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Trial record **1 of 1** for: CQAB149BDE01

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Effect of Indacaterol on Inspiratory Capacity (IC)

This study has been completed.

Sponsor:
Novartis Pharmaceuticals

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

ClinicalTrials.gov Identifier:
NCT01012765

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History of Changes

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Results First Received: January 17, 2012

Study Type:	Interventional
Study Design:	Allocation: Randomized; Intervention Model: Crossover Assignment; Masking: Double Blind (Subject, Caregiver, Investigator, Outcomes Assessor); Primary Purpose: Treatment
Condition:	Chronic Obstructive Pulmonary Disease
Interventions:	Drug: Indacaterol Drug: Tiotropium Drug: Placebo

Participant Flow

Hide Participant Flow

Recruitment Details

Key information relevant to the recruitment process for the overall study, such as dates of the recruitment period and locations
No text entered.

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment
173 participants were screened. 129 participants entered the study.

Reporting Groups

	Description
Tiotropium - Placebo - Indacaterol	In treatment period 1, patients received tiotropium 18µg twice daily; in treatment period 2, patients received placebo to indacaterol once daily; in treatment period 3, patients received indacaterol 150µg once daily. Patients received indacaterol and placebo by single-dose dry powder inhaler (SDDPI); tiotropium was delivered via a proprietary inhalation device. There was a washout period of 13 days between each period. Use of fixed-dose combination of an anticholinergic plus a short-acting β2-agonist and use of long-acting β2-agonists were discontinued. Salbutamol rescue use was allowed during the treatment period as needed.
Indacaterol - Placebo - Tiotropium	In treatment period 1, patients received indacaterol 150µg once daily; in treatment period 2, patients received placebo to indacaterol once daily; in treatment period 3, patients received tiotropium 18µg twice daily. Patients received indacaterol and placebo by single-dose dry powder inhaler (SDDPI); tiotropium was delivered via a proprietary inhalation device. There was a washout period of 13 days between each period. Use of fixed-dose combination of an anticholinergic plus a short-acting β2-agonist and use of long-acting β2-agonists were discontinued. Salbutamol rescue use was allowed during the treatment period as needed.
Indacaterol - Tiotropium - Placebo	In treatment period 1, patients received indacaterol 150µg once daily; in treatment period 2, patients received tiotropium 18µg twice daily; in treatment period 3, patients received placebo to indacaterol once daily. Patients received indacaterol and placebo by single-dose dry powder inhaler (SDDPI); tiotropium was delivered via a proprietary inhalation device. There was a washout period of 13 days between each

	period. Use of fixed-dose combination of an anticholinergic plus a short-acting β2-agonist and use of long-acting β2-agonists were discontinued. Salbutamol rescue use was allowed during the treatment period as needed.
Placebo - Indacaterol - Tiotropium	In treatment period 1, patients received placebo to indacaterol once daily; in treatment period 2, patients received indacaterol 150µg once daily; in treatment period 3, patients received tiotropium 18µg twice daily. Patients received indacaterol and placebo by single-dose dry powder inhaler (SDDPI); tiotropium was delivered via a proprietary inhalation device. There was a washout period of 13 days between each period. Use of fixed-dose combination of an anticholinergic plus a short-acting β2-agonist and use of long-acting β2-agonists were discontinued. Salbutamol rescue use was allowed during the treatment period as needed.
Placebo - Tiotropium - Indacaterol	In treatment period 1, patients received placebo to indacaterol once daily; in treatment period 2, patients received tiotropium 18µg twice daily; in treatment period 3, patients received indacaterol 150µg once daily. Patients received indacaterol and placebo by single-dose dry powder inhaler (SDDPI); tiotropium was delivered via a proprietary inhalation device. There was a washout period of 13 days between each period. Use of fixed-dose combination of an anticholinergic plus a short-acting β2-agonist and use of long-acting β2-agonists were discontinued. Salbutamol rescue use was allowed during the treatment period as needed.
Tiotropium - Indacaterol - Placebo	In treatment period 1, patients received tiotropium 18µg twice daily; in treatment period 2, patients received indacaterol 150µg once daily; in treatment period 3, patients received placebo to indacaterol once daily. Patients received indacaterol and placebo by single-dose dry powder inhaler (SDDPI); tiotropium was delivered via a proprietary inhalation device. There was a washout period of 13 days between each period. Use of fixed-dose combination of an anticholinergic plus a short-acting β2-agonist and use of long-acting β2-agonists were discontinued. Salbutamol rescue use was allowed during the treatment period as needed.

