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Trial record 1 of 1 for: CQAB149B2305

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Study of Indacaterol Dosed in the Evening in Patients With Chronic Obstructive Pulmonary Disease (COPD)

This study has been completed.

Sponsor:
Novartis

Information provided by:
Novartis

ClinicalTrials.gov Identifier:
NCT00615030

First received: February 1, 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/Efficacy Study; Intervention Model: Crossover Assignment; Masking: Double Blind (Subject, Caregiver); Primary Purpose: Treatment
Condition:	Chronic Obstructive Pulmonary Disease (COPD)
Interventions:	Drug: Indacaterol Drug: Salmeterol Drug: Placebo to Indacaterol Drug: Placebo to Salmeterol

Participant Flow

Hide Participant Flow

Recruitment Details

Key information relevant to the recruitment process for the overall study, such as dates of the recruitment period and locations
Patients were randomized to one of the 12 possible treatment sequences of the double-blind 10-week treatment phase (Week 1 – 10). Each treatment sequence was divided into three treatment periods (I/II/III) of 15-day duration each. The first and second treatment period of each sequence was followed by a 2-week washout period.

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment

Total 96 patients were randomized; one randomized patient discontinued from the study prior to exposure to study drug because of abnormal test procedure(s) result.

Reporting Groups

	Description
Sequence 1:Indacaterol Morning,Indacaterol Evening, Salmeterol	In period I, indacaterol 300 µg once a day in the morning delivered via single dose dry powder inhaler (SDDPI) with a placebo to salmeterol delivered via dry powder inhaler (DPI). Patients were also instructed to take evening doses of a placebo to indacaterol via SDDPI and placebo to salmeterol via DPI. In period II, patients were instructed to take morning doses of a placebo to indacaterol delivered via SDDPI and placebo to salmeterol delivered via DPI. Indacaterol 300 µg once a day in the evening delivered via SDDPI with placebo to salmeterol delivered via DPI. In period III, Salmeterol 50 µg twice daily delivered via DPI. One of the two daily doses of salmeterol was administered in the morning and second dose in the evening along with placebo matching indacaterol delivered by SDDPI. Daily inhaled corticosteroid treatment (if applicable) was allowed to remain stable throughout the study. The short acting (beta) β2-agonist (SABA) was available for rescue use throughout the study.
Sequence 2:Indacaterol Evening,Indacaterol Morning, Placebo	In period I, patients were instructed to take morning doses of a placebo to indacaterol delivered via SDDPI and placebo to salmeterol delivered via DPI. Indacaterol 300 µg once a day in the evening delivered via SDDPI with placebo to salmeterol delivered via DPI. In period II, indacaterol 300 µg once a day in the morning delivered via SDDPI with a placebo to salmeterol delivered via DPI. Patients were also instructed to take evening doses of a placebo to indacaterol via SDDPI and placebo to salmeterol via DPI. In period III, during morning and evening, placebo matching indacaterol was delivered via SDDPI and placebo matching salmeterol was delivered via DPI. Daily inhaled corticosteroid treatment (if applicable) was allowed to remain stable throughout the study. The short acting (beta) β2-agonist (SABA) was available for rescue use throughout the study.
Sequence 3: Salmeterol, Placebo, Indacaterol Morning	In period I, salmeterol 50 µg twice daily delivered via DPI. One of the two daily doses of salmeterol was administered in the morning and the second dose was in the evening along with placebo matching indacaterol delivered by SDDPI. In period II, during morning and evening, placebo matching indacaterol was delivered via SDDPI and placebo matching salmeterol was delivered via DPI. In period III, indacaterol 300 µg once a day in the morning delivered via SDDPI with a placebo to salmeterol delivered via DPI. Patients were also instructed to take evening doses of a placebo to indacaterol via SDDPI and placebo to salmeterol via DPI. Daily inhaled corticosteroid treatment (if applicable) was allowed to remain stable throughout the study. The short acting (beta) β2-agonist (SABA) was available for rescue use throughout the study.
Sequence 4: Placebo, Salmeterol, Indacaterol Evening	In period I, during morning and evening, placebo matching indacaterol was delivered via SDDPI and placebo matching salmeterol was delivered via DPI. In period II, salmeterol 50 µg twice daily delivered via dry powder inhaler (DPI). One of the two daily doses of salmeterol was administered in the morning and the second dose was in the evening along with placebo matching indacaterol delivered by SDDPI. In period III, patients were instructed to take morning doses of a placebo to indacaterol delivered via SDDPI and placebo to salmeterol delivered via DPI. Indacaterol 300 µg once a day in the evening delivered via SDDPI with placebo to salmeterol delivered via dry DPI. Daily inhaled corticosteroid treatment (if applicable) was allowed to remain stable throughout the study. The short acting (beta) β2-agonist (SABA) was available for rescue use throughout the study.
