ClinicalTrials.gov

A service of the U.S. National Institutes of Health

Trial record **1 of 1** for: CQAB149BIT01

Previous Study | Return to List | Next Study

Comparison of the Effects of Indacaterol and Tiotropium on Inspiratory Capacity

This study has been completed.

Sponsor:
Novartis Pharmaceuticals

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

ClinicalTrials.gov Identifier:
NCT00999908

First received: October 21, 2009
Last updated: February 16, 2016
Last verified: February 2016
History of Changes

Full Text View | Tabular View | Study Results | Disclaimer | How to Read a Study Record

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 150 µg Drug: Tiotropium 18 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 150 µg-tiotropium 18 µg-placebo	Patients received indacaterol 150 µg once. After a 5-9 days washout period, patients received tiotropium 18 µg once. After a second 5-9 days washout period, patients received placebo (matching indacaterol) once. All treatments were delivered via a single dose dry powder inhaler (SDDPI). The short-acting β2-agonist salbutamol was available for rescue use throughout the study.
Tiotropium 18 µg-placebo-indacaterol 150 µg	Patients received tiotropium 18 µg once. After a 5-9 days washout period, patients received placebo (matching indacaterol) once. After a second 5-9 days washout period, patients received indacaterol 150 µg once. All treatments were delivered via a single dose dry powder inhaler (SDDPI). The short-acting β2-agonist salbutamol was available for rescue use throughout the study.
Placebo-indacaterol 150 µg-tiotropium 18 µg	Patients received placebo (matching indacaterol) once. After a 5-9 days washout period, patients received indacaterol 150 µg once. After a second 5-9 days washout period, patients received tiotropium 18 µg once. All treatments were delivered via a single dose dry powder inhaler (SDDPI). The short-acting β2-agonist salbutamol was available for rescue use throughout the study.

Participant Flow for 3 periods

Period 1: Treatment Period 1

	Indacaterol 150 µg-tiotropium 18 µg-placebo	Tiotropium 18 µg-placebo-indacaterol 150 µg	Placebo-indacaterol 150 µg-tiotropium 18 µg
STARTED	19	16	19
COMPLETED	17	16	19
NOT COMPLETED	2	0	0
Subject withdrew consent	2	0	0

Period 2: Treatment Period 2

	Indacaterol 150 µg-tiotropium 18 µg-placebo	Tiotropium 18 µg-placebo-indacaterol 150 µg	Placebo-indacaterol 150 µg-tiotropium 18 µg
STARTED	17	16	19
COMPLETED	16	16	19
NOT COMPLETED	1	0	0
Protocol Violation	1	0	0

Period 3: Treatment Period 3

	Indacaterol 150 µg-tiotropium 18 µg-placebo	Tiotropium 18 µg-placebo-indacaterol 150 µg	Placebo-indacaterol 150 µg-tiotropium 18 µg
STARTED	16	16	19
COMPLETED	16	16	19
NOT COMPLETED	0	0	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
Entire Study Population	The entire study population includes the 3 groups of patients who received indacaterol 150 µg, tiotropium 18 µg, and placebo (matching indacaterol) once each in 1 of 3 different orders in this crossover study. All treatments were delivered via a single dose dry powder inhaler (SDDPI). The short-acting β2-agonist salbutamol was available for rescue use throughout the study.

Baseline Measures

	Entire Study Population
Number of Participants [units: participants]	**54**
Age [units: years] Mean (Standard Deviation)	**69.3 (9.2)**
Gender [units: participants]	
Female	**5**
Male	**49**

Outcome Measures

Hide All Outcome Measures

1. Primary: Peak Inspiratory Capacity Assessed With Spirometry in the 4 Hours After Treatment [Time Frame: 4 hour period following inhalation of study treatment]

Measure Type	Primary
Measure Title	Peak Inspiratory Capacity Assessed With Spirometry in the 4 Hours After Treatment
Measure Description	During the 4 hours following inhalation of the study treatment, inspiratory capacity (IC) was measured with spirometry conducted according to internationally accepted standards. IC was measured 3 times each at 30, 60, 120, 180, and 240 minutes post-dose and the highest value was reported in liters.
Time Frame	4 hour period following inhalation of study treatment
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.
Per protocol population: All randomized patients who received all the study drugs and had at least 1 post-dose inspiratory capacity measurement within 4 hours after inhalation in each treatment period and who were compliant with the protocol and without any major deviation likely to affect the analysis of pulmonary function measurements.

