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Trial record **1 of 1** for: CQAB149B2340

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A Crossover Study to Determine the 24 Hour Lung Function Profile of Indacaterol in Patients With Moderate-to-severe Chronic Obstructive Pulmonary Disease (COPD)

This study has been completed.

Sponsor:
Novartis Pharmaceuticals

Information provided by:
Novartis

ClinicalTrials.gov Identifier:
NCT00622635

First received: February 4, 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: Safety 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 to indacaterol

	Drug: Salmeterol 50 µg

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 - Placebo to Indacaterol - Salmeterol 50 µg	In treatment period 1, patients received indacaterol 300 µg once daily for 14 days via single-dose dry-powder inhaler (SDDPI); in treatment period 2, patients received placebo to indacaterol once daily for 14 days via SDDPI; and in treatment period 3, patients received salmeterol 50 µg twice daily for 14 days via multi-dose dry-powder inhaler (MDDPI). There was a washout period of 14 days between each treatment period. Indacaterol and placebo to indacaterol were administered double-blind; salmeterol was administered open-label. 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 to Indacaterol - Salmeterol 50 µg - Indacaterol 300 µg	In treatment period 1, patients received placebo to indacaterol once daily for 14 days via single-dose dry-powder inhaler (SDDPI); in treatment period 2, patients received salmeterol 50 µg twice daily for 14 days via multi-dose dry-powder inhaler (MDDPI); and in treatment period 3, patients received indacaterol 300 µg once daily for 14 days via SDDPI. There was a washout period of 14 days between each treatment period. Indacaterol and placebo to

	indacaterol were administered double-blind; salmeterol was administered open-label. 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.
Salmeterol 50 µg - Indacaterol 300 µg - Placebo to Indacaterol	In treatment period 1, patients received salmeterol 50 µg twice daily for 14 days via multi-dose dry-powder inhaler (MDDPI); in treatment period 2, patients received indacaterol 300 µg once daily for 14 days via single-dose dry-powder inhaler (SDDPI); and in treatment period 3, patients received placebo to indacaterol once daily for 14 days via SDDPI. There was a washout period of 14 days between each treatment period. Indacaterol and placebo to indacaterol were administered double-blind; salmeterol was administered open-label. 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 to Indacaterol - Indacaterol 300 µg - Salmeterol 50 µg	In treatment period 1, patients received placebo to indacaterol once daily for 14 days via single-dose dry-powder inhaler (SDDPI); in treatment period 2, patients received indacaterol 300 µg once daily for 14 days via SDDPI; and in treatment period 3, patients received salmeterol 50 µg twice daily for 14 days via multi-dose dry-powder inhaler (MDDPI). There was a washout period of 14 days between each treatment period. Indacaterol and placebo to indacaterol were administered double-blind; salmeterol was administered open-label. 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.
Indacaterol 300 µg - Salmeterol 50 µg - Placebo to Indacaterol	In treatment period 1, patients received indacaterol 300 µg once daily for 14 days via single-dose dry-powder inhaler (SDDPI); in treatment period 2, patients received salmeterol 50 µg twice daily for 14 days via multi-dose dry-powder inhaler (MDDPI); and in treatment period 3, patients received placebo to indacaterol once daily for 14 days via SDDPI. There was a washout period of 14 days between each treatment period. Indacaterol and placebo to indacaterol were administered double-blind; salmeterol was administered open-label. 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.
Salmeterol 50 µg - Placebo to Indacaterol - Indacaterol 300 µg	In treatment period 1, patients received salmeterol 50 µg twice daily for 14

days via multi-dose dry-powder inhaler (MDDPI); in treatment period 2, patients received placebo to indacaterol once daily for 14 days via single-dose dry-powder inhaler (SDDPI); and in treatment period 3, patients received indacaterol 300 µg once daily for 14 days via SDDPI. There was a washout period of 14 days between each treatment period. Indacaterol and placebo to indacaterol were administered double-blind; salmeterol was administered open-label. 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 3 periods

Period 1: Treatment Period 1

	Indacaterol 300 µg - Placebo to Indacaterol - Salmeterol 50 µg	Placebo to Indacaterol - Salmeterol 50 µg - Indacaterol 300 µg	Salmeterol 50 µg - Indacaterol 300 µg - Placebo to Indacaterol	Placebo to Indacaterol - Indacaterol 300 µg - Salmeterol 50 µg	Indacaterol 300 µg - Salmeterol 50 µg - Placebo to Indacaterol	Salmeterol 50 µg - Placebo to Indacaterol - Indacaterol 300 µg
STARTED	13	11	11	13	10	10
COMPLETED	13	10	10	13	9	10
NOT COMPLETED	0	1	1	0	1	0
Adverse Event	0	0	1	0	0	0
Withdrawal by Subject	0	1	0	0	0	0
Abnormal test procedure result(s)	0	0	0	0	1	0

Period 2: Treatment Period 2

	Indacaterol 300 µg - Placebo to Indacaterol - Salmeterol 50 µg	Placebo to Indacaterol - Salmeterol 50 µg - Indacaterol 300 µg	Salmeterol 50 µg - Indacaterol 300 µg - Placebo to Indacaterol	Placebo to Indacaterol - Indacaterol 300 µg - Salmeterol 50 µg	Indacaterol 300 µg - Salmeterol 50 µg - Placebo to Indacaterol	Salmeterol 50 µg - Placebo to Indacaterol - Indacaterol 300 µg
STARTED	13	10	10	13	9	10
COMPLETED	12	10	10	13	9	10
NOT COMPLETED	1	0	0	0	0	0
Adverse Event	1	0	0	0	0	0