Sequence 5: Indacaterol Morning, Placebo, Indacaterol Evening	In period I, indacaterol 300 µg once a day in the morning delivered via SDDPI with a placebo to salmeterol delivered via DPI. Patients were also instructed to take evening doses of a placebo to indacaterol via SDDPI and placebo to salmeterol via DPI. In period II, During morning and evening, placebo matching indacaterol was delivered via SDDPI and placebo matching salmeterol was delivered via DPI. In period III, Patients were instructed to take morning doses of a placebo to indacaterol delivered via SDDPI and placebo to salmeterol delivered via DPI. Indacaterol 300 µg once a day in the evening delivered via SDDPI with placebo to salmeterol delivered via DPI. Daily inhaled corticosteroid treatment (if applicable) was allowed to remain stable throughout the study. The short acting (beta) β2-agonist (SABA) was available for rescue use throughout the study.
Sequence 6:Indacaterol Evening,Salmeterol, Indacaterol Morning	In period I, patients were instructed to take morning doses of a placebo to indacaterol delivered via SDDPI and placebo to salmeterol delivered via DPI. Indacaterol 300 µg once a day in the evening delivered via SDDPI with placebo to salmeterol delivered via DPI. In period II, salmeterol 50 µg twice daily delivered via DPI. One of the two daily doses of salmeterol was administered in the morning and the second dose in evening along with placebo matching indacaterol delivered by SDDPI. In period III, indacaterol 300 µg once a day in the morning delivered via SDDPI with a placebo to salmeterol delivered via DPI. Patients were also instructed to take evening doses of a placebo to indacaterol via SDDPI and placebo to salmeterol via DPI. Daily inhaled corticosteroid treatment (if applicable) was allowed to remain stable throughout the study. The short acting (beta) β2-agonist (SABA) was available for rescue use throughout the study.
Sequence 7: Salmeterol, Indacaterol Evening, Placebo	In period I, salmeterol 50 µg twice daily delivered via DPI. One of the two daily doses of salmeterol was administered in the morning and the second dose in evening along with placebo matching indacaterol delivered by SDDPI. In period II, patients were instructed to take morning doses of a placebo to indacaterol delivered via SDDPI and placebo to salmeterol delivered via DPI. Indacaterol 300 µg once a day in the evening delivered via SDDPI with placebo to salmeterol delivered via DPI. In period III, during morning and evening, placebo matching indacaterol was delivered via SDDPI and placebo matching salmeterol was delivered via DPI. Daily inhaled corticosteroid treatment (if applicable) was allowed to remain stable throughout the study. The short acting (beta) β2-agonist (SABA) was available for rescue use throughout the study.
Sequence 8: Placebo, Indacaterol Morning, Salmeterol	In period I, during morning and evening, placebo matching indacaterol was delivered via SDDPI and placebo matching salmeterol was delivered via DPI. In period II, indacaterol 300 µg once a day in the morning delivered via SDDPI with a placebo to salmeterol delivered via dry powder inhaler DPI. Patients were also instructed to take evening doses of a placebo to indacaterol via SDDPI and placebo to salmeterol via DPI. In period III, salmeterol 50 µg twice daily delivered via DPI. One of the two daily doses of salmeterol was administered in the morning and the second dose in evening along with placebo matching indacaterol delivered by SDDPI. Daily inhaled corticosteroid treatment (if applicable) was allowed to remain stable throughout the study. The short acting (beta) β2-agonist (SABA) was available for rescue use throughout the study.
Sequence 9:Indacaterol Morning, Salmeterol, Placebo	In period I, indacaterol 300 µg once a day in the morning delivered via SDDPI with a placebo to salmeterol delivered via DPI. Patients were also instructed to take evening doses of a placebo to indacaterol via SDDPI and placebo to salmeterol via DPI. In period II, salmeterol 50 µg twice daily delivered via DPI. One of the two daily doses of salmeterol was administered in the morning and the second dose in evening along with placebo matching indacaterol delivered by SDDPI. In period III, during morning and evening, placebo matching indacaterol was delivered via SDDPI and placebo matching salmeterol was delivered via DPI. Daily inhaled corticosteroid treatment (if applicable) was allowed to remain stable throughout the study. The short acting (beta) β2-agonist (SABA) was available for rescue use throughout the study.
Sequence 10: Indacaterol Evening, Placebo, Salmeterol	In period I, patients were instructed to take morning doses of a placebo to indacaterol delivered via SDDPI and placebo to salmeterol delivered via DPI. Indacaterol 300 µg once a day in the evening delivered via SDDPI with placebo to salmeterol delivered via DPI. In period II, during morning and evening, placebo matching indacaterol was delivered via SDDPI and placebo matching salmeterol was delivered via DPI. In period III, salmeterol 50 µg twice daily delivered via DPI. One of the two daily doses of salmeterol was administered in the morning and the second dose in evening along

