure Type	Secondary

Measure Title	Change in Systolic Pulmonary Arterial Pressure
Measure Description	On Day 1 patients underwent acute hemodynamic testing prior to and immediately after (no more than 15 minutes) the first dose of inhaled iloprost or placebo. All hemodynamic variables were measured using a Swan-Ganz catheter.
Time Frame	15 minutes
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 prematurely terminated as after 1 year it was not possible to identify a suitable number of patients who satisfied the selection criteria. Only 2 patients were randomized prior to the termination of the study, and 1 patient received a single dose of active treatment. Therefore, there are inadequate data to evaluate efficacy.

Reporting Groups

	Description
Iloprost	single dose inhalation using the power disc-6 with I-neb AAD system Iloprost: 5ug dose of inhaled iloprost (20ug/mL solution) administered 6 to 9 times per day for 4 weeks
Placebo	matching placebo using the power disc-6 with I-neb AAD system Placebo: matching placebo

Measured Values

	Iloprost	**Placebo**
Number of Participants Analyzed [units: participants]	**0**	**0**
Change in Systolic Pulmonary Arterial Pressure		

No statistical analysis provided for Change in Systolic Pulmonary Arterial Pressure

4. Secondary: Change in Diastolic Pulmonary Arterial Pressure [Time Frame: 15 minutes]

Measure Type	Secondary
Measure Title	Change in Diastolic Pulmonary Arterial Pressure
Measure Description	On Day 1 patients underwent acute hemodynamic testing prior to and immediately after (no more than 15 minutes) the first dose of inhaled iloprost or placebo. All hemodynamic variables were measured using a Swan-Ganz catheter.
Time Frame	15 minutes
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 prematurely terminated as after 1 year it was not possible to identify a suitable number of patients who satisfied the selection criteria. Only 2 patients were randomized prior to the termination of the study, and 1 patient received a single dose of active treatment. Therefore, there are inadequate data to evaluate efficacy.

Reporting Groups

	Description
Iloprost	single dose inhalation using the power disc-6 with I-neb AAD system Iloprost: 5ug dose of inhaled iloprost (20ug/mL solution) administered 6 to 9 times per day for 4 weeks
Placebo	matching placebo using the power disc-6 with I-neb AAD system Placebo: matching placebo

Measured Values

	Iloprost	Placebo
Number of Participants Analyzed [units: participants]	**0**	**0**
Change in Diastolic Pulmonary Arterial Pressure		

No statistical analysis provided for Change in Diastolic Pulmonary Arterial Pressure

5. Secondary: Change in Mean Pulmonary Arterial Pressure [Time Frame: 15 minutes]

Measure Type	Secondary
Measure Title	Change in Mean Pulmonary Arterial Pressure
Measure Description	On Day 1 patients underwent acute hemodynamic testing prior to and immediately after (no more than 15 minutes) the first dose of inhaled iloprost or placebo. All hemodynamic variables were measured using a Swan-Ganz catheter.
Time Frame	15 minutes
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 prematurely terminated as after 1 year it was not possible to identify a suitable number of patients who satisfied the selection criteria. Only 2 patients were randomized prior to the termination of the study, and 1 patient received a single dose of active treatment. Therefore, there are inadequate data to evaluate efficacy.

Reporting Groups

	Description
Iloprost	single dose inhalation using the power disc-6 with I-neb AAD system

	Iloprost: 5ug dose of inhaled iloprost (20ug/mL solution) administered 6 to 9 times per day for 4 weeks
Placebo	matching placebo using the power disc-6 with I-neb AAD system Placebo: matching placebo

Measured Values

	Iloprost	**Placebo**
Number of Participants Analyzed [units: participants]	**0**	**0**
Change in Mean Pulmonary Arterial Pressure		

No statistical analysis provided for Change in Mean Pulmonary Arterial Pressure

6. Secondary: Change in Mean Right Atrial Pressure [Time Frame: 15 minutes]

Measure Type	Secondary
Measure Title	Change in Mean Right Atrial Pressure
Measure Description	On Day 1 patients underwent acute hemodynamic testing prior to and immediately after (no more than 15 minutes) the first dose of inhaled iloprost or placebo. All hemodynamic variables were measured using a Swan-Ganz catheter.
Time Frame	15 minutes
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 prematurely terminated as after 1 year it was not possible to identify a suitable number of patients who satisfied the selection criteria. Only 2 patients were randomized prior to the termination of the study, and 1 patient received a single dose of active treatment.