Period 3: Treatment Period 3

	Indacaterol 300 µg - Placebo to Indacaterol - Salmeterol 50 µg	Placebo to Indacaterol - Salmeterol 50 µg - Indacaterol 300 µg	Salmeterol 50 µg - Indacaterol 300 µg - Placebo to Indacaterol	Placebo to Indacaterol - Indacaterol 300 µg - Salmeterol 50 µg	Indacaterol 300 µg - Salmeterol 50 µg - Placebo to Indacaterol	Salmeterol 50 µg - Placebo to Indacaterol - Indacaterol 300 µg
STARTED	12	10	10	13	9	10
COMPLETED	12	10	10	10	9	10
NOT COMPLETED	0	0	0	3	0	0
Adverse Event	0	0	0	2	0	0

Withdrawal by Subject	**0**	**0**	**0**	**1**	**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 included all 6 treatment groups who received indacaterol 300 µg once daily, placebo to indacaterol once daily, and salmeterol 50 µg twice daily via a single-dose (indacaterol and placebo to indacaterol) or multi-dose (salmeterol) dry-powder inhaler in 6 different sequences. Patients received each treatment for 14 days with a 14 day washout between each treatment period. Indacaterol and placebo to indacaterol were administered double-blind; salmeterol was administered open-label. 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]	**68**
Age [units: years] Mean (Standard Deviation)	**65.6 (9.03)**

Gender [units: participants]	
Female	16
Male	52

Outcome Measures

Hide All Outcome Measures

1. Primary: Trough Forced Expiratory Volume in 1 Second (FEV1) 24 Hours Post-dose at the End of Each Treatment Period (Day 15) [Time Frame: After 14 days]

Measure Type	Primary
Measure Title	Trough Forced Expiratory Volume in 1 Second (FEV1) 24 Hours Post-dose at the End of Each Treatment Period (Day 15)
Measure Description	FEV1 was measured with spirometry conducted according to internationally accepted standards. Trough FEV1 was defined as the average of measurements made 23 hours 10 minutes and 23 hours 45 minutes post-dose at the end of each treatment period. The analysis included baseline FEV1, defined as the average of the FEV1 values measured at 50 and 15 minutes prior to the first study drug administration in that period, as a covariate.
Time Frame	After 14 days
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.

Reporting Groups

	Description

Indacaterol 300 µg	Indacaterol 300 µg was inhaled once daily for 14 days using a single-dose dry-powder inhaler (SDDPI) device. 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 to Indacaterol	Placebo to indacaterol was inhaled once daily for 14 days using a single-dose dry-powder inhaler (SDDPI) device. 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.
Salmeterol 50 µg	Salmeterol 50 µg was inhaled twice daily for 14 days using a multi-dose dry-powder inhaler (MDDPI) device. 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 to Indacaterol	Salmeterol 50 µg
Number of Participants Analyzed [units: participants]	**61**	**61**	**59**
Trough Forced Expiratory Volume in 1 Second (FEV1) 24 Hours Post-dose at the End of Each Treatment Period (Day 15) [units: Liters] Least Squares Mean (Standard Error)	**1.46 (0.027)**	**1.26 (0.027)**	**1.37 (0.027)**

No statistical analysis provided for Trough Forced Expiratory Volume in 1 Second (FEV1) 24 Hours Post-dose at the End of Each Treatment Period (Day 15)

2. Secondary: Forced Expiratory Volume in 1 Second (FEV1) 5 Minutes Post-dose at the End of Each Treatment Period (Day 14) [Time Frame: 5 minutes post-dose at the end of each treatment period (Day 14)]

Measure Type	Secondary
Measure Title	Forced Expiratory Volume in 1 Second (FEV1) 5 Minutes Post-dose at the End of Each Treatment Period (Day 14)
Measure Description	FEV1 was measured with spirometry conducted according to internationally accepted standards. The analysis

	included baseline FEV1, defined as the average of the FEV1 values measured at 50 and 15 minutes prior to the first study drug administration in that period, as a covariate.
Time Frame	5 minutes post-dose at the end of each treatment period (Day 14)
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.

Reporting Groups

	Description
Indacaterol 300 µg	Indacaterol 300 µg was inhaled once daily for 14 days using a single-dose dry-powder inhaler (SDDPI) device. 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 to Indacaterol	Placebo to indacaterol was inhaled once daily for 14 days using a single-dose dry-powder inhaler (SDDPI) device. 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.
Salmeterol 50 µg	Salmeterol 50 µg was inhaled twice daily for 14 days using a multi-dose dry-powder inhaler (MDDPI) device. 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 to Indacaterol	Salmeterol 50 µg
Number of Participants Analyzed [units: participants]	**63**	**64**	**60**
Forced Expiratory Volume in 1 Second (FEV1) 5 Minutes Post-dose at the End of Each Treatment Period (Day 14)	**1.44 (0.022)**	**1.24 (0.022)**	**1.36 (0.022)**

[units: Liters] **Least Squares Mean (Standard Error)**			

No statistical analysis provided for Forced Expiratory Volume in 1 Second (FEV1) 5 Minutes Post-dose at the End of Each Treatment Period (Day 14)

3. Secondary: Forced Expiratory Volume in 1 Second (FEV1) 15 Minutes Post-dose at the End of Each Treatment Period (Day 14) [Time Frame: 15 minutes post-dose at the end of each treatment period (Day 14)]

Measure Type	Secondary
Measure Title	Forced Expiratory Volume in 1 Second (FEV1) 15 Minutes Post-dose at the End of Each Treatment Period (Day 14)
Measure Description	FEV1 was measured with spirometry conducted according to internationally accepted standards. The analysis included baseline FEV1, defined as the average of the FEV1 values measured at 50 and 15 minutes prior to the first study drug administration in that period, as a covariate.
Time Frame	15 minutes post-dose at the end of each treatment period (Day 14)
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.