	with placebo matching indacaterol delivered by SDDPI. Daily inhaled corticosteroid treatment (if applicable) was allowed to remain stable throughout the study. The short acting (beta) β2-agonist (SABA) was available for rescue use throughout the study.
Sequence 11:Salmeterol,Indacaterol Morning,Indacaterol Evening	In period I, salmeterol 50 µg twice daily delivered via DPI. One of the two daily doses of salmeterol was administered in the morning and the second dose in evening along with placebo matching indacaterol delivered by SDDPI. In period II, indacaterol 300 µg once a day in the morning delivered via SDDPI with a placebo to salmeterol delivered via DPI. Patients were also instructed to take evening doses of a placebo to indacaterol via SDDPI and placebo to salmeterol via DPI. In period III, patients were instructed to take morning doses of a placebo to indacaterol delivered via SDDPI and placebo to salmeterol delivered via DPI. Indacaterol 300 µg once a day in the evening delivered via SDDPI with placebo to salmeterol delivered via DPI. Daily inhaled corticosteroid treatment (if applicable) was allowed to remain stable throughout the study. The short acting (beta) β2-agonist (SABA) was available for rescue use throughout the study.
Sequence 12: Placebo, Indacaterol Evening, Indacaterol Morning	In period, during morning and evening, placebo matching indacaterol was delivered via SDDPI and placebo matching salmeterol was delivered via DPI. In period II, patients were instructed to take morning doses of a placebo to indacaterol delivered via SDDPI and placebo to salmeterol delivered via DPI. Indacaterol 300 µg once a day in the evening delivered via SDDPI with placebo to salmeterol delivered via DPI. In period III, indacaterol 300 µg once a day in the morning delivered via SDDPI with a placebo to salmeterol delivered via DPI. Patients were also instructed to take evening doses of a placebo to indacaterol via SDDPI and placebo to salmeterol via DPI. Daily inhaled corticosteroid treatment (if applicable) was allowed to remain stable throughout the study. The short acting (beta) β2-agonist (SABA) was available for rescue use throughout the study.