Reporting Groups

	Description
Indacaterol 150 µg	Patients received indacaterol 150 µg once, delivered via a single dose dry powder inhaler (SDDPI). The short-acting β2-agonist salbutamol was available for rescue use throughout the study.
Tiotropium 18 µg	Patients received tiotropium 18 µg once, delivered via a single dose dry powder inhaler (SDDPI). The short-acting β2-agonist salbutamol was available for rescue use throughout the study.
Placebo	Patients received placebo (matching indacaterol) once, delivered via a single dose dry powder inhaler (SDDPI). The

	short-acting β2-agonist salbutamol was available for rescue use throughout the study.

Measured Values

	Indacaterol 150 µg	Tiotropium 18 µg	Placebo
Number of Participants Analyzed [units: participants]	**44**	**44**	**44**
Peak Inspiratory Capacity Assessed With Spirometry in the 4 Hours After Treatment [units: Liters] Mean (Standard Deviation)	**2.705 (0.676)**	**2.630 (0.601)**	**2.557 (0.561)**

No statistical analysis provided for Peak Inspiratory Capacity Assessed With Spirometry in the 4 Hours After Treatment

2. Secondary: Forced Expiratory Volume in 1 Second (FEV1) Standardized (With Respect to Length of Time) Area Under the Curve (AUC) in the 4 Hours After Treatment [Time Frame: 4 hour period following inhalation of study treatment]

Measure Type	Secondary
Measure Title	Forced Expiratory Volume in 1 Second (FEV1) Standardized (With Respect to Length of Time) Area Under the Curve (AUC) in the 4 Hours After Treatment
Measure Description	FEV1 was measured with spirometry conducted according to internationally accepted standards. Measurements were made 30, 60, 120, 180, and 240 minutes post-dose. The standardized AUC FEV1 was calculated as the sum of trapezoids divided by the length of time.
Time Frame	4 hour period following inhalation of study treatment
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.

Intent-to-treat population: All randomized patients who received all the study drugs and had at least 1 post-dose inspiratory capacity measurement within 4 hours after inhalation in each treatment period.

Reporting Groups

	Description
Indacaterol 150 µg	Patients received indacaterol 150 µg once, delivered via a single dose dry powder inhaler (SDDPI). The short-acting β2-agonist salbutamol was available for rescue use throughout the study.
Tiotropium 18 µg	Patients received tiotropium 18 µg once, delivered via a single dose dry powder inhaler (SDDPI). The short-acting β2-agonist salbutamol was available for rescue use throughout the study.
Placebo	Patients received placebo (matching indacaterol) once, delivered via a single dose dry powder inhaler (SDDPI). The short-acting β2-agonist salbutamol was available for rescue use throughout the study.

Measured Values

	Indacaterol 150 µg	Tiotropium 18 µg	Placebo
Number of Participants Analyzed [units: participants]	**49**	**49**	**49**
Forced Expiratory Volume in 1 Second (FEV1) Standardized (With Respect to Length of Time) Area Under the Curve (AUC) in the 4 Hours After Treatment [units: Liters] Mean (Standard Deviation)	**1.744 (0.419)**	**1.767 (0.449)**	**1.642 (0.409)**

No statistical analysis provided for Forced Expiratory Volume in 1 Second (FEV1) Standardized (With Respect to Length of Time) Area Under the Curve (AUC) in the 4 Hours After Treatment

3. Secondary: Force Vital Capacity (FVC) Standardized (With Respect to Length of Time) Area Under the Curve (AUC) in the 4 Hours After Treatment [Time Frame: 4 hour period following inhalation of study treatment]

Measure Type	Secondary
Measure Title	Force Vital Capacity (FVC) Standardized (With Respect to Length of Time) Area Under the Curve (AUC) in the 4 Hours After Treatment
Measure Description	FVC was measured with spirometry conducted according to internationally accepted standards. Measurements were made 30, 60, 120, 180, and 240 minutes post-dose. The standardized AUC FEV1 was calculated as the sum of trapezoids divided by the length of time.
Time Frame	4 hour period following inhalation of study treatment
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.
Intent-to-treat population: All randomized patients who received all the study drugs and had at least 1 post-dose inspiratory capacity measurement within 4 hours after inhalation in each treatment period.

