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Trial record **1 of 1** for: CQAB149B2223

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# Efficacy, Safety and Pharmacokinetics of Different Regimens of Indacaterol

**This study has been completed.**

**Sponsor:**
Novartis Pharmaceuticals

**Information provided by:**
Novartis

**ClinicalTrials.gov Identifier:**
NCT01156844

First received: June 30, 2010
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; Intervention Model: Parallel Assignment;<br>Masking: Double Blind (Subject, Caregiver, Investigator, Outcomes Assessor);<br>Primary Purpose: Treatment |
| **Condition:** | Persistent Asthma |
| **Interventions:** | Drug: Indacaterol<br>Drug: Placebo to Indacaterol |

## 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 |
|---|
| The study consisted of a 21 day screening period, a 14 day run-in period and a baseline assessment day prior to the 16 day treatment period. 1 participant randomized to 75 ug Indacaterol and 1 participant randomized to Placebo did not receive study drug and were not included in the Safety set milestone. |

### Reporting Groups

| | Description |
|---|---|
| **Indacaterol 37.5 µg (Twice a Day)** | Indacaterol 37.5 µg twice a day (bid) inhaled via Concept1, a single dose dry powder inhaler (SDDPI), in the morning and in the evening for 16 days. All patients had to receive daily treatment with inhaled corticosteroid up to the maximum dose per day in a stable regimen for at least 4-weeks prior to screening and remain stable through out the study. The short acting (beta) β2-agonist (SABA) salbutamol/albuterol was available for rescue use throughout the study. |
| **Indacaterol 75 µg (Once a Day)** | Indacaterol 75 µg once a day (qd) inhaled via Concept1, a single dose dry powder inhaler (SDDPI), in the morning and Placebo to Indacaterol inhaled once daily via Concept1 in the evening for 16 days. All patients had to receive daily treatment with inhaled corticosteroid up to the maximum dose per day in a stable regimen for at least 4-weeks prior to screening and remain stable through out the study. The short acting (beta) β2-agonist (SABA) salbutamol/albuterol was available for rescue use throughout the study. |
| **Indacaterol 150 µg (Every Other Day)** | Indacaterol 150 µg every other day (qod) inhaled via Concept1, a single dose dry powder inhaler (SDDPI) for a total of 16 days. Indacaterol 150 µg inhaled via Concept1, a SDDPI, in the morning and Placebo to Indacaterol inhaled via Concept1 in the evening on odd days; and Placebo to Indacaterol inhaled via Concept1 in the morning and in the evening on even days. All patients had to receive daily treatment with inhaled corticosteroid up to the maximum dose per day in a stable regimen for at least 4-weeks prior to screening and remain stable through out the study. The short acting (beta) β2-agonist |

| | |
|---|---|
| | (SABA) salbutamol/albuterol was available for rescue use throughout the study. |
| **Placebo** | Placebo to Indacaterol twice daily (bid) inhaled via Concept1, a single dose dry powder inhaler (SDDPI), in the morning and in the evening for 16 days. All patients had to receive daily treatment with inhaled corticosteroid up to the maximum dose per day in a stable regimen for at least 4-weeks prior to screening and remain stable through out the study. The short acting (beta) β2-agonist (SABA) salbutamol/albuterol was available for rescue use throughout the study. |

**Participant Flow: Overall Study**

| | Indacaterol 37.5 µg (Twice a Day) | Indacaterol 75 µg (Once a Day) | Indacaterol 150 µg (Every Other Day) | Placebo |
|---|---|---|---|---|
| **STARTED** | 48 [1] | 48 | 48 | 47 |
| **PD & Safety Sets: Received Study Drug** | 48 [2] | 47 | 48 | 46 |
| **COMPLETED** | 46 | 46 | 42 | 41 |
| **NOT COMPLETED** | 2 | 2 | 6 | 6 |
| **Adverse Event** | 0 | 0 | 1 | 1 |
| **Abnormal test procedure result(s)** | 0 | 1 | 2 | 2 |
| **Withdrawal by Subject** | 0 | 0 | 2 | 2 |
| **Lost to Follow-up** | 0 | 0 | 1 | 0 |
| **Administrative problems** | 0 | 1 | 0 | 1 |
| **Protocol deviation** | 2 | 0 | 0 | 0 |

