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Trial record **1 of 1** for: CQAB149B2311

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The Effect of Indacaterol on Exercise Endurance in Patients With Moderate to Severe Chronic Obstructive Pulmonary Disease

This study has been completed.

Sponsor:
Novartis

Information provided by:
Novartis

ClinicalTrials.gov Identifier:
NCT00620022

First received: February 8, 2008
Last updated: July 22, 2011
Last verified: July 2011
History of Changes

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Results First Received: July 22, 2011

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Efficacy Study; Intervention Model: Crossover Assignment; Masking: Double Blind (Subject, Caregiver, Investigator, Outcomes Assessor); Primary Purpose: Treatment
Condition:	Chronic Obstructive Pulmonary Disease
Interventions:	Drug: Indacaterol 300 µg 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
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
Indacaterol 300 µg Followed by Placebo	Patients first received indacaterol 300 µg delivered via a single dose dry powder inhaler (SDDPI) once daily (od) in the morning for 3 weeks. After a 3-week washout period, patients received placebo delivered od via a SDDPI in the morning for 3 weeks. Daily inhaled corticosteroid treatment (if applicable) was to remain stable throughout the study. The short-acting β2-agonist salbutamol/albuterol was available for rescue use throughout the study.
Placebo Followed by Indacaterol 300 µg	Patients first received placebo delivered via a single dose dry powder inhaler (SDDPI) once daily (od) in the morning for 3 weeks. After a 3-week washout period, patients received indacaterol 300 µg delivered od via a SDDPI in the morning for 3 weeks. Daily inhaled corticosteroid treatment (if applicable) was to remain stable throughout the study. The short-acting β2-agonist salbutamol/albuterol was available for rescue use throughout the study.

Participant Flow for 2 periods

Period 1: Treatment Period 1

	Indacaterol 300 µg Followed by Placebo	Placebo Followed by Indacaterol 300 µg
STARTED	**46**	**43** [1]

COMPLETED	**41**	**37**
NOT COMPLETED	**5**	**6**
Adverse Event	**4**	**6**
Subject withdrew consent	**1**	**0**

[1] Of 44 randomized patients, 1 patient discontinued before receiving any study treatment.

Period 2: Treatment Period 2

	Indacaterol 300 µg Followed by Placebo	Placebo Followed by Indacaterol 300 µg
STARTED	**41**	**37**
COMPLETED	**39**	**35**
NOT COMPLETED	**2**	**2**
Adverse Event	**2**	**2**

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
Entire Study Population	The entire study population includes the group of patients who received indacaterol 300 µg in the first treatment period followed by placebo in the second treatment period and the group of patients who received placebo in the first treatment period followed by indacaterol 300 µg in the second treatment period. Daily inhaled corticosteroid

	treatment (if applicable) was to remain stable throughout the study. The short-acting β2-agonist salbutamol/albuterol was available for rescue use throughout the study.

Baseline Measures

	Entire Study Population
Number of Participants [units: participants]	**89**
Age [units: years] Mean (Standard Deviation)	**62.8 (8.20)**
Gender [units: participants]	
Female	**27**
Male	**62**

Outcome Measures

Hide All Outcome Measures

1. Primary: Exercise Duration Time Assessed by Constant-load Cycle Ergometry at the End of Each Treatment Period [Time Frame: End of each 3 week treatment period (last day of Weeks 3 and 9)]

Measure Type	Primary
Measure Title	Exercise Duration Time Assessed by Constant-load Cycle Ergometry at the End of Each Treatment Period
Measure Description	At the end of each 3 week treatment period, patients completed constant-load cycle ergometry testing at a work-rate of 75% of the Wmax determined at Screening. This work-rate was maintained until symptom limitation caused the patient to stop exercising. The time from the start of loaded pedaling until the patient stopped exercising was recorded.
Time Frame	End of each 3 week treatment period (last day of Weeks 3 and 9)

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.
Modified intent-to-treat (modified ITT) population: All randomized patients who received at least 1 dose of study drug. The number of patients analyzed for each treatment group was the number with non-missing values for the dependent and independent variables in the mixed model.

Reporting Groups

	Description
Indacaterol 300 µg	Patients received indacaterol 300 µg delivered via a single dose dry powder inhaler (SDDPI) once daily (od) in the morning for 3 weeks. Daily inhaled corticosteroid treatment (if applicable) was to remain stable throughout the study. The short-acting β2-agonist salbutamol/albuterol was available for rescue use throughout the study.
Placebo	Patients received placebo delivered via a single dose dry powder inhaler (SDDPI) once daily (od) in the morning for 3 weeks. Daily inhaled corticosteroid treatment (if applicable) was to remain stable throughout the study. The short-acting β2-agonist salbutamol/albuterol was available for rescue use throughout the study.

Measured Values

	Indacaterol 300 µg	**Placebo**
Number of Participants Analyzed [units: participants]	**78**	**73**
Exercise Duration Time Assessed by Constant-load Cycle Ergometry at the End of Each Treatment Period [units: Seconds] Least Squares Mean (Standard Error)	**586 (30.3)**	**475 (31.3)**

No statistical analysis provided for Exercise Duration Time Assessed by Constant-load Cycle Ergometry at the End of Each Treatment Period

2. Secondary: Inspiratory Capacity (IC) Assessed at Rest With Spirometry at the End of Each Treatment Period 60 Minutes Pre-dose [Time Frame: End of each 3 week treatment period (last day of Weeks 3 and 9)]

Measure Type	Secondary
Measure Title	Inspiratory Capacity (IC) Assessed at Rest With Spirometry at the End of Each Treatment Period 60 Minutes Pre-dose
Measure Description	At the end of each 3 week treatment period 60 minutes before inhalation of study drug, IC was measured with spirometry conducted according to internationally accepted standards. The mean of 3 acceptable measurements was calculated and reported in liters.
Time Frame	End of each 3 week treatment period (last day of Weeks 3 and 9)
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.
Modified-intent-to-treat (modified ITT) population: All randomized patients who received at least 1 dose of study drug. The number of patients analyzed for each treatment group was the number with non-missing values for the dependent and independent variables in the mixed model.