Reporting Groups

	Description
Indacaterol 300 µg	Indacaterol 300 µg was inhaled once daily for 14 days using a single-dose dry-powder inhaler (SDDPI) device. 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 to Indacaterol	Placebo to indacaterol was inhaled once daily for 14 days using a single-dose dry-powder inhaler (SDDPI) device.

	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.
Salmeterol 50 µg	Salmeterol 50 µg was inhaled twice daily for 14 days using a multi-dose dry-powder inhaler (MDDPI) device. 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 to Indacaterol	Salmeterol 50 µg
Number of Participants Analyzed [units: participants]	**64**	**64**	**59**
Forced Expiratory Volume in 1 Second (FEV1) 15 Minutes Post-dose at the End of Each Treatment Period (Day 14) [units: Liters] Least Squares Mean (Standard Error)	**1.47 (0.023)**	**1.27 (0.023)**	**1.41 (0.024)**

No statistical analysis provided for Forced Expiratory Volume in 1 Second (FEV1) 15 Minutes Post-dose at the End of Each Treatment Period (Day 14)

4. Secondary: Forced Expiratory Volume in 1 Second (FEV1) 30 Minutes Post-dose at the End of Each Treatment Period (Day 14) [Time Frame: 30 minutes post-dose at the end of each treatment period (Day 14)]

Measure Type	Secondary
Measure Title	Forced Expiratory Volume in 1 Second (FEV1) 30 Minutes Post-dose at the End of Each Treatment Period (Day 14)
Measure Description	FEV1 was measured with spirometry conducted according to internationally accepted standards. The analysis included baseline FEV1, defined as the average of the FEV1 values measured at 50 and 15 minutes prior to the first study drug administration in that period, as a covariate.
Time Frame	30 minutes post-dose at the end of each treatment period (Day 14)
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.

Reporting Groups

	Description
Indacaterol 300 µg	Indacaterol 300 µg was inhaled once daily for 14 days using a single-dose dry-powder inhaler (SDDPI) device. 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 to Indacaterol	Placebo to indacaterol was inhaled once daily for 14 days using a single-dose dry-powder inhaler (SDDPI) device. 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.
Salmeterol 50 µg	Salmeterol 50 µg was inhaled twice daily for 14 days using a multi-dose dry-powder inhaler (MDDPI) device. 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 to Indacaterol**	**Salmeterol 50 µg**
Number of Participants Analyzed [units: participants]	**64**	**64**	**60**
Forced Expiratory Volume in 1 Second (FEV1) 30 Minutes Post-dose at the End of Each Treatment Period (Day 14) [units: Liters] Least Squares Mean (Standard Error)	**1.49 (0.023)**	**1.26 (0.023)**	**1.42 (0.024)**

No statistical analysis provided for Forced Expiratory Volume in 1 Second (FEV1) 30 Minutes Post-dose at the End of Each Treatment Period (Day 14)

5. Secondary: Forced Expiratory Volume in 1 Second (FEV1) 1 Hour Post-dose at the End of Each Treatment Period (Day 14) [Time Frame: 1 hour post-dose at the end of each treatment period (Day 14)]

Measure Type	Secondary
Measure Title	Forced Expiratory Volume in 1 Second (FEV1) 1 Hour Post-dose at the End of Each Treatment Period (Day 14)
Measure Description	FEV1 was measured with spirometry conducted according to internationally accepted standards. The analysis included baseline FEV1, defined as the average of the FEV1 values measured at 50 and 15 minutes prior to the first study drug administration in that period, as a covariate.
Time Frame	1 hour post-dose at the end of each treatment period (Day 14)
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.

Reporting Groups

	Description
Indacaterol 300 µg	Indacaterol 300 µg was inhaled once daily for 14 days using a single-dose dry-powder inhaler (SDDPI) device. 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 to Indacaterol	Placebo to indacaterol was inhaled once daily for 14 days using a single-dose dry-powder inhaler (SDDPI) device. 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.
Salmeterol 50 µg	Salmeterol 50 µg was inhaled twice daily for 14 days using a multi-dose dry-powder inhaler (MDDPI) device. 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 to Indacaterol	Salmeterol 50 µg
Number of Participants Analyzed [units: participants]	**64**	**64**	**60**
Forced Expiratory Volume in 1 Second (FEV1) 1 Hour Post-dose at the End of Each Treatment Period (Day 14) [units: Liters] Least Squares Mean (Standard Error)	**1.49 (0.023)**	**1.26 (0.023)**	**1.42 (0.023)**

No statistical analysis provided for Forced Expiratory Volume in 1 Second (FEV1) 1 Hour Post-dose at the End of Each Treatment Period (Day 14)

6. Secondary: Forced Expiratory Volume in 1 Second (FEV1) 2 Hours Post-dose at the End of Each Treatment Period (Day 14) [Time Frame: 2 hours post-dose at the end of each treatment period (Day 14)]

Measure Type	Secondary
Measure Title	Forced Expiratory Volume in 1 Second (FEV1) 2 Hours Post-dose at the End of Each Treatment Period (Day 14)
Measure Description	FEV1 was measured with spirometry conducted according to internationally accepted standards. The analysis included baseline FEV1, defined as the average of the FEV1 values measured at 50 and 15 minutes prior to the first study drug administration in that period, as a covariate.
Time Frame	2 hours post-dose at the end of each treatment period (Day 14)
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.