Participant Flow for 3 periods

Period 1: Treatment Period 1

	Tiotropium - Placebo - Indacaterol	Indacaterol - Placebo - Tiotropium	Indacaterol - Tiotropium - Placebo	Placebo - Indacaterol - Tiotropium	Placebo - Tiotropium - Indacaterol	Tiotropium - Indacaterol - Placebo
STARTED	**20**	**21**	**23**	**18**	**22**	**25**
COMPLETED	**17**	**21**	**21**	**15**	**19**	**25**

NOT COMPLETED	**3**	**0**	**2**	**3**	**3**	**0**
Adverse Event	**1**	**0**	**1**	**0**	**0**	**0**
Withdrawal by Subject	**2**	**0**	**0**	**0**	**0**	**0**
Administrative problems	**0**	**0**	**1**	**1**	**1**	**0**
Protocol Violation	**0**	**0**	**0**	**2**	**1**	**0**
Unsatisfactory therapeutic effect	**0**	**0**	**0**	**0**	**1**	**0**

Period 2: Treatment Period 2

	Tiotropium - Placebo - Indacaterol	Indacaterol - Placebo - Tiotropium	Indacaterol - Tiotropium - Placebo	Placebo - Indacaterol - Tiotropium	Placebo - Tiotropium - Indacaterol	Tiotropium - Indacaterol - Placebo
STARTED	**17**	**21**	**21**	**15**	**19**	**25**
COMPLETED	**16**	**19**	**18**	**15**	**18**	**24**
NOT COMPLETED	**1**	**2**	**3**	**0**	**1**	**1**
Withdrawal by Subject	**1**	**0**	**1**	**0**	**1**	**0**
Abnormal laboratory value(s)	**0**	**0**	**0**	**0**	**0**	**1**
Adverse Event	**0**	**1**	**1**	**0**	**0**	**0**
Unsatisfactory						

therapeutic effect	**0**	**1**	**1**	**0**	**0**	**0**

Period 3: Treatment Period 3

	Tiotropium - Placebo - Indacaterol	Indacaterol - Placebo - Tiotropium	Indacaterol - Tiotropium - Placebo	Placebo - Indacaterol - Tiotropium	Placebo - Tiotropium - Indacaterol	Tiotropium - Indacaterol - Placebo
STARTED	**16**	**19**	**18**	**15**	**18**	**24**
COMPLETED	**16**	**19**	**18**	**15**	**18**	**24**
NOT COMPLETED	**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
Safety Set	The safety set included all participants who received at least one dose of study medication during at least one study period.

Baseline Measures

	Safety Set

Number of Participants [units: participants]	**129**
Age [units: years] Mean (Standard Deviation)	**61.4 (8.9)**
Gender [units: participants]	
Female	**42**
Male	**87**

Outcome Measures

Hide All Outcome Measures

1. Primary: Peak Inspiratory Capacity (IC) After 21 Days of Treatment [Time Frame: 21 days]

Measure Type	Primary
Measure Title	Peak Inspiratory Capacity (IC) After 21 Days of Treatment
Measure Description	IC was measured with spirometry conducted according to internationally accepted standards. Peak IC was defined as the maximum IC of the mean over the 3 values which were measured each at 30min, 2 hour, 3 hour and 4 hour post dose by body plethysmography. Analysis of variance model was used with the factors: center, period, treatment, and patients within center.
Time Frame	21 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.

Full analysis set (FAS) included all randomized patients who received at least one dose of study medication during at least one study period. Participants with observations after 21 days were included in the analysis.