Participant Flow for 3 periods

Period 1: Period I

	Sequence 1:Indacaterol Morning,Indacaterol Evening, Salmeterol	Sequence 2:Indacaterol Evening,Indacaterol Morning, Placebo	Sequence 3: Salmeterol, Placebo, Indacaterol Morning	Sequence 4: Placebo, Salmeterol, Indacaterol Evening	Sequence 5: Indacaterol Morning, Placebo, Indacaterol Evening	Sequence 6:Indacaterol Evening,Salmeterol, Indacaterol Morning	Sequence 7: Salmeterol, Indacaterol Evening, Placebo	Sequence 8: Placebo, Indacaterol Morning, Salmeterol	Sequence 9:Indacaterol Morning, Salmeterol, Placebo	Sequence 10: Indacaterol Evening, Placebo, Salmeterol	Sequence 11:Salmeterol,Indacaterol Morning,Indacaterol Evening	Sequence 12: Placebo, Indacaterol Evening, Indacaterol Morning
STARTED	9	8	9	8	9	6	7	7	9	8	8	7
COMPLETED	8	8	9	8	8	5	7	7	8	8	7	6
NOT COMPLETED	1	0	0	0	1	1	0	0	1	0	1	1
Administrative problem	0	0	0	0	1	0	0	0	0	0	0	0
Protocol deviation	1	0	0	0	0	0	0	0	0	0	0	0
Subject withdrew consent	0	0	0	0	0	0	0	0	1	0	1	1
Abnormal laboratory value(s)	0	0	0	0	0	1	0	0	0	0	0	0

[1] 1 randomized patient in this sequence dropped out before exposure to study drug in Period I.

Period 2: Period II

	Sequence 1:Indacaterol Morning,Indacaterol Evening, Salmeterol	Sequence 2:Indacaterol Evening,Indacaterol Morning, Placebo	Sequence 3: Salmeterol, Placebo, Indacaterol Morning	Sequence 4: Placebo, Salmeterol, Indacaterol Evening	Sequence 5: Indacaterol Morning, Placebo, Indacaterol Evening	Sequence 6:Indacaterol Evening,Salmeterol, Indacaterol Morning	Sequence 7: Salmeterol, Indacaterol Evening, Placebo	Sequence 8: Placebo, Indacaterol Morning, Salmeterol	Sequence 9:Indacaterol Morning, Salmeterol, Placebo	Sequence 10: Indacaterol Evening, Placebo, Salmeterol	Sequence 11:Salmeterol,Indacaterol Morning,Indacaterol Evening	Sequence 12: Placebo, Indacaterol Evening, Indacaterol Morning
STARTED	8	8	9	8	8	5	7	7	8	8	7	6
COMPLETED	8	8	8	7	8	5	6	7	7	8	7	6
NOT												

COMPLETED	0	0	1	1	0	0	1	0	1	0	0	0
Adverse Event	0	0	1	0	0	0	0	0	1	0	0	0
Subject withdrew consent	0	0	0	1	0	0	1	0	0	0	0	0

Period 3: Period III

	Sequence 1:Indacaterol Morning,Indacaterol Evening, Salmeterol	Sequence 2:Indacaterol Evening,Indacaterol Morning, Placebo	Sequence 3: Salmeterol, Placebo, Indacaterol Morning	Sequence 4: Placebo, Salmeterol, Indacaterol Evening	Sequence 5: Indacaterol Morning, Placebo, Indacaterol Evening	Sequence 6:Indacaterol Evening,Salmeterol, Indacaterol Morning	Sequence 7: Salmeterol, Indacaterol Evening, Placebo	Sequence 8: Placebo, Indacaterol Morning, Salmeterol	Sequence 9:Indacaterol Morning, Salmeterol, Placebo	Sequence 10: Indacaterol Evening, Placebo, Salmeterol	Sequence 11:Salmeterol,Indacaterol Morning,Indacaterol Evening	Sequence 12: Placebo, Indacaterol Evening, Indacaterol Morning
STARTED	8	8	8	7	8	5	6	7	7	8	7	6
COMPLETED	7	8	8	6	8	5	6	7	7	8	7	6
NOT COMPLETED	1	0	0	1	0	0	0	0	0	0	0	0
Administrative problems	1	0	0	1	0	0	0	0	0	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
Total Patients	No text entered.

Baseline Measures

	Total Patients
Number of Participants [units: participants]	95
Age [units: years] Mean (Standard Deviation)	64.1 (8.70)
Gender [units: participants]	

Female	**15**
Male	**80**

[1] Baseline measures were based on safety population.