Reporting Groups

	Description
Indacaterol 300 µg	Indacaterol 300 µg was inhaled once daily for 14 days using a single-dose dry-powder inhaler (SDDPI) device. 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 to Indacaterol	Placebo to indacaterol was inhaled once daily for 14 days using a single-dose dry-powder inhaler (SDDPI) device. 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.
Salmeterol 50 µg	Salmeterol 50 µg was inhaled twice daily for 14 days using a multi-dose dry-powder inhaler (MDDPI) device. 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 to Indacaterol	Salmeterol 50 µg
Number of Participants Analyzed [units: participants]	**64**	**62**	**60**
Forced Expiratory Volume in 1 Second (FEV1) 2 Hours Post-dose at the End of Each Treatment Period (Day 14) [units: Liters] Least Squares Mean (Standard Error)	**1.50 (0.024)**	**1.27 (0.024)**	**1.44 (0.025)**

No statistical analysis provided for Forced Expiratory Volume in 1 Second (FEV1) 2 Hours Post-dose at the End of Each Treatment Period (Day 14)

7. Secondary: Forced Expiratory Volume in 1 Second (FEV1) 3 Hours Post-dose at the End of Each Treatment Period (Day 14) [Time Frame: 3 hours post-dose at the end of each treatment period (Day 14)]

Measure Type	Secondary

Measure Title	Forced Expiratory Volume in 1 Second (FEV1) 3 Hours Post-dose at the End of Each Treatment Period (Day 14)
Measure Description	FEV1 was measured with spirometry conducted according to internationally accepted standards. The analysis included baseline FEV1, defined as the average of the FEV1 values measured at 50 and 15 minutes prior to the first study drug administration in that period, as a covariate.
Time Frame	3 hours post-dose at the end of each treatment period (Day 14)
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.

Reporting Groups

	Description
Indacaterol 300 µg	Indacaterol 300 µg was inhaled once daily for 14 days using a single-dose dry-powder inhaler (SDDPI) device. 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 to Indacaterol	Placebo to indacaterol was inhaled once daily for 14 days using a single-dose dry-powder inhaler (SDDPI) device. 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.
Salmeterol 50 µg	Salmeterol 50 µg was inhaled twice daily for 14 days using a multi-dose dry-powder inhaler (MDDPI) device. 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 to Indacaterol	Salmeterol 50 µg
Number of Participants Analyzed [units: participants]	**64**	**61**	**60**

Forced Expiratory Volume in 1 Second (FEV1) 3 Hours Post-dose at the End of Each Treatment Period (Day 14) [units: Liters] Least Squares Mean (Standard Error)	**1.51 (0.023)**	**1.29 (0.024)**	**1.45 (0.024)**

No statistical analysis provided for Forced Expiratory Volume in 1 Second (FEV1) 3 Hours Post-dose at the End of Each Treatment Period (Day 14)

8. Secondary: Forced Expiratory Volume in 1 Second (FEV1) 4 Hours Post-dose at the End of Each Treatment Period (Day 14) [Time Frame: 4 hours post-dose at the end of each treatment period (Day 14)]

Measure Type	Secondary
Measure Title	Forced Expiratory Volume in 1 Second (FEV1) 4 Hours Post-dose at the End of Each Treatment Period (Day 14)
Measure Description	FEV1 was measured with spirometry conducted according to internationally accepted standards. The analysis included baseline FEV1, defined as the average of the FEV1 values measured at 50 and 15 minutes prior to the first study drug administration in that period, as a covariate.
Time Frame	4 hours post-dose at the end of each treatment period (Day 14)
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.

Reporting Groups

	Description
Indacaterol 300 µg	Indacaterol 300 µg was inhaled once daily for 14 days using a single-dose dry-powder inhaler (SDDPI) device. 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 to Indacaterol	Placebo to indacaterol was inhaled once daily for 14 days using a single-dose dry-powder inhaler (SDDPI) device. 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.
Salmeterol 50 µg	Salmeterol 50 µg was inhaled twice daily for 14 days using a multi-dose dry-powder inhaler (MDDPI) device. 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 to Indacaterol	Salmeterol 50 µg
Number of Participants Analyzed [units: participants]	**63**	**60**	**59**
Forced Expiratory Volume in 1 Second (FEV1) 4 Hours Post-dose at the End of Each Treatment Period (Day 14) [units: Liters] Least Squares Mean (Standard Error)	**1.49 (0.023)**	**1.29 (0.023)**	**1.44 (0.023)**

No statistical analysis provided for Forced Expiratory Volume in 1 Second (FEV1) 4 Hours Post-dose at the End of Each Treatment Period (Day 14)

9. Secondary: Forced Expiratory Volume in 1 Second (FEV1) 5 Hours Post-dose at the End of Each Treatment Period (Day 14) [Time Frame: 5 hours post-dose at the end of each treatment period (Day 14)]

Measure Type	Secondary
Measure Title	Forced Expiratory Volume in 1 Second (FEV1) 5 Hours Post-dose at the End of Each Treatment Period (Day 14)
Measure Description	FEV1 was measured with spirometry conducted according to internationally accepted standards. The analysis included baseline FEV1, defined as the average of the FEV1 values measured at 50 and 15 minutes prior to the first study drug administration in that period, as a covariate.
Time Frame	5 hours post-dose at the end of each treatment period (Day 14)
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.