[1] Randomized participants.
[2] PD=Pharmacodynamic

## 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** |
|---|---|
| **Indacaterol 37.5 µg (Twice a Day)** | Indacaterol 37.5 µg twice a day (bid) inhaled via Concept1, a single dose dry powder inhaler (SDDPI), in the morning and in the evening for 16 days. All patients had to receive daily treatment with inhaled corticosteroid up to the maximum dose per day in a stable regimen for at least 4-weeks prior to screening and remain stable through out the study. The short acting (beta) β2-agonist (SABA) salbutamol/albuterol was available for rescue use throughout the study. |
| **Indacaterol 75 µg (Once a Day)** | Indacaterol 75 µg once a day (qd) inhaled via Concept1, a single dose dry powder inhaler (SDDPI), in the morning and Placebo to Indacaterol inhaled once daily via Concept1 in the evening for 16 days. All patients had to receive daily treatment with inhaled corticosteroid up to the maximum dose per day in a stable regimen for at least 4-weeks prior to screening and remain stable through out the study. The short acting (beta) β2-agonist (SABA) salbutamol/albuterol was available for rescue use throughout the study. |
| **Indacaterol 150 µg (Every Other Day)** | Indacaterol 150 µg every other day (qod) inhaled via Concept1, a single dose dry powder inhaler (SDDPI) for a total of 16 days. Indacaterol 150 µg inhaled via Concept1, a SDDPI, in the morning and Placebo to Indacaterol inhaled via Concept1 in the evening on odd days; and Placebo to Indacaterol inhaled via Concept1 in the morning and in the evening on even days. All patients had to receive daily treatment with inhaled corticosteroid up to the maximum dose per day in a stable regimen for at least 4-weeks prior to screening and remain stable through out the study. The short acting (beta) β2-agonist (SABA) salbutamol/albuterol was available for rescue use throughout the study. |
| **Placebo** | Placebo to Indacaterol twice daily (bid) inhaled via Concept1, a single dose dry powder inhaler (SDDPI), in the morning and in the evening for 16 days. All patients had to receive daily treatment with |

| | |
|---|---|
| | inhaled corticosteroid up to the maximum dose per day in a stable regimen for at least 4-weeks prior to screening and remain stable through out the study. The short acting (beta) β2-agonist (SABA) salbutamol/albuterol was available for rescue use throughout the study. |
| **Total** | Total of all reporting groups |

**Baseline Measures**

| | Indacaterol 37.5 µg (Twice a Day) | Indacaterol 75 µg (Once a Day) | Indacaterol 150 µg (Every Other Day) | Placebo | Total |
|---|---|---|---|---|---|
| **Number of Participants [units: participants]** | **48** | **47** | **48** | **46** | **189** |
| **Age [1] [units: years] Mean (Standard Deviation)** | **37.4 (11.0)** | **41.1 (14.7)** | **42.0 (12.2)** | **40.8 (12.7)** | **40.3 (12.7)** |
| **Gender [units: participants]** | | | | | |
| **Female** | **21** | **24** | **16** | **18** | **79** |
| **Male** | **27** | **23** | **32** | **28** | **110** |

[1] Baseline measures used the Safety Set that included all participants who received at least one dose of study drug.

## Outcome Measures

Hide All Outcome Measures

1. Primary: Change From Baseline in the Trough Forced Expiratory Volume in One Second (FEV1) After Two Weeks of Treatment [ Time Frame: Baseline to week 2 ]

| | |
|---|---|
| **Measure Type** | Primary |

| | |
|---|---|
| **Measure Title** | Change From Baseline in the Trough Forced Expiratory Volume in One Second (FEV1) After Two Weeks of Treatment |
| **Measure Description** | Spirometry was conducted according to internationally accepted standards. Trough FEV1 values were calculated as the mean of the 23.17 hours and 23.75 hours post morning dose FEV1 measurements. Analysis of covariance model was used with baseline FEV1 as a continuous covariate. |
| **Time Frame** | Baseline to week 2 |
| **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.** |
|---|
| Pharmacodynamic (PD) Analysis Set included all randomized participants who received at least one dose of study drug and who had evaluable PD data. |

**Reporting Groups**

| | **Description** |
|---|---|
| **Indacaterol 37.5 µg (Twice a Day)** | Indacaterol 37.5 µg twice a day (bid) inhaled via Concept1, a single dose dry powder inhaler (SDDPI), in the morning and in the evening for 16 days. All patients had to receive daily treatment with inhaled corticosteroid up to the maximum dose per day in a stable regimen for at least 4-weeks prior to screening and remain stable through out the study. The short acting (beta) β2-agonist (SABA) salbutamol/albuterol was available for rescue use throughout the study. |
| **Indacaterol 75 µg (Once a Day)** | Indacaterol 75 µg once a day (qd) inhaled via Concept1, a single dose dry powder inhaler (SDDPI), in the morning and Placebo to Indacaterol inhaled once daily via Concept1 in the evening for 16 days. All patients had to receive daily treatment with inhaled corticosteroid up to the maximum dose per day in a stable regimen for at least 4-weeks prior to screening and remain stable through out the study. The short acting (beta) β2-agonist (SABA) salbutamol/albuterol was available for rescue use throughout the study. |
| **Indacaterol 150 µg (Every Other Day)** | Indacaterol 150 µg every other day (qod) inhaled via Concept1, a single dose dry powder inhaler (SDDPI) for a total of 16 days. Indacaterol 150 µg inhaled via Concept1, a SDDPI, in the morning and Placebo to Indacaterol inhaled via Concept1 in the evening on odd days; and Placebo to Indacaterol inhaled via Concept1 in the morning and in the evening on even days. All patients had to receive daily treatment with inhaled corticosteroid up to the maximum dose per day in a stable regimen for at least |

| | |
|---|---|
| | 4-weeks prior to screening and remain stable through out the study. The short acting (beta) β2-agonist (SABA) salbutamol/albuterol was available for rescue use throughout the study. |
| **Placebo** | Placebo to Indacaterol twice daily (bid) inhaled via Concept1, a single dose dry powder inhaler (SDDPI), in the morning and in the evening for 16 days. All patients had to receive daily treatment with inhaled corticosteroid up to the maximum dose per day in a stable regimen for at least 4-weeks prior to screening and remain stable through out the study. The short acting (beta) β2-agonist (SABA) salbutamol/albuterol was available for rescue use throughout the study. |