Outcome Measures

Show All Outcome Measures

1. Primary: Trough Forced Expiratory Volume in 1 Second (FEV1) Following 14 Days of Evening Dosing of Indacaterol Versus Placebo [Time Frame: After 14 days of treatment]

Hide Outcome Measure 1

Measure Type	Primary
Measure Title	Trough Forced Expiratory Volume in 1 Second (FEV1) Following 14 Days of Evening Dosing of Indacaterol Versus Placebo
Measure Description	Trough FEV1 was assessed by performing spirometry measurements in the clinic for each treatment period. For the primary efficacy variable, trough FEV1 is the mean of two measurements taken at 23h 10 min and 23h 45 min post dose. The primary variable was analyzed using an analysis of covariance (ANCOVA) model with the (period) baseline FEV1 as covariate. The (period) baseline FEV1 was defined as the value measured before the study drug administration in that treatment period.
Time Frame	After 14 days of 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.
The modified intention-to-treat (mITT) population included all randomized patients who received at least one dose of study drug. Patients who received only one treatment were also included for calculation of treatment means. This analysis included all patients who received indacaterol in the evening or placebo in their assigned treatment sequence.

Reporting Groups

	Description
Indacaterol Evening	Patients were instructed to take morning doses of a placebo to indacaterol delivered via single dose dry powder inhaler (SDDPI) and placebo to salmeterol delivered via dry powder inhaler (DPI). Indacaterol 300 µg once a day in the evening delivered via single dose dry powder inhaler (SDDPI) with placebo to salmeterol delivered via dry powder inhaler (DPI). Daily inhaled corticosteroid treatment (if applicable) was allowed to remain stable throughout the study. The short acting (beta) β2-agonist (SABA) was available for rescue use throughout the study.
Placebo	During evening, placebo matching indacaterol was delivered via SDDPI and placebo matching salmeterol was delivered via DPI. Daily inhaled corticosteroid treatment (if applicable) was allowed to remain stable throughout the study. The short acting (beta) β2-agonist (SABA) was available for rescue use throughout the study.

Measured Values

	Indacaterol Evening	**Placebo**
Number of Participants Analyzed [units: participants]	**63**	**64**
Trough Forced Expiratory Volume in 1 Second (FEV1) Following 14 Days of Evening Dosing of Indacaterol Versus Placebo [units: Liters] Least Squares Mean (Standard Error)	**1.57 (0.025)**	**1.37 (0.025)**

No statistical analysis provided for Trough Forced Expiratory Volume in 1 Second (FEV1) Following 14 Days of Evening Dosing of Indacaterol Versus Placebo

2. Secondary: Trough FEV1 Assessed After 14 Days of Dosing for All Other Treatment Comparisons [Time Frame: After 14 days of dosing]

Hide Outcome Measure 2

Measure Type	Secondary
Measure Title	Trough FEV1 Assessed After 14 Days of Dosing for All Other Treatment Comparisons
Measure Description	Trough FEV1 was assessed by performing spirometry measurements in the clinic for each treatment period. On the morning and evening of Day 15 trough FEV1 (i.e. mean of measurements performed 23 h 10 min and 23 h 45 min post-dose) were assessed. An analysis of covariance (ANCOVA) model was used with the (period) baseline FEV1 as covariate. The (period) baseline FEV1 was defined as the value measured before the study drug administration in that treatment period.
Time Frame	After 14 days of dosing
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The modified intention-to-treat (mITT) population included all randomized patients who received at least one dose of study drug. Patients who received only one treatment were also included for calculation of treatment means.