Reporting Groups

	Description
Indacaterol 300 µg	Indacaterol 300 µg was inhaled once daily for 14 days using a single-dose dry-powder inhaler (SDDPI) device. 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 to Indacaterol	Placebo to indacaterol was inhaled once daily for 14 days using a single-dose dry-powder inhaler (SDDPI) device. 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.
Salmeterol 50 µg	Salmeterol 50 µg was inhaled twice daily for 14 days using a multi-dose dry-powder inhaler (MDDPI) device. 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 to Indacaterol**	**Salmeterol 50 µg**
Number of Participants Analyzed [units: participants]	**63**	**59**	**59**
Forced Expiratory Volume in 1 Second (FEV1) 5 Hours Post-dose at the End of Each Treatment Period (Day 14) [units: Liters] Least Squares Mean (Standard Error)	**1.49 (0.025)**	**1.26 (0.026)**	**1.45 (0.026)**

No statistical analysis provided for Forced Expiratory Volume in 1 Second (FEV1) 5 Hours Post-dose at the End of Each Treatment Period (Day 14)

10. Secondary: Forced Expiratory Volume in 1 Second (FEV1) 6 Hours Post-dose at the End of Each Treatment Period (Day 14) [Time Frame: 6 hours post-dose at the end of each treatment period (Day 14)]

Measure Type	Secondary
Measure Title	Forced Expiratory Volume in 1 Second (FEV1) 6 Hours Post-dose at the End of Each Treatment Period (Day 14)
Measure Description	FEV1 was measured with spirometry conducted according to internationally accepted standards. The analysis included baseline FEV1, defined as the average of the FEV1 values measured at 50 and 15 minutes prior to the first study drug administration in that period, as a covariate.
Time Frame	6 hours post-dose at the end of each treatment period (Day 14)
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.

Reporting Groups

	Description
Indacaterol 300 µg	Indacaterol 300 µg was inhaled once daily for 14 days using a single-dose dry-powder inhaler (SDDPI) device. 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 to Indacaterol	Placebo to indacaterol was inhaled once daily for 14 days using a single-dose dry-powder inhaler (SDDPI) device. 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.
Salmeterol 50 µg	Salmeterol 50 µg was inhaled twice daily for 14 days using a multi-dose dry-powder inhaler (MDDPI) device. 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 to Indacaterol	Salmeterol 50 µg
Number of Participants Analyzed [units: participants]	**63**	**57**	**59**
Forced Expiratory Volume in 1 Second (FEV1) 6 Hours Post-dose at the End of Each Treatment Period (Day 14) [units: Liters] Least Squares Mean (Standard Error)	**1.48 (0.025)**	**1.29 (0.026)**	**1.42 (0.025)**

No statistical analysis provided for Forced Expiratory Volume in 1 Second (FEV1) 6 Hours Post-dose at the End of Each Treatment Period (Day 14)

11. Secondary: Forced Expiratory Volume in 1 Second (FEV1) 8 Hours Post-dose at the End of Each Treatment Period (Day 14) [Time Frame: 8 hours post-dose at the end of each treatment period (Day 14)]

Measure Type	Secondary
Measure Title	Forced Expiratory Volume in 1 Second (FEV1) 8 Hours Post-dose at the End of Each Treatment Period (Day 14)
Measure Description	FEV1 was measured with spirometry conducted according to internationally accepted standards. The analysis included baseline FEV1, defined as the average of the FEV1 values measured at 50 and 15 minutes prior to the first study drug administration in that period, as a covariate.
Time Frame	8 hours post-dose at the end of each treatment period (Day 14)
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.

Reporting Groups

	Description
Indacaterol 300 µg	Indacaterol 300 µg was inhaled once daily for 14 days using a single-dose dry-powder inhaler (SDDPI) device. 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 to Indacaterol	Placebo to indacaterol was inhaled once daily for 14 days using a single-dose dry-powder inhaler (SDDPI) device. 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.
Salmeterol 50 µg	Salmeterol 50 µg was inhaled twice daily for 14 days using a multi-dose dry-powder inhaler (MDDPI) device. 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 to Indacaterol	Salmeterol 50 µg
Number of Participants Analyzed [units: participants]	**63**	**56**	**59**
Forced Expiratory Volume in 1 Second (FEV1) 8 Hours Post-dose at the End of Each Treatment Period (Day 14) [units: Liters] Least Squares Mean (Standard Error)	**1.44 (0.025)**	**1.27 (0.026)**	**1.40 (0.026)**

No statistical analysis provided for Forced Expiratory Volume in 1 Second (FEV1) 8 Hours Post-dose at the End of Each Treatment Period (Day 14)

12. Secondary: Forced Expiratory Volume in 1 Second (FEV1) 10 Hours Post-dose at the End of Each Treatment Period (Day 14) [Time Frame: 10 hours post-dose at the end of each treatment period (Day 14)]

Measure Type	Secondary
Measure Title	Forced Expiratory Volume in 1 Second (FEV1) 10 Hours Post-dose at the End of Each Treatment Period (Day 14)

Measure Description	FEV1 was measured with spirometry conducted according to internationally accepted standards. The analysis included baseline FEV1, defined as the average of the FEV1 values measured at 50 and 15 minutes prior to the first study drug administration in that period, as a covariate.
Time Frame	10 hours post-dose at the end of each treatment period (Day 14)
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.

Reporting Groups

	Description
Indacaterol 300 µg	Indacaterol 300 µg was inhaled once daily for 14 days using a single-dose dry-powder inhaler (SDDPI) device. 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 to Indacaterol	Placebo to indacaterol was inhaled once daily for 14 days using a single-dose dry-powder inhaler (SDDPI) device. 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.
Salmeterol 50 µg	Salmeterol 50 µg was inhaled twice daily for 14 days using a multi-dose dry-powder inhaler (MDDPI) device. 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 to Indacaterol	Salmeterol 50 µg
Number of Participants Analyzed [units: participants]	**63**	**56**	**58**
Forced Expiratory Volume in 1 Second (FEV1) 10 Hours Post-dose at the End of Each			

Treatment Period (Day 14) **[units: Liters]** **Least Squares Mean (Standard Error)**	**1.43 (0.024)**	**1.25 (0.026)**	**1.36 (0.025)**

No statistical analysis provided for Forced Expiratory Volume in 1 Second (FEV1) 10 Hours Post-dose at the End of Each Treatment Period (Day 14)

13. Secondary: Forced Expiratory Volume in 1 Second (FEV1) 11 Hours 10 Minutes Post-dose at the End of Each Treatment Period (Day 14)
[Time Frame: 11 hours 10 minutes post-dose at the end of each treatment period (Day 14)]

Measure Type	Secondary
Measure Title	Forced Expiratory Volume in 1 Second (FEV1) 11 Hours 10 Minutes Post-dose at the End of Each Treatment Period (Day 14)
Measure Description	FEV1 was measured with spirometry conducted according to internationally accepted standards. The analysis included baseline FEV1, defined as the average of the FEV1 values measured at 50 and 15 minutes prior to the first study drug administration in that period, as a covariate.
Time Frame	11 hours 10 minutes post-dose at the end of each treatment period (Day 14)
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.