Reporting Groups

	Description
Indacaterol	Indacaterol 150µg once daily was administered by a single-dose dry powder inhaler (SDDPI). Use of fixed-dose combination of an anticholinergic plus a short-acting β2-agonist and use of long-acting β2-agonists were discontinued. Salbutamol rescue use was allowed during the treatment period as needed.
Placebo	Placebo to indacaterol was administered once daily by a single-dose dry powder inhaler (SDDPI). Use of fixed-dose combination of an anticholinergic plus a short-acting β2-agonist and use of long-acting β2-agonists were discontinued. Salbutamol rescue use was allowed during the treatment period as needed.
Tiotropium	Tiotropium 18µg once daily was administered via a proprietary inhalation device. Use of fixed-dose combination of an anticholinergic plus a short-acting β2-agonist and use of long-acting β2-agonists were discontinued. Salbutamol rescue use was allowed during the treatment period as needed.

Measured Values

	Indacaterol	Placebo	Tiotropium
Number of Participants Analyzed [units: participants]	**110**	**106**	**105**
Peak Inspiratory Capacity (IC) After 21 Days of Treatment [units: Liters] Least Squares Mean (95% Confidence Interval)	**2.69 (2.64 to 2.75)**	**2.48 (2.42 to 2.53)**	**2.63 (2.58 to 2.69)**

No statistical analysis provided for Peak Inspiratory Capacity (IC) After 21 Days of Treatment

2. Secondary: Trough IC After 20 Days of Treatment [Time Frame: 20 days]

Measure Type	Secondary
Measure Title	Trough IC After 20 Days of Treatment

Measure Description	Trough IC was measured with spirometry conducted according to internationally accepted standards. Trough IC was calculated as the mean of the three measurements of pre-dose body plethysmography (days 21, 55 and 89). Analysis of variance model was used with the factors: center, period, treatment, and patients within center.
Time Frame	20 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 (mITT) excluded patients from centers who performed invalid body plethysmography. Participants with observations after 20 days were included in this analysis.

Reporting Groups

	Description
Indacaterol	Indacaterol 150µg once daily was administered by a single-dose dry powder inhaler (SDDPI). Use of fixed-dose combination of an anticholinergic plus a short-acting β2-agonist and use of long-acting β2-agonists were discontinued. Salbutamol rescue use was allowed during the treatment period as needed.
Placebo	Placebo to indacaterol was administered once daily by a single-dose dry powder inhaler (SDDPI). Use of fixed-dose combination of an anticholinergic plus a short-acting β2-agonist and use of long-acting β2-agonists were discontinued. Salbutamol rescue use was allowed during the treatment period as needed.
Tiotropium	Tiotropium 18µg once daily was administered via a proprietary inhalation device. Use of fixed-dose combination of an anticholinergic plus a short-acting β2-agonist and use of long-acting β2-agonists were discontinued. Salbutamol rescue use was allowed during the treatment period as needed.

Measured Values

	Indacaterol	**Placebo**	**Tiotropium**
Number of Participants Analyzed [units: participants]	**87**	**83**	**84**
Trough IC After 20 Days of Treatment			

[units: Liters] Least Squares Mean (95% Confidence Interval)	**2.43 (2.37 to 2.50)**	**2.28 (2.21 to 2.34)**	**2.39 (2.32 to 2.45)**

No statistical analysis provided for Trough IC After 20 Days of Treatment

3. Secondary: Peak Residual Volume (RV) After 21 Days of Treatment [Time Frame: 21 days]

Measure Type	Secondary
Measure Title	Peak Residual Volume (RV) After 21 Days of Treatment
Measure Description	Peak RV was measured with spirometry conducted according to internationally accepted standards. Peak RV was calculated as the Total Lung Capacity minus the maximum of the three Inspiratory Vital Capacity measurements which were measured each at 30 min, 2 hours, 3 hours and 4 hours post dose (at days 21, 55 and 89). Analysis of variance model was used with the factors: center, period, treatment, and patients within center.
Time Frame	21 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 (mITT) excluded patients from centers who performed invalid body plethysmography. Participants with observations after 21 days were included in this analysis.