Reporting Groups

	Description
Indacaterol 150 µg	Patients received indacaterol 150 µg once, delivered via a single dose dry powder inhaler (SDDPI). The short-acting β2-agonist salbutamol was available for rescue use throughout the study.
Tiotropium 18 µg	Patients received tiotropium 18 µg once, delivered via a single dose dry powder inhaler (SDDPI). The short-acting β2-agonist salbutamol was available for rescue use throughout the study.
Placebo	Patients received placebo (matching indacaterol) once, delivered via a single dose dry powder inhaler (SDDPI). The short-acting β2-agonist salbutamol was available for rescue use throughout the study.

Measured Values

	Indacaterol 150 µg	**Tiotropium 18 µg**	**Placebo**
Number of Participants Analyzed [units: participants]	**49**	**49**	**49**

Force Vital Capacity (FVC) Standardized (With Respect to Length of Time) Area Under the Curve (AUC) in the 4 Hours After Treatment [units: Liters] Mean (Standard Deviation)	**3.140 (0.700)**	**3.176 (0.788)**	**3.048 (0.753)**

No statistical analysis provided for Force Vital Capacity (FVC) Standardized (With Respect to Length of Time) Area Under the Curve (AUC) in the 4 Hours After Treatment

Serious Adverse Events

Hide Serious Adverse Events

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

Reporting Groups

	Description
Indacaterol 150 µg	Patients received indacaterol 150 µg once, delivered via a single dose dry powder inhaler (SDDPI). The short-acting β2-agonist salbutamol was available for rescue use throughout the study.
Tiotropium 18 µg	Patients received tiotropium 18 µg once, delivered via a single dose dry powder inhaler (SDDPI). The short-acting β2-agonist salbutamol was available for rescue use throughout the study.
Placebo	Patients received placebo (matching indacaterol) once, delivered via a single dose dry powder inhaler (SDDPI). The short-acting β2-agonist salbutamol was available for rescue use throughout the study.

Serious Adverse Events

	Indacaterol 150 µg	Tiotropium 18 µg	Placebo
Total, serious adverse events			
# participants affected / at risk	**0/54 (0.00%)**	**0/52 (0.00%)**	**0/51 (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
Indacaterol 150 µg	Patients received indacaterol 150 µg once, delivered via a single dose dry powder inhaler (SDDPI). The short-acting β2-agonist salbutamol was available for rescue use throughout the study.
Tiotropium 18 µg	Patients received tiotropium 18 µg once, delivered via a single dose dry powder inhaler (SDDPI). The short-acting β2-agonist salbutamol was available for rescue use throughout the study.
Placebo	Patients received placebo (matching indacaterol) once, delivered via a single dose dry powder inhaler (SDDPI). The short-acting β2-agonist salbutamol was available for rescue use throughout the study.

Other Adverse Events

	Indacaterol 150 µg	Tiotropium 18 µg	Placebo
Total, other (not including serious) adverse events			
# participants affected / at risk	**0/54 (0.00%)**	**0/52 (0.00%)**	**0/51 (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:** 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:

Rossi A, Centanni S, Cerveri I, Gulotta C, Foresi A, Cazzola M, Brusasco V. Acute effects of indacaterol on lung hyperinflation in moderate COPD: a comparison with tiotropium. Respir Med. 2012 Jan;106(1):84-90. doi: 10.1016/j.rmed.2011.09.006. Epub 2011 Oct 27.

Responsible Party:	Novartis (Novartis Pharmaceuticals)
ClinicalTrials.gov Identifier:	NCT00999908 History of Changes
Other Study ID Numbers:	**CQAB149BIT01**
	2009-013763-19 (EudraCT Number)
Study First Received:	October 21, 2009
Results First Received:	July 22, 2011
Last Updated:	February 16, 2016
Health Authority:	Italy: Ethics Committee