Reporting Groups

	Description
Indacaterol 300 µg	Indacaterol 300 µg was inhaled once daily for 14 days using a single-dose dry-powder inhaler (SDDPI) device. 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 to Indacaterol	Placebo to indacaterol was inhaled once daily for 14 days using a single-dose dry-powder inhaler (SDDPI) device. 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.
Salmeterol 50 µg	Salmeterol 50 µg was inhaled twice daily for 14 days using a multi-dose dry-powder inhaler (MDDPI) device. 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 to Indacaterol	Salmeterol 50 µg
Number of Participants Analyzed [units: participants]	**63**	**55**	**57**
Forced Expiratory Volume in 1 Second (FEV1) 11 Hours 10 Minutes Post-dose at the End of Each Treatment Period (Day 14) [units: Liters] Least Squares Mean (Standard Error)	**1.45 (0.025)**	**1.25 (0.027)**	**1.35 (0.027)**

No statistical analysis provided for Forced Expiratory Volume in 1 Second (FEV1) 11 Hours 10 Minutes Post-dose at the End of Each Treatment Period (Day 14)

14. Secondary: Forced Expiratory Volume in 1 Second (FEV1) 11 Hours 45 Minutes Post-dose at the End of Each Treatment Period (Day 14) [Time Frame: 11 hours 45 minutes post-dose at the end of each treatment period (Day 14)]

Measure Type	Secondary
Measure Title	Forced Expiratory Volume in 1 Second (FEV1) 11 Hours 45 Minutes Post-dose at the End of Each Treatment Period (Day 14)
Measure Description	FEV1 was measured with spirometry conducted according to internationally accepted standards. The analysis included baseline FEV1, defined as the average of the FEV1 values measured at 50 and 15 minutes prior to the first study drug administration in that period, as a covariate.

Time Frame	11 hours 45 minutes post-dose at the end of each treatment period (Day 14)
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.

Reporting Groups

	Description
Indacaterol 300 µg	Indacaterol 300 µg was inhaled once daily for 14 days using a single-dose dry-powder inhaler (SDDPI) device. 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 to Indacaterol	Placebo to indacaterol was inhaled once daily for 14 days using a single-dose dry-powder inhaler (SDDPI) device. 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.
Salmeterol 50 µg	Salmeterol 50 µg was inhaled twice daily for 14 days using a multi-dose dry-powder inhaler (MDDPI) device. 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 to Indacaterol**	**Salmeterol 50 µg**
Number of Participants Analyzed [units: participants]	**63**	**54**	**57**
Forced Expiratory Volume in 1 Second (FEV1) 11 Hours 45 Minutes Post-dose at the End of Each Treatment Period (Day 14) [units: Liters] Least Squares Mean (Standard Error)	**1.46 (0.026)**	**1.24 (0.028)**	**1.35 (0.027)**

No statistical analysis provided for Forced Expiratory Volume in 1 Second (FEV1) 11 Hours 45 Minutes Post-dose at the End of Each Treatment Period (Day 14)

15. Secondary: Forced Expiratory Volume in 1 Second (FEV1) 14 Hours Post-dose at the End of Each Treatment Period (Day 14) [Time Frame: 14 hours post-dose at the end of each treatment period (Day 14)]

Measure Type	Secondary
Measure Title	Forced Expiratory Volume in 1 Second (FEV1) 14 Hours Post-dose at the End of Each Treatment Period (Day 14)
Measure Description	FEV1 was measured with spirometry conducted according to internationally accepted standards. The analysis included baseline FEV1, defined as the average of the FEV1 values measured at 50 and 15 minutes prior to the first study drug administration in that period, as a covariate.
Time Frame	14 hours post-dose at the end of each treatment period (Day 14)
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.

Reporting Groups

	Description
Indacaterol 300 µg	Indacaterol 300 µg was inhaled once daily for 14 days using a single-dose dry-powder inhaler (SDDPI) device. 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 to Indacaterol	Placebo to indacaterol was inhaled once daily for 14 days using a single-dose dry-powder inhaler (SDDPI) device. 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.
Salmeterol 50 µg	Salmeterol 50 µg was inhaled twice daily for 14 days using a multi-dose dry-powder inhaler (MDDPI) device. 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 to Indacaterol	Salmeterol 50 µg
Number of Participants Analyzed [units: participants]	**61**	**55**	**58**
Forced Expiratory Volume in 1 Second (FEV1) 14 Hours Post-dose at the End of Each Treatment Period (Day 14) [units: Liters] Least Squares Mean (Standard Error)	**1.45 (0.026)**	**1.24 (0.027)**	**1.39 (0.026)**

No statistical analysis provided for Forced Expiratory Volume in 1 Second (FEV1) 14 Hours Post-dose at the End of Each Treatment Period (Day 14)

16. Secondary: Forced Expiratory Volume in 1 Second (FEV1) 20 Hours 10 Minutes Post-dose at the End of Each Treatment Period (Day 15) [Time Frame: 20 hours 10 minutes post-dose at the end of each treatment period (Day 15)]

Measure Type	Secondary
Measure Title	Forced Expiratory Volume in 1 Second (FEV1) 20 Hours 10 Minutes Post-dose at the End of Each Treatment Period (Day 15)
Measure Description	FEV1 was measured with spirometry conducted according to internationally accepted standards. The analysis included baseline FEV1, defined as the average of the FEV1 values measured at 50 and 15 minutes prior to the first study drug administration in that period, as a covariate.
Time Frame	20 hours 10 minutes post-dose at the end of each treatment period (Day 15)
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.