Reporting Groups

	Description
Indacaterol	Indacaterol 150µg once daily was administered by a single-dose dry powder inhaler (SDDPI). Use of fixed-dose combination of an anticholinergic plus a short-acting β2-agonist and use of long-acting β2-agonists were discontinued. Salbutamol rescue use was allowed during the treatment period as needed.
Placebo	Placebo to indacaterol was administered once daily by a single-dose dry powder inhaler (SDDPI). Use of fixed-dose

	combination of an anticholinergic plus a short-acting β2-agonist and use of long-acting β2-agonists were discontinued. Salbutamol rescue use was allowed during the treatment period as needed.
Tiotropium	Tiotropium 18µg once daily was administered via a proprietary inhalation device. Use of fixed-dose combination of an anticholinergic plus a short-acting β2-agonist and use of long-acting β2-agonists were discontinued. Salbutamol rescue use was allowed during the treatment period as needed.

Measured Values

	Indacaterol	Placebo	Tiotropium
Number of Participants Analyzed [units: participants]	**85**	**82**	**84**
Peak Residual Volume (RV) After 21 Days of Treatment [units: Liters] Least Squares Mean (95% Confidence Interval)	**3.77 (3.67 to 3.87)**	**4.17 (4.07 to 4.27)**	**3.79 (3.69 to 3.89)**

No statistical analysis provided for Peak Residual Volume (RV) After 21 Days of Treatment

4. Secondary: Peak Total Lung Capacity (TLC) After 21 Days of Treatment [Time Frame: 21 days]

Measure Type	Secondary
Measure Title	Peak Total Lung Capacity (TLC) After 21 Days of Treatment
Measure Description	TLC was measured with spirometry conducted according to internationally accepted standards. Peak TLC was calculated as the mean of the three Functional Residual Capacity peak measurements plus the mean of the three Inspiratory Capacity measurements which were measured each at 30 min, 2 hours, 3 hours and 4 hours post dose (at days 21, 55 and 89). Analysis of variance model was used with the factors: center, period, treatment, and patients within center.
Time Frame	21 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 (mITT) excluded patients from centers who performed invalid body plethysmography. Participants with observations after 21 days were included in this analysis.

Reporting Groups

	Description
Indacaterol	Indacaterol 150µg once daily was administered by a single-dose dry powder inhaler (SDDPI). Use of fixed-dose combination of an anticholinergic plus a short-acting β2-agonist and use of long-acting β2-agonists were discontinued. Salbutamol rescue use was allowed during the treatment period as needed.
Placebo	Placebo to indacaterol was administered once daily by a single-dose dry powder inhaler (SDDPI). Use of fixed-dose combination of an anticholinergic plus a short-acting β2-agonist and use of long-acting β2-agonists were discontinued. Salbutamol rescue use was allowed during the treatment period as needed.
Tiotropium	Tiotropium 18µg once daily was administered via a proprietary inhalation device. Use of fixed-dose combination of an anticholinergic plus a short-acting β2-agonist and use of long-acting β2-agonists were discontinued. Salbutamol rescue use was allowed during the treatment period as needed.

Measured Values

	Indacaterol	**Placebo**	**Tiotropium**
Number of Participants Analyzed [units: participants]	**86**	**82**	**84**
Peak Total Lung Capacity (TLC) After 21 Days of Treatment [units: Liters] Least Squares Mean (95% Confidence Interval)	**7.25 (7.16 to 7.33)**	**7.38 (7.30 to 7.47)**	**7.25 (7.16 to 7.33)**

No statistical analysis provided for Peak Total Lung Capacity (TLC) After 21 Days of Treatment

5. Secondary: Peak Residual Volume/Peak Total Lung Capacity (RV/TLC) Ratio After 21 Days of Treatment [Time Frame: 21 days]

Measure Type	Secondary
Measure Title	Peak Residual Volume/Peak Total Lung Capacity (RV/TLC) Ratio After 21 Days of Treatment
Measure Description	Peak RV/TLC ratio was measured with spirometry conducted according to internationally accepted standards. Peak RV/TLC was defined as the peak RV/peak TLC. Analysis of variance model was used with the factors: center, period, treatment, and patients within center.
Time Frame	21 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 (mITT) excluded patients from centers who performed invalid body plethysmography. Participants with observations after 21 days were included in this analysis.