Therefore, there are inadequate data to evaluate efficacy.

Reporting Groups

	Description
Iloprost	single dose inhalation using the power disc-6 with I-neb AAD system Iloprost: 5ug dose of inhaled iloprost (20ug/mL solution) administered 6 to 9 times per day for 4 weeks
Placebo	matching placebo using the power disc-6 with I-neb AAD system Placebo: matching placebo

Measured Values

	Iloprost	Placebo
Number of Participants Analyzed [units: participants]	**0**	**0**
Change in Mean Right Atrial Pressure		

No statistical analysis provided for Change in Mean Right Atrial Pressure

7. Secondary: Change in Cardiac Output [Time Frame: 15 minutes]

Measure Type	Secondary
Measure Title	Change in Cardiac Output
Measure Description	On Day 1 patients underwent acute hemodynamic testing prior to and immediately after (no more than 15 minutes) the first dose of inhaled iloprost or placebo. All hemodynamic variables were measured using a Swan-Ganz catheter.
Time Frame	15 minutes
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 prematurely terminated as after 1 year it was not possible to identify a suitable number of patients who satisfied the selection criteria. Only 2 patients were randomized prior to the termination of the study, and 1 patient received a single dose of active treatment. Therefore, there are inadequate data to evaluate efficacy.

Reporting Groups

	Description
Iloprost	single dose inhalation using the power disc-6 with I-neb AAD system Iloprost: 5ug dose of inhaled iloprost (20ug/mL solution) administered 6 to 9 times per day for 4 weeks
Placebo	matching placebo using the power disc-6 with I-neb AAD system Placebo: matching placebo

Measured Values

	Iloprost	**Placebo**
Number of Participants Analyzed [units: participants]	**0**	**0**
Change in Cardiac Output		

No statistical analysis provided for Change in Cardiac Output

8. Secondary: Change in Right Ventricular Pressure [Time Frame: 15 minutes]

Measure Type	Secondary

Measure Title	Change in Right Ventricular Pressure
Measure Description	On Day 1 patients underwent acute hemodynamic testing prior to and immediately after (no more than 15 minutes) the first dose of inhaled iloprost or placebo. All hemodynamic variables were measured using a Swan-Ganz catheter.
Time Frame	15 minutes
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 prematurely terminated as after 1 year it was not possible to identify a suitable number of patients who satisfied the selection criteria. Only 2 patients were randomized prior to the termination of the study, and 1 patient received a single dose of active treatment. Therefore, there are inadequate data to evaluate efficacy.

Reporting Groups

	Description
Iloprost	single dose inhalation using the power disc-6 with I-neb AAD system Iloprost: 5ug dose of inhaled iloprost (20ug/mL solution) administered 6 to 9 times per day for 4 weeks
Placebo	matching placebo using the power disc-6 with I-neb AAD system Placebo: matching placebo

Measured Values

	Iloprost	**Placebo**
Number of Participants Analyzed [units: participants]	**0**	**0**
Change in Right Ventricular Pressure		

No statistical analysis provided for Change in Right Ventricular Pressure

9. Secondary: Change in Pulmonary Vascular Resistance [Time Frame: 15 minutes]

Measure Type	Secondary
Measure Title	Change in Pulmonary Vascular Resistance
Measure Description	On Day 1 patients underwent acute hemodynamic testing prior to and immediately after (no more than 15 minutes) the first dose of inhaled iloprost or placebo. All hemodynamic variables were measured using a Swan-Ganz catheter.
Time Frame	15 minutes
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 prematurely terminated as after 1 year it was not possible to identify a suitable number of patients who satisfied the selection criteria. Only 2 patients were randomized prior to the termination of the study, and 1 patient received a single dose of active treatment. Therefore, there are inadequate data to evaluate efficacy.