Reporting Groups

	Description
Indacaterol 300 µg	Indacaterol 300 µg was inhaled once daily for 14 days using a single-dose dry-powder inhaler (SDDPI) device. 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 to Indacaterol	Placebo to indacaterol was inhaled once daily for 14 days using a single-dose dry-powder inhaler (SDDPI) device. 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.
Salmeterol 50 µg	Salmeterol 50 µg was inhaled twice daily for 14 days using a multi-dose dry-powder inhaler (MDDPI) device. 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 to Indacaterol**	**Salmeterol 50 µg**
Number of Participants Analyzed **[units: participants]**	**60**	**57**	**61**
Forced Expiratory Volume in 1 Second (FEV1) 20 Hours 10 Minutes Post-dose at the End of Each Treatment Period (Day 15) **[units: Liters]** **Least Squares Mean (Standard Error)**	**1.36 (0.027)**	**1.17 (0.028)**	**1.31 (0.027)**

No statistical analysis provided for Forced Expiratory Volume in 1 Second (FEV1) 20 Hours 10 Minutes Post-dose at the End of Each Treatment Period (Day 15)

17. Secondary: Forced Expiratory Volume in 1 Second (FEV1) 20 Hours 45 Minutes Post-dose at the End of Each Treatment Period (Day 15) [Time Frame: 20 hours 45 minutes post-dose at the end of each treatment period (Day 15)]

Measure Type	Secondary
Measure Title	Forced Expiratory Volume in 1 Second (FEV1) 20 Hours 45 Minutes Post-dose at the End of Each Treatment Period (Day 15)
Measure Description	FEV1 was measured with spirometry conducted according to internationally accepted standards. The analysis included baseline FEV1, defined as the average of the FEV1 values measured at 50 and 15 minutes prior to the first study drug administration in that period, as a covariate.
Time Frame	20 hours 45 minutes post-dose at the end of each treatment period (Day 15)
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.

Reporting Groups

	Description
Indacaterol 300 µg	Indacaterol 300 µg was inhaled once daily for 14 days using a single-dose dry-powder inhaler (SDDPI) device. 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 to Indacaterol	Placebo to indacaterol was inhaled once daily for 14 days using a single-dose dry-powder inhaler (SDDPI) device. 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.
Salmeterol 50 µg	Salmeterol 50 µg was inhaled twice daily for 14 days using a multi-dose dry-powder inhaler (MDDPI) device. 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 to Indacaterol	Salmeterol 50 µg
Number of Participants Analyzed [units: participants]	**62**	**59**	**59**
Forced Expiratory Volume in 1 Second (FEV1) 20 Hours 45 Minutes Post-dose at the End of Each Treatment Period (Day 15) [units: Liters] Least Squares Mean (Standard Error)	**1.40 (0.025)**	**1.19 (0.026)**	**1.35 (0.026)**

No statistical analysis provided for Forced Expiratory Volume in 1 Second (FEV1) 20 Hours 45 Minutes Post-dose at the End of Each Treatment Period (Day 15)

18. Secondary: Forced Expiratory Volume in 1 Second (FEV1) 22 Hours Post-dose at the End of Each Treatment Period (Day 15) [Time Frame: 22 hours post-dose at the end of each treatment period (Day 15)]

Measure Type	Secondary
Measure Title	Forced Expiratory Volume in 1 Second (FEV1) 22 Hours Post-dose at the End of Each Treatment Period (Day 15)
Measure Description	FEV1 was measured with spirometry conducted according to internationally accepted standards. The analysis included baseline FEV1, defined as the average of the FEV1 values measured at 50 and 15 minutes prior to the first study drug administration in that period, as a covariate.
Time Frame	22 hours post-dose at the end of each treatment period (Day 15)
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.

Reporting Groups

	Description
Indacaterol 300 µg	Indacaterol 300 µg was inhaled once daily for 14 days using a single-dose dry-powder inhaler (SDDPI) device. 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 to Indacaterol	Placebo to indacaterol was inhaled once daily for 14 days using a single-dose dry-powder inhaler (SDDPI) device. 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.
Salmeterol 50 µg	Salmeterol 50 µg was inhaled twice daily for 14 days using a multi-dose dry-powder inhaler (MDDPI) device. 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 to Indacaterol	Salmeterol 50 µg
Number of Participants Analyzed [units: participants]	**62**	**60**	**59**
Forced Expiratory Volume in 1 Second (FEV1) 22 Hours Post-dose at the End of Each Treatment Period (Day 15) [units: Liters] Least Squares Mean (Standard Error)	**1.43 (0.026)**	**1.25 (0.026)**	**1.38 (0.026)**

No statistical analysis provided for Forced Expiratory Volume in 1 Second (FEV1) 22 Hours Post-dose at the End of Each Treatment Period (Day 15)

19. Secondary: Forced Expiratory Volume in 1 Second (FEV1) 23 Hours 10 Minutes Post-dose at the End of Each Treatment Period (Day 15) [Time Frame: 23 hours 10 minutes post-dose at the end of each treatment period (Day 15)]

Measure Type	Secondary

Measure Title	Forced Expiratory Volume in 1 Second (FEV1) 23 Hours 10 Minutes Post-dose at the End of Each Treatment Period (Day 15)
Measure Description	FEV1 was measured with spirometry conducted according to internationally accepted standards. The analysis included baseline FEV1, defined as the average of the FEV1 values measured at 50 and 15 minutes prior to the first study drug administration in that period, as a covariate.
Time Frame	23 hours 10 minutes post-dose at the end of each treatment period (Day 15)
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.