Reporting Groups

	Description
Indacaterol	Indacaterol 150µg once daily was administered by a single-dose dry powder inhaler (SDDPI). Use of fixed-dose combination of an anticholinergic plus a short-acting β2-agonist and use of long-acting β2-agonists were discontinued. Salbutamol rescue use was allowed during the treatment period as needed.
Placebo	Placebo to indacaterol was administered once daily by a single-dose dry powder inhaler (SDDPI). Use of fixed-dose combination of an anticholinergic plus a short-acting β2-agonist and use of long-acting β2-agonists were discontinued. Salbutamol rescue use was allowed during the treatment period as needed.
Tiotropium	Tiotropium 18µg once daily was administered via a proprietary inhalation device. Use of fixed-dose combination of an anticholinergic plus a short-acting β2-agonist and use of long-acting β2-agonists were discontinued. Salbutamol rescue use was allowed during the treatment period as needed.

Measured Values

	Indacaterol	**Placebo**	**Tiotropium**

Number of Participants Analyzed [units: participants]	**83**	**81**	**84**
Peak Residual Volume/Peak Total Lung Capacity (RV/TLC) Ratio After 21 Days of Treatment [units: Ratio] Least Squares Mean (95% Confidence Interval)	**0.52 (0.51 to 0.53)**	**0.57 (0.56 to 0.58)**	**0.53 (0.52 to 0.53)**

No statistical analysis provided for Peak Residual Volume/Peak Total Lung Capacity (RV/TLC) Ratio After 21 Days of Treatment

6. Secondary: Peak Specific Airway Resistance (sRaw) After 21 Days of Treatment [Time Frame: 21 days]

Measure Type	Secondary
Measure Title	Peak Specific Airway Resistance (sRaw) After 21 Days of Treatment
Measure Description	Peak sRaw was measured with spirometry conducted according to internationally accepted standards. Peak sRaw was the mean of the three measurements which were measured each at 30 min, 2 hours, 3 hours and 4 hours post dose (at days 21, 55 and 89). Analysis of variance model was used with the factors: center, period, treatment, and patients within center.
Time Frame	21 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.
Full analysis set (FAS) included all randomized patients who received at least one dose of study medication during at least one study period. Participants with observations after 21 days were included in the analysis.

Reporting Groups

	Description

Indacaterol	Indacaterol 150µg once daily was administered by a single-dose dry powder inhaler (SDDPI). Use of fixed-dose combination of an anticholinergic plus a short-acting β2-agonist and use of long-acting β2-agonists were discontinued. Salbutamol rescue use was allowed during the treatment period as needed.
Placebo	Placebo to indacaterol was administered once daily by a single-dose dry powder inhaler (SDDPI). Use of fixed-dose combination of an anticholinergic plus a short-acting β2-agonist and use of long-acting β2-agonists were discontinued. Salbutamol rescue use was allowed during the treatment period as needed.
Tiotropium	Tiotropium 18µg once daily was administered via a proprietary inhalation device. Use of fixed-dose combination of an anticholinergic plus a short-acting β2-agonist and use of long-acting β2-agonists were discontinued. Salbutamol rescue use was allowed during the treatment period as needed.

Measured Values

	Indacaterol	**Placebo**	**Tiotropium**
Number of Participants Analyzed [units: participants]	**101**	**97**	**99**
Peak Specific Airway Resistance (sRaw) After 21 Days of Treatment [units: kPa*sec] Least Squares Mean (95% Confidence Interval)	**2.05 (1.89 to 2.22)**	**3.08 (2.91 to 3.24)**	**2.00 (1.83 to 2.16)**

No statistical analysis provided for Peak Specific Airway Resistance (sRaw) After 21 Days of Treatment

7. Secondary: FEV1 30 Minutes Post-dose After 21 Days of Treatment [Time Frame: 21 days]

Measure Type	Secondary
Measure Title	FEV1 30 Minutes Post-dose After 21 Days of Treatment
Measure Description	FEV1 was measured with spirometry conducted according to internationally accepted standards. FEV1 was measured 30 minutes post-dose. Analysis of variance model was used with the factors: center, period, treatment, and patients within center.
Time Frame	21 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.
Full analysis set (FAS) included all randomized patients who received at least one dose of study medication during at least one study period. Participants with observations after 21 days were included in the analysis.