Reporting Groups

	Description
Indacaterol 300 µg	Patients received indacaterol 300 µg delivered via a single dose dry powder inhaler (SDDPI) once daily (od) in the morning for 3 weeks. Daily inhaled corticosteroid treatment (if applicable) was to remain stable throughout the study. The short-acting β2-agonist salbutamol/albuterol was available for rescue use throughout the study.
Placebo	Patients received placebo delivered via a single dose dry powder inhaler (SDDPI) once daily (od) in the morning for 3 weeks. Daily inhaled corticosteroid treatment (if applicable) was to remain stable throughout the study. The short-acting β2-agonist salbutamol/albuterol was available for rescue use throughout the study.

Measured Values

	Indacaterol 300 µg	Placebo
Number of Participants Analyzed [units: participants]	**78**	**77**
Inspiratory Capacity (IC) Assessed at Rest With Spirometry at the End of Each Treatment Period 60 Minutes Pre-dose [units: Liters] Least Squares Mean (Standard Error)	**2.39 (0.034)**	**2.25 (0.034)**

No statistical analysis provided for Inspiratory Capacity (IC) Assessed at Rest With Spirometry at the End of Each Treatment Period 60 Minutes Pre-dose

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	Baseline to the end of the study (Week 9)
Additional Description	Adverse events are reported for the safety population which included all patients who received at least one dose of study drug.

Reporting Groups

	Description
Indacaterol 300 µg	Patients received indacaterol 300 µg delivered via a single dose dry powder inhaler (SDDPI) once daily (od) in the morning for 3 weeks. Daily inhaled corticosteroid treatment (if applicable) was to remain stable throughout the study. The short-acting β2-agonist salbutamol/albuterol was available for rescue use throughout the study.
Placebo	Patients received placebo delivered via a single dose dry powder inhaler (SDDPI) once daily (od) in the morning for 3 weeks. Daily inhaled corticosteroid treatment (if applicable) was to remain stable throughout the study. The short-acting β2-agonist salbutamol/albuterol was available for rescue use throughout the study.

Serious Adverse Events

	Indacaterol 300 µg	Placebo
Total, serious adverse events		
# participants affected / at risk	**3/83 (3.61%)**	**1/84 (1.19%)**
Cardiac disorders		
Angina pectoris † 1		
# participants affected / at risk	**0/83 (0.00%)**	**1/84 (1.19%)**
Injury, poisoning and procedural complications		
Femur fracture † 1		
# participants affected / at risk	**1/83 (1.20%)**	**0/84 (0.00%)**
Road traffic accident † 1		
# participants affected / at risk	**1/83 (1.20%)**	**0/84 (0.00%)**
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		
Breast cancer † 1		
# participants affected / at risk	**1/83 (1.20%)**	**0/84 (0.00%)**
Respiratory, thoracic and mediastinal disorders		
Chronic obstructive pulmonary disease † 1		
# participants affected / at risk	**1/83 (1.20%)**	**0/84 (0.00%)**

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

Other Adverse Events

Hide Other Adverse Events

Time Frame	Baseline to the end of the study (Week 9)

Additional Description	Adverse events are reported for the safety population which included all patients who received at least one dose of study drug.

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
Indacaterol 300 µg	Patients received indacaterol 300 µg delivered via a single dose dry powder inhaler (SDDPI) once daily (od) in the morning for 3 weeks. Daily inhaled corticosteroid treatment (if applicable) was to remain stable throughout the study. The short-acting β2-agonist salbutamol/albuterol was available for rescue use throughout the study.
Placebo	Patients received placebo delivered via a single dose dry powder inhaler (SDDPI) once daily (od) in the morning for 3 weeks. Daily inhaled corticosteroid treatment (if applicable) was to remain stable throughout the study. The short-acting β2-agonist salbutamol/albuterol was available for rescue use throughout the study.

Other Adverse Events

	Indacaterol 300 µg	Placebo
Total, other (not including serious) adverse events		
# participants affected / at risk	**6/83 (7.23%)**	**10/84 (11.90%)**
Infections and infestations		
Nasopharyngitis † [1]		
# participants affected / at risk	**6/83 (7.23%)**	**6/84 (7.14%)**
Respiratory, thoracic and mediastinal disorders		
Chronic obstructive pulmonary disease † [1]		
# participants affected / at risk	**1/83 (1.20%)**	**5/84 (5.95%)**

† 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 (ie, 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 by Novartis

Publications automatically indexed to this study:

O'Donnell DE, Casaburi R, Vincken W, Puente-Maestu L, Swales J, Lawrence D, Kramer B; INABLE 1 study group. Effect of indacaterol on exercise endurance and lung hyperinflation in COPD. Respir Med. 2011 Jul;105(7):1030-6. doi: 10.1016/j.rmed.2011.03.014. Epub 2011 Apr 16.

Responsible Party:	External Affairs, Novartis
ClinicalTrials.gov Identifier:	NCT00620022 History of Changes
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Results First Received:	July 22, 2011
Last Updated:	July 22, 2011
Health Authority:	United States: Food and Drug Administration Canada: Health Canada Belgium: Federal Agency for Medicinal Products and Health Products Denmark: Danish Medicines Agency Italy: The Italian Medicines Agency Spain: Spanish Agency of Medicines