Reporting Groups

	Description
Indacaterol 300 µg	Indacaterol 300 µg was inhaled once daily for 14 days using a single-dose dry-powder inhaler (SDDPI) device. 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 to Indacaterol	Placebo to indacaterol was inhaled once daily for 14 days using a single-dose dry-powder inhaler (SDDPI) device. 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.
Salmeterol 50 µg	Salmeterol 50 µg was inhaled twice daily for 14 days using a multi-dose dry-powder inhaler (MDDPI) device. 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 to Indacaterol	Salmeterol 50 µg
Number of Participants Analyzed	**61**	**61**	**59**

[units: participants]			
Forced Expiratory Volume in 1 Second (FEV1) 23 Hours 10 Minutes Post-dose at the End of Each Treatment Period (Day 15) [units: Liters] Least Squares Mean (Standard Error)	**1.48 (0.030)**	**1.24 (0.030)**	**1.37 (0.031)**

No statistical analysis provided for Forced Expiratory Volume in 1 Second (FEV1) 23 Hours 10 Minutes Post-dose at the End of Each Treatment Period (Day 15)

20. Secondary: Forced Expiratory Volume in 1 Second (FEV1) 23 Hours 45 Minutes Post-dose at the End of Each Treatment Period (Day 15)
[Time Frame: 23 hours 45 minutes post-dose at the end of each treatment period (Day 15)]

Measure Type	Secondary
Measure Title	Forced Expiratory Volume in 1 Second (FEV1) 23 Hours 45 Minutes Post-dose at the End of Each Treatment Period (Day 15)
Measure Description	FEV1 was measured with spirometry conducted according to internationally accepted standards. The analysis included baseline FEV1, defined as the average of the FEV1 values measured at 50 and 15 minutes prior to the first study drug administration in that period, as a covariate.
Time Frame	23 hours 45 minutes post-dose at the end of each treatment period (Day 15)
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.

Reporting Groups

	Description

Indacaterol 300 µg	Indacaterol 300 µg was inhaled once daily for 14 days using a single-dose dry-powder inhaler (SDDPI) device. 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 to Indacaterol	Placebo to indacaterol was inhaled once daily for 14 days using a single-dose dry-powder inhaler (SDDPI) device. 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.
Salmeterol 50 µg	Salmeterol 50 µg was inhaled twice daily for 14 days using a multi-dose dry-powder inhaler (MDDPI) device. 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 to Indacaterol	Salmeterol 50 µg
Number of Participants Analyzed [units: participants]	**61**	**61**	**59**
Forced Expiratory Volume in 1 Second (FEV1) 23 Hours 45 Minutes Post-dose at the End of Each Treatment Period (Day 15) [units: Liters] Least Squares Mean (Standard Error)	**1.45 (0.026)**	**1.28 (0.026)**	**1.38 (0.026)**

No statistical analysis provided for Forced Expiratory Volume in 1 Second (FEV1) 23 Hours 45 Minutes Post-dose at the End of Each Treatment Period (Day 15)

Serious Adverse Events

Hide Serious Adverse Events

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

Reporting Groups

	Description
Indacaterol 300 µg	Indacaterol 300 µg was inhaled once daily for 14 days using a single-dose dry-powder inhaler (SDDPI) device. 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.
Salmeterol 50 µg	Salmeterol 50 µg was inhaled twice daily for 14 days using a multi-dose dry-powder inhaler (MDDPI) device. 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 to Indacaterol	Placebo to indacaterol was inhaled once daily for 14 days using a single-dose dry-powder inhaler (SDDPI) device. 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	Salmeterol 50 µg	Placebo to Indacaterol
Total, serious adverse events			
# participants affected / at risk	**1/66 (1.52%)**	**0/65 (0.00%)**	**0/66 (0.00%)**
Respiratory, thoracic and mediastinal disorders			
Chronic obstructive pulmonary disease † 1			
# participants affected / at risk	**1/66 (1.52%)**	**0/65 (0.00%)**	**0/66 (0.00%)**

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

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 300 µg	Indacaterol 300 µg was inhaled once daily for 14 days using a single-dose dry-powder inhaler (SDDPI) device. 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.
Salmeterol 50 µg	Salmeterol 50 µg was inhaled twice daily for 14 days using a multi-dose dry-powder inhaler (MDDPI) device. 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 to Indacaterol	Placebo to indacaterol was inhaled once daily for 14 days using a single-dose dry-powder inhaler (SDDPI) device. 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	Salmeterol 50 µg	Placebo to Indacaterol
Total, other (not including serious) adverse events			
# participants affected / at risk	**0/66 (0.00%)**	**0/65 (0.00%)**	**4/66 (6.06%)**
Musculoskeletal and connective tissue disorders			
Back pain † 1			
# participants affected / at risk	**0/66 (0.00%)**	**0/65 (0.00%)**	**4/66 (6.06%)**

† 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

Responsible Party:	External Affairs, Novartis Pharmaceuticals
ClinicalTrials.gov Identifier:	NCT00622635 History of Changes
Other Study ID Numbers:	**CQAB149B2340**
Study First Received:	February 4, 2008
Results First Received:	July 22, 2011
Last Updated:	July 22, 2011
Health Authority:	United States: Food and Drug Administration Spain: Spanish Agency of Medicines Belgium: Federal Agency for Medicinal Products and Health Products