Reporting Groups

	Description
Indacaterol	Indacaterol 150µg once daily was administered by a single-dose dry powder inhaler (SDDPI). Use of fixed-dose combination of an anticholinergic plus a short-acting β2-agonist and use of long-acting β2-agonists were discontinued. Salbutamol rescue use was allowed during the treatment period as needed.
Placebo	Placebo to indacaterol was administered once daily by a single-dose dry powder inhaler (SDDPI). Use of fixed-dose combination of an anticholinergic plus a short-acting β2-agonist and use of long-acting β2-agonists were discontinued. Salbutamol rescue use was allowed during the treatment period as needed.
Tiotropium	Tiotropium 18µg once daily was administered via a proprietary inhalation device. Use of fixed-dose combination of an anticholinergic plus a short-acting β2-agonist and use of long-acting β2-agonists were discontinued. Salbutamol rescue use was allowed during the treatment period as needed.

Measured Values

	Indacaterol	**Placebo**	**Tiotropium**
Number of Participants Analyzed [units: participants]	**108**	**106**	**109**
FEV1 30 Minutes Post-dose After 21 Days of Treatment [units: Liters] Least Squares Mean (95% Confidence Interval)	**1.92 (1.89 to 1.96)**	**1.68 (1.64 to 1.71)**	**1.91 (1.88 to 1.95)**

No statistical analysis provided for FEV1 30 Minutes Post-dose After 21 Days of Treatment

8. Secondary: Trough Forced Expiratory Volume in 1 Second (FEV1) After 20 Days of Treatment [Time Frame: 20 days]

Measure Type	Secondary
Measure Title	Trough Forced Expiratory Volume in 1 Second (FEV1) After 20 Days of Treatment
Measure Description	FEV1 was measured with spirometry conducted according to internationally accepted standards. FEV1 was measured pre-dose after 20 days of treatment. Analysis of variance model was used with the factors: center, period, treatment, and patients within center.
Time Frame	20 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.
Full analysis set (FAS) included all randomized patients who received at least one dose of study medication during at least one study period. Participants with observations after 20 days were included in the analysis.

Reporting Groups

	Description
Indacaterol	Indacaterol 150µg once daily was administered by a single-dose dry powder inhaler (SDDPI). Use of fixed-dose combination of an anticholinergic plus a short-acting β2-agonist and use of long-acting β2-agonists were discontinued. Salbutamol rescue use was allowed during the treatment period as needed.
Placebo	Placebo to indacaterol was administered once daily by a single-dose dry powder inhaler (SDDPI). Use of fixed-dose combination of an anticholinergic plus a short-acting β2-agonist and use of long-acting β2-agonists were discontinued. Salbutamol rescue use was allowed during the treatment period as needed.
Tiotropium	Tiotropium 18µg once daily was administered via a proprietary inhalation device. Use of fixed-dose combination of an anticholinergic plus a short-acting β2-agonist and use of long-acting β2-agonists were discontinued. Salbutamol rescue use was allowed during the treatment period as needed.

Measured Values

	Indacaterol	Placebo	Tiotropium
Number of Participants Analyzed [units: participants]	**111**	**110**	**112**
Trough Forced Expiratory Volume in 1 Second (FEV1) After 20 Days of Treatment [units: Liters] Least Squares Mean (95% Confidence Interval)	**1.80 (1.77 to 1.84)**	**1.61 (1.57 to 1.64)**	**1.78 (1.75 to 1.82)**

No statistical analysis provided for Trough Forced Expiratory Volume in 1 Second (FEV1) After 20 Days of Treatment

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	No text entered.
Additional Description	The safety set included all participants who received at least one dose of study medication during at least one study period.

Reporting Groups

	Description
Indacaterol 150ug	Indacaterol 150µg once daily was administered by a single-dose dry powder inhaler (SDDPI). Use of fixed-dose combination of an anticholinergic plus a short-acting β2-agonist and use of long-acting β2-agonists were discontinued. Salbutamol rescue use was allowed during the treatment period as needed.
Placebo	Placebo to indacaterol was administered once daily by a single-dose dry powder inhaler (SDDPI). Use of fixed-dose combination of an anticholinergic plus a short-acting β2-agonist and use of long-acting β2-agonists were discontinued. Salbutamol rescue use was allowed during the treatment period as needed.
Tiotropium 18ug	Tiotropium 18µg once daily was administered via a proprietary inhalation device. Use of fixed-dose combination of an

	anticholinergic plus a short-acting β2-agonist and use of long-acting β2-agonists were discontinued. Salbutamol rescue use was allowed during the treatment period as needed.