Reporting Groups

	Description
Iloprost	single dose inhalation using the power disc-6 with I-neb AAD system Iloprost: 5ug dose of inhaled iloprost (20ug/mL solution) administered 6 to 9 times per day for 4 weeks
Placebo	matching placebo using the power disc-6 with I-neb AAD system Placebo: matching placebo

Measured Values

	Iloprost	Placebo
Number of Participants Analyzed [units: participants]	**0**	**0**
Change in Pulmonary Vascular Resistance		

No statistical analysis provided for Change in Pulmonary Vascular Resistance

10. Secondary: Change in End Tidal Partial Pressure of Carbon Dioxide [Time Frame: Baseline to week 4]

Measure Type	Secondary
Measure Title	Change in End Tidal Partial Pressure of Carbon Dioxide
Measure Description	Change from baseline to week 4. Pulmonary gas exchange was measured during incremental and constant work rate exercise testing.
Time Frame	Baseline to week 4
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 prematurely terminated as after 1 year it was not possible to identify a suitable number of patients who satisfied the selection criteria. Only 2 patients were randomized prior to the termination of the study, and 1 patient received a single dose of active treatment. Therefore, there are inadequate data to evaluate efficacy.

Reporting Groups

	Description
Iloprost	single dose inhalation using the power disc-6 with I-neb AAD system

	Iloprost: 5ug dose of inhaled iloprost (20ug/mL solution) administered 6 to 9 times per day for 4 weeks
Placebo	matching placebo using the power disc-6 with I-neb AAD system Placebo: matching placebo

Measured Values

	Iloprost	**Placebo**
Number of Participants Analyzed [units: participants]	**0**	**0**
Change in End Tidal Partial Pressure of Carbon Dioxide		

No statistical analysis provided for Change in End Tidal Partial Pressure of Carbon Dioxide

11. Secondary: Change in End Tidal Partial Pressure of Oxygen [Time Frame: Baseline to week 4]

Measure Type	Secondary
Measure Title	Change in End Tidal Partial Pressure of Oxygen
Measure Description	Change from baseline to week 4. Pulmonary gas exchange was measured during incremental and constant work rate exercise testing.
Time Frame	Baseline to week 4
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 prematurely terminated as after 1 year it was not possible to identify a suitable number of patients who satisfied the selection criteria. Only 2 patients were randomized prior to the termination of the study, and 1 patient received a single dose of active treatment.

Therefore, there are inadequate data to evaluate efficacy.

Reporting Groups

	Description
Iloprost	single dose inhalation using the power disc-6 with I-neb AAD system Iloprost: 5ug dose of inhaled iloprost (20ug/mL solution) administered 6 to 9 times per day for 4 weeks
Placebo	matching placebo using the power disc-6 with I-neb AAD system Placebo: matching placebo

Measured Values

	Iloprost	Placebo
Number of Participants Analyzed [units: participants]	**0**	**0**
Change in End Tidal Partial Pressure of Oxygen		

No statistical analysis provided for Change in End Tidal Partial Pressure of Oxygen

12. Secondary: Change in Oxygen Uptake [Time Frame: Baseline to week 4]

Measure Type	Secondary
Measure Title	Change in Oxygen Uptake
Measure Description	Change from baseline to week 4. Pulmonary gas exchange was measured during incremental and constant work rate exercise testing.
Time Frame	Baseline to week 4
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 prematurely terminated as after 1 year it was not possible to identify a suitable number of patients who satisfied the selection criteria. Only 2 patients were randomized prior to the termination of the study, and 1 patient received a single dose of active treatment. Therefore, there are inadequate data to evaluate efficacy.

Reporting Groups

	Description
Iloprost	single dose inhalation using the power disc-6 with I-neb AAD system Iloprost: 5ug dose of inhaled iloprost (20ug/mL solution) administered 6 to 9 times per day for 4 weeks
Placebo	matching placebo using the power disc-6 with I-neb AAD system Placebo: matching placebo

Measured Values

	Iloprost	**Placebo**
Number of Participants Analyzed [units: participants]	**0**	**0**
Change in Oxygen Uptake		

No statistical analysis provided for Change in Oxygen Uptake

13. Secondary: Change in Carbon Dioxide Output [Time Frame: Baseline to week 4]

Measure Type	Secondary

Measure Title	Change in Carbon Dioxide Output
Measure Description	Change from baseline to week 4. Pulmonary gas exchange was measured during incremental and constant work rate exercise testing.
Time Frame	Baseline to week 4
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 prematurely terminated as after 1 year it was not possible to identify a suitable number of patients who satisfied the selection criteria. Only 2 patients were randomized prior to the termination of the study, and 1 patient received a single dose of active treatment. Therefore, there are inadequate data to evaluate efficacy.