Reporting Groups

	Description
Indacaterol Morning	Indacaterol 300 µg once a day in the morning delivered via single dose dry powder inhaler (SDDPI) with a placebo to salmeterol delivered via dry powder inhaler (DPI). Patients were also instructed to take evening doses of a placebo to indacaterol via SDDPI and placebo to salmeterol via DPI. Daily inhaled corticosteroid treatment (if applicable) was allowed to remain stable throughout the study. The short acting (beta) β2-agonist (SABA) was available for rescue use throughout the study.
Indacaterol Evening	Patients were instructed to take morning doses of a placebo to indacaterol delivered via SDDPI and placebo to salmeterol delivered via DPI. Indacaterol 300 µg once a day in the evening delivered via single dose dry powder inhaler (SDDPI) with placebo to salmeterol delivered via dry powder inhaler (DPI). Daily inhaled corticosteroid treatment (if applicable) was allowed to remain stable throughout the study. The short acting (beta) β2-agonist (SABA) was available for rescue use throughout the study.
Salmeterol Morning	In the morning, Salmeterol 50 µg delivered via dry powder inhaler (DPI) along with placebo matching indacaterol via SDDPI. Daily inhaled corticosteroid treatment (if applicable) was allowed to remain stable throughout the study. The short acting (beta) β2-agonist (SABA) was available for rescue use throughout the study.
Salmeterol Evening	In the evening, Salmeterol 50 µg delivered via dry powder inhaler (DPI) along with placebo matching indacaterol via SDDPI. Daily inhaled corticosteroid treatment (if applicable) was allowed to remain stable throughout the study. The short acting (beta) β2-agonist (SABA) was available for rescue use throughout the study.
Placebo Morning	Placebo to indacaterol delivered via SDDPI and placebo to salmeterol delivered via manufacturer's proprietary DPI. Daily inhaled corticosteroid treatment (if applicable) was allowed to remain stable throughout the study. The short acting (beta) β2-agonist (SABA) was available for rescue use throughout the study.
Placebo Evening	Placebo to indacaterol delivered via SDDPI and placebo to salmeterol delivered via manufacturer's proprietary DPI. Daily inhaled corticosteroid treatment (if applicable) was allowed to remain stable throughout the study. The short acting (beta) β2-agonist (SABA) was available for rescue use throughout the study.

Measured Values

	Indacaterol Morning	Indacaterol Evening	Salmeterol Morning	Salmeterol Evening	Placebo Morning	Placebo Evening
Number of Participants Analyzed [units: participants]	**65**	**63**	**65**	**65**	**66**	**64**
Trough FEV1 Assessed After 14 Days of Dosing for All Other Treatment Comparisons [units: Liters] Least Squares Mean (Standard Error)	**1.56 (0.025)**	**1.57 (0.025)**	**1.51 (0.025)**	**1.46 (0.025)**	**1.36 (0.025)**	**1.37 (0.025)**

No statistical analysis provided for Trough FEV1 Assessed After 14 Days of Dosing for All Other Treatment Comparisons

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	10 weeks
Additional Description	In the safety population, all patients were analyzed according to treatment received.

Reporting Groups

	Description
Indacaterol Evening	Patients were instructed to take morning doses of a placebo to indacaterol delivered via SDDPI and placebo to salmeterol delivered via DPI. Indacaterol 300 µg once a day in the evening delivered via single dose dry powder inhaler (SDDPI) with placebo to salmeterol delivered via dry powder inhaler (DPI). Daily inhaled corticosteroid treatment (if applicable) was allowed to remain stable throughout the study. All patients were provided with a SABA for use (if needed) as rescue medication throughout the study.
Indacaterol Morning	Indacaterol 300 µg once a day in the morning delivered via single dose dry powder inhaler (SDDPI) with a placebo to salmeterol delivered via dry powder inhaler (DPI). Patients were also instructed to take evening doses of a placebo to indacaterol via SDDPI and placebo to salmeterol via DPI. Daily inhaled corticosteroid treatment (if applicable) was allowed to remain stable throughout the study. All patients were provided with a SABA for use (if needed) as rescue medication throughout the study.
Salmeterol	Salmeterol 50 µg twice daily delivered via dry powder inhaler (DPI). One of the two daily doses of salmeterol was administered in the morning along with placebo matching indacaterol delivered by single dose dry powder inhaler (SDDPI). The second dose of salmeterol was administered in the evening along with placebo matching indacaterol delivered by SDDPI. Daily inhaled corticosteroid treatment (if applicable) was allowed to remain stable throughout the study. All patients were provided with a SABA for use (if needed) as rescue medication throughout the study.
Placebo	During morning and evening, placebo matching indacaterol was delivered via SDDPI and placebo matching salmeterol was delivered via DPI. Daily inhaled corticosteroid treatment (if applicable) was allowed to remain stable throughout the study. All patients were provided with a SABA for use (if needed) as rescue medication throughout the study.