Serious Adverse Events

	Indacaterol 150ug	Placebo	Tiotropium 18ug
Total, serious adverse events			
# participants affected / at risk	**1/118 (0.85%)**	**1/120 (0.83%)**	**3/119 (2.52%)**
Infections and infestations			
PNEUMONIA † 1			
# participants affected / at risk	**0/118 (0.00%)**	**0/120 (0.00%)**	**1/119 (0.84%)**
Injury, poisoning and procedural complications			
HAND FRACTURE † 1			
# participants affected / at risk	**1/118 (0.85%)**	**0/120 (0.00%)**	**0/119 (0.00%)**
INJURY † 1			
# participants affected / at risk	**0/118 (0.00%)**	**0/120 (0.00%)**	**1/119 (0.84%)**
Respiratory, thoracic and mediastinal disorders			
LUNG DISORDER † 1			
# participants affected / at risk	**0/118 (0.00%)**	**1/120 (0.83%)**	**1/119 (0.84%)**

† 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	The safety set included all participants who received at least one dose of study medication during at least one study period.

Frequency Threshold

Threshold above which other adverse events are reported	1%

Reporting Groups

	Description
Indacaterol 150ug	Indacaterol 150µg once daily was administered by a single-dose dry powder inhaler (SDDPI). Use of fixed-dose combination of an anticholinergic plus a short-acting β2-agonist and use of long-acting β2-agonists were discontinued. Salbutamol rescue use was allowed during the treatment period as needed.
Placebo	Placebo to indacaterol was administered once daily by a single-dose dry powder inhaler (SDDPI). Use of fixed-dose combination of an anticholinergic plus a short-acting β2-agonist and use of long-acting β2-agonists were discontinued. Salbutamol rescue use was allowed during the treatment period as needed.
Tiotropium 18ug	Tiotropium 18µg once daily was administered via a proprietary inhalation device. Use of fixed-dose combination of an anticholinergic plus a short-acting β2-agonist and use of long-acting β2-agonists were discontinued. Salbutamol rescue use was allowed during the treatment period as needed.

Other Adverse Events

	Indacaterol 150ug	Placebo	Tiotropium 18ug
Total, other (not including serious) adverse events			
# participants affected / at risk	**20/118 (16.95%)**	**16/120 (13.33%)**	**10/119 (8.40%)**
Infections and infestations			
NASOPHARYNGITIS † [1]			
# participants affected / at risk	**9/118 (7.63%)**	**8/120 (6.67%)**	**3/119 (2.52%)**
RHINITIS † [1]			
# participants affected / at risk	**2/118 (1.69%)**	**0/120 (0.00%)**	**0/119 (0.00%)**
Musculoskeletal and connective tissue disorders			

BACK PAIN † 1			
# participants affected / at risk	**2/118 (1.69%)**	**2/120 (1.67%)**	**5/119 (4.20%)**
Nervous system disorders			
HEADACHE † 1			
# participants affected / at risk	**2/118 (1.69%)**	**3/120 (2.50%)**	**2/119 (1.68%)**
Respiratory, thoracic and mediastinal disorders			
COUGH † 1			
# participants affected / at risk	**4/118 (3.39%)**	**0/120 (0.00%)**	**0/119 (0.00%)**
DYSPNOEA † 1			
# participants affected / at risk	**3/118 (2.54%)**	**2/120 (1.67%)**	**1/119 (0.84%)**
Vascular disorders			
HYPOTENSION † 1			
# participants affected / at risk	**0/118 (0.00%)**	**2/120 (1.67%)**	**0/119 (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:

Watz H, Krippner F, Kirsten A, Magnussen H, Vogelmeier C. Indacaterol improves lung hyperinflation and physical activity in patients with moderate chronic obstructive pulmonary disease--a randomized, multicenter, double-blind, placebo-controlled study. BMC Pulm Med. 2014 Oct 4;14:158. doi: 10.1186/1471-2466-14-158.

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