Reporting Groups

	Description
Iloprost	single dose inhalation using the power disc-6 with I-neb AAD system Iloprost: 5ug dose of inhaled iloprost (20ug/mL solution) administered 6 to 9 times per day for 4 weeks
Placebo	matching placebo using the power disc-6 with I-neb AAD system Placebo: matching placebo

Measured Values

	Iloprost	**Placebo**
Number of Participants Analyzed [units: participants]	**0**	**0**
Change in Carbon Dioxide Output		

No statistical analysis provided for Change in Carbon Dioxide Output

14. Secondary: Change in Oxygen Uptake Per Heartbeat [Time Frame: Baseline to week 4]

Measure Type	Secondary
Measure Title	Change in Oxygen Uptake Per Heartbeat
Measure Description	Change from baseline to week 4. Pulmonary gas exchange was measured during incremental and constant work rate exercise testing.
Time Frame	Baseline to week 4
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 prematurely terminated as after 1 year it was not possible to identify a suitable number of patients who satisfied the selection criteria. Only 2 patients were randomized prior to the termination of the study, and 1 patient received a single dose of active treatment. Therefore, there are inadequate data to evaluate efficacy.

Reporting Groups

	Description
Iloprost	single dose inhalation using the power disc-6 with I-neb AAD system Iloprost: 5ug dose of inhaled iloprost (20ug/mL solution) administered 6 to 9 times per day for 4 weeks
Placebo	matching placebo using the power disc-6 with I-neb AAD system Placebo: matching placebo

Measured Values

	Iloprost	Placebo
Number of Participants Analyzed [units: participants]	**0**	**0**
Change in Oxygen Uptake Per Heartbeat		

No statistical analysis provided for Change in Oxygen Uptake Per Heartbeat

15. Secondary: Change in Heart Rate [Time Frame: Baseline to week 4]

Measure Type	Secondary
Measure Title	Change in Heart Rate
Measure Description	Change from baseline to week 4. Heart rate was measured during incremental and constant work rate exercise testing.
Time Frame	Baseline to week 4
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 prematurely terminated as after 1 year it was not possible to identify a suitable number of patients who satisfied the selection criteria. Only 2 patients were randomized prior to the termination of the study, and 1 patient received a single dose of active treatment. Therefore, there are inadequate data to evaluate efficacy.

Reporting Groups

	Description
Iloprost	single dose inhalation using the power disc-6 with I-neb AAD system Iloprost: 5ug dose of inhaled iloprost (20ug/mL solution) administered 6 to 9 times per day for 4 weeks

Placebo	matching placebo using the power disc-6 with I-neb AAD system Placebo: matching placebo

Measured Values

	Iloprost	Placebo
Number of Participants Analyzed [units: participants]	**0**	**0**
Change in Heart Rate		

No statistical analysis provided for Change in Heart Rate

16. Secondary: Change in Arterial Oxygen Saturation as Indicated by Pulse Oximetry [Time Frame: Baseline to week 4]

Measure Type	Secondary
Measure Title	Change in Arterial Oxygen Saturation as Indicated by Pulse Oximetry
Measure Description	Change from baseline to week 4. Arterial oxygen was determined by pulse oximetry during incremental and constant work rate exercise testing.
Time Frame	Baseline to week 4
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 prematurely terminated as after 1 year it was not possible to identify a suitable number of patients who satisfied the selection criteria. Only 2 patients were randomized prior to the termination of the study, and 1 patient received a single dose of active treatment. Therefore, there are inadequate data to evaluate efficacy.