Serious Adverse Events

	Indacaterol Evening	Indacaterol Morning	Salmeterol	Placebo
Total, serious adverse events				
# participants affected / at risk	**0/65 (0.00%)**	**1/68 (1.47%)**	**0/68 (0.00%)**	**0/68 (0.00%)**
Injury, poisoning and procedural complications				
Rib fracture				
# participants affected / at risk	**0/65 (0.00%)**	**1/68 (1.47%)**	**0/68 (0.00%)**	**0/68 (0.00%)**

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

Other Adverse Events

Hide Other Adverse Events

Time Frame	10 weeks
Additional Description	In the safety population, all patients were analyzed according to treatment received.

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
Indacaterol Evening	Patients were instructed to take morning doses of a placebo to indacaterol delivered via SDDPI and placebo to salmeterol delivered via DPI. Indacaterol 300 µg once a day in the evening delivered via single dose dry powder inhaler (SDDPI) with placebo to salmeterol delivered via dry powder inhaler (DPI). Daily inhaled corticosteroid treatment (if applicable) was allowed to remain stable throughout the study. All patients were provided with a SABA for use (if needed) as rescue medication throughout the study.
Indacaterol Morning	Indacaterol 300 µg once a day in the morning delivered via single dose dry powder inhaler (SDDPI) with a placebo to salmeterol delivered via dry powder inhaler (DPI). Patients were also instructed to take evening doses of a placebo to indacaterol via SDDPI and placebo to salmeterol via DPI. Daily inhaled corticosteroid treatment (if applicable) was allowed to remain stable throughout the study. All patients were provided with a SABA for use (if needed) as rescue medication throughout the study.
Salmeterol	Salmeterol 50 µg twice daily delivered via dry powder inhaler (DPI). One of the two daily doses of salmeterol was administered in the morning along with placebo matching indacaterol delivered by single dose dry powder inhaler (SDDPI). The second dose of salmeterol was administered in the evening along with placebo matching indacaterol delivered by SDDPI. Daily inhaled corticosteroid treatment (if applicable) was allowed to remain stable throughout the study. All patients were provided with a SABA for use (if needed) as rescue medication throughout the study.
Placebo	During morning and evening, placebo matching indacaterol was delivered via SDDPI and placebo matching salmeterol was delivered via DPI. Daily inhaled corticosteroid treatment (if applicable) was allowed to remain stable throughout the study. All patients were provided with a SABA for use (if needed) as rescue medication throughout the study.

Other Adverse Events

	Indacaterol Evening	Indacaterol Morning	Salmeterol	Placebo
Total, other (not including serious) adverse events				
# participants affected / at risk	**10/65 (15.38%)**	**4/68 (5.88%)**	**3/68 (4.41%)**	**5/68 (7.35%)**
Respiratory, thoracic and mediastinal disorders				
Chronic obstructive pulmonary disease				
# participants affected / at risk	**5/65 (7.69%)**	**0/68 (0.00%)**	**2/68 (2.94%)**	**5/68 (7.35%)**
Cough				
# participants affected / at risk	**5/65 (7.69%)**	**4/68 (5.88%)**	**1/68 (1.47%)**	**0/68 (0.00%)**

† 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 (i.e., 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:

Magnussen H, Verkindre C, Jack D, Jadayel D, Henley M, Woessner R, Higgins M, Kramer B; INPUT study investigators. Indacaterol once-daily is equally effective dosed in the evening or morning in COPD. Respir Med. 2010 Dec;104(12):1869-76. doi: 10.1016/j.rmed.2010.08.010. Epub 2010 Sep 20.

Responsible Party:	External Affairs, Novartis
ClinicalTrials.gov Identifier:	NCT00615030 History of Changes
Other Study ID Numbers:	CQAB149B2305
Study First Received:	February 1, 2008
Results First Received:	July 22, 2011
Last Updated:	July 22, 2011
Health Authority:	Germany: Federal Institute for Drugs and Medical Devices