Reporting Groups

	Description
Iloprost	single dose inhalation using the power disc-6 with I-neb AAD system Iloprost: 5ug dose of inhaled iloprost (20ug/mL solution) administered 6 to 9 times per day for 4 weeks
Placebo	matching placebo using the power disc-6 with I-neb AAD system Placebo: matching placebo

Measured Values

	Iloprost	Placebo
Number of Participants Analyzed [units: participants]	**0**	**0**
Change in Arterial Oxygen Saturation as Indicated by Pulse Oximetry		

No statistical analysis provided for Change in Arterial Oxygen Saturation as Indicated by Pulse Oximetry

17. Secondary: Change in Tidal Volume [Time Frame: Baseline to week 4]

Measure Type	Secondary
Measure Title	Change in Tidal Volume
Measure Description	Change from baseline to week 4. Tidal volume was measured during incremental and constant work rate exercise testing.
Time Frame	Baseline to week 4
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 prematurely terminated as after 1 year it was not possible to identify a suitable number of patients who satisfied the selection criteria. Only 2 patients were randomized prior to the termination of the study, and 1 patient received a single dose of active treatment. Therefore, there are inadequate data to evaluate efficacy.

Reporting Groups

	Description
Iloprost	single dose inhalation using the power disc-6 with I-neb AAD system Iloprost: 5ug dose of inhaled iloprost (20ug/mL solution) administered 6 to 9 times per day for 4 weeks
Placebo	matching placebo using the power disc-6 with I-neb AAD system Placebo: matching placebo

Measured Values

	Iloprost	**Placebo**
Number of Participants Analyzed [units: participants]	**0**	**0**
Change in Tidal Volume		

No statistical analysis provided for Change in Tidal Volume

18. Secondary: Change in Minute Ventilation [Time Frame: Baseline to week 4]

Measure Type	Secondary

Measure Title	Change in Minute Ventilation
Measure Description	Change from baseline to week 4. Minute ventilation was measured during incremental and constant work rate exercise testing.
Time Frame	Baseline to week 4
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 prematurely terminated as after 1 year it was not possible to identify a suitable number of patients who satisfied the selection criteria. Only 2 patients were randomized prior to the termination of the study, and 1 patient received a single dose of active treatment. Therefore, there are inadequate data to evaluate efficacy.

Reporting Groups

	Description
Iloprost	single dose inhalation using the power disc-6 with I-neb AAD system Iloprost: 5ug dose of inhaled iloprost (20ug/mL solution) administered 6 to 9 times per day for 4 weeks
Placebo	matching placebo using the power disc-6 with I-neb AAD system Placebo: matching placebo

Measured Values

	Iloprost	**Placebo**
Number of Participants Analyzed [units: participants]	**0**	**0**
Change in Minute Ventilation		

No statistical analysis provided for Change in Minute Ventilation

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	up to 24 hours post-end of treatment
Additional Description	Treatment-emergent adverse events

Reporting Groups

	Description
Iloprost	single dose inhalation using the power disc-6 with I-neb AAD system Iloprost: 5ug dose of inhaled iloprost (20ug/mL solution) administered 6 to 9 times per day for 4 weeks
Placebo	matching placebo using the power disc-6 with I-neb AAD system Placebo: matching placebo

Serious Adverse Events

	Iloprost	Placebo
Total, serious adverse events		
# participants affected / at risk	**0/1 (0.00%)**	**0/1 (0.00%)**

Other Adverse Events

Hide Other Adverse Events

Time Frame	up to 24 hours post-end of treatment

Additional Description	Treatment-emergent adverse events

Frequency Threshold

Threshold above which other adverse events are reported	0

Reporting Groups

	Description
Iloprost	single dose inhalation using the power disc-6 with I-neb AAD system Iloprost: 5ug dose of inhaled iloprost (20ug/mL solution) administered 6 to 9 times per day for 4 weeks
Placebo	matching placebo using the power disc-6 with I-neb AAD system Placebo: matching placebo

Other Adverse Events

	Iloprost	**Placebo**
Total, other (not including serious) adverse events		
# participants affected / at risk	**0/1 (0.00%)**	**0/1 (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:** No text entered.

Results Point of Contact:

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Responsible Party:	Actelion
ClinicalTrials.gov Identifier:	NCT01437878 History of Changes
Other Study ID Numbers:	**AC-063B201**
Study First Received:	September 20, 2011
Results First Received:	December 12, 2014
Last Updated:	October 16, 2015
Health Authority:	Spain: Comité Ético de Investigación Clínica

United States: Food and Drug Administration
France: Conseil National de l'Ordre des Médecins
France: Afssaps - Agence française de sécurité sanitaire des produits de santé (Saint-Denis)
United States: Institutional Review Board
Spain: Agencia Española de Medicamentos y Productos Sanitarios
France: Committee for the Protection of Personnes