**Measured Values**

| | Indacaterol 37.5 µg (Twice a Day) | Indacaterol 75 µg (Once a Day) | Indacaterol 150 µg (Every Other Day) | Placebo |
|---|---|---|---|---|
| **Number of Participants Analyzed [units: participants]** | **48** | **47** | **48** | **46** |
| **Change From Baseline in the Trough Forced Expiratory Volume in One Second (FEV1) After Two Weeks of Treatment [units: Liters] Least Squares Mean (90% Confidence Interval)** | **0.156 (0.083 to 0.228)** | **0.197 (0.125 to 0.269)** | **0.199 (0.125 to 0.272)** | **-0.005 (-0.080 to 0.071)** |

**No statistical analysis provided for Change From Baseline in the Trough Forced Expiratory Volume in One Second (FEV1) After Two Weeks of Treatment**

2. Primary: Change From Baseline in the Forced Expiratory Volume in 1 Second Standardized (With Respect to Time) Area Under the Curve (AUC) From 0 to 24 Hours Post Dose (FEV1 AUC 0-24h) After Two Weeks of Treatment [ Time Frame: Baseline, 0-24 hours post dose week 2 ]

| | |
|---|---|
| **Measure Type** | Primary |
| **Measure Title** | Change From Baseline in the Forced Expiratory Volume in 1 Second Standardized (With Respect to Time) Area Under the Curve (AUC) From 0 to 24 Hours Post Dose (FEV1 AUC 0-24h) After Two Weeks of Treatment |

| | |
|---|---|
| **Measure Description** | Spirometry was conducted according to internationally accepted standards. Standardized area under the curve (AUC 0-24 hours) of FEV1 measurements taken at pre-dose to 24 hours post-dose was calculated based on the trapezoidal rule and was adjusted for the area per time unit using the scheduled time of measurements for FEV1. Analysis of covariance model was used with baseline FEV1 as a continuous covariate. |
| **Time Frame** | Baseline, 0-24 hours post dose week 2 |
| **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.** |
|---|
| Pharmacodynamic (PD) Analysis Set included all randomized participants who received at least one dose of study drug and who had evaluable PD data. |

**Reporting Groups**

| | **Description** |
|---|---|
| **Indacaterol 37.5 µg (Twice a Day)** | Indacaterol 37.5 µg twice a day (bid) inhaled via Concept1, a single dose dry powder inhaler (SDDPI), in the morning and in the evening for 16 days. All patients had to receive daily treatment with inhaled corticosteroid up to the maximum dose per day in a stable regimen for at least 4-weeks prior to screening and remain stable through out the study. The short acting (beta) β2-agonist (SABA) salbutamol/albuterol was available for rescue use throughout the study. |
| **Indacaterol 75 µg (Once a Day)** | Indacaterol 75 µg once a day (qd) inhaled via Concept1, a single dose dry powder inhaler (SDDPI), in the morning and Placebo to Indacaterol inhaled once daily via Concept1 in the evening for 16 days. All patients had to receive daily treatment with inhaled corticosteroid up to the maximum dose per day in a stable regimen for at least 4-weeks prior to screening and remain stable through out the study. The short acting (beta) β2-agonist (SABA) salbutamol/albuterol was available for rescue use throughout the study. |
| **Placebo** | Placebo to Indacaterol twice daily (bid) inhaled via Concept1, a single dose dry powder inhaler (SDDPI), in the morning and in the evening for 16 days. All patients had to receive daily treatment with inhaled corticosteroid up to the maximum dose per day in a stable regimen for at least 4-weeks prior to screening and remain stable through out the study. The short acting (beta) β2-agonist (SABA) such as salbutamol/albuterol was available for rescue use throughout the study. |

**Measured Values**

| | Indacaterol 37.5 µg (Twice a Day) | Indacaterol 75 µg (Once a Day) | Placebo |
|---|---|---|---|
| **Number of Participants Analyzed [units: participants]** | **48** | **47** | **46** |
| **Change From Baseline in the Forced Expiratory Volume in 1 Second Standardized (With Respect to Time) Area Under the Curve (AUC) From 0 to 24 Hours Post Dose (FEV1 AUC 0-24h) After Two Weeks of Treatment [units: Liters] Least Squares Mean (90% Confidence Interval)** | **0.196 (0.127 to 0.266)** | **0.198 (0.127 to 0.269)** | **0.030 (-0.044 to 0.103)** |

**No statistical analysis provided for Change From Baseline in the Forced Expiratory Volume in 1 Second Standardized (With Respect to Time) Area Under the Curve (AUC) From 0 to 24 Hours Post Dose (FEV1 AUC 0-24h) After Two Weeks of Treatment**

3. Primary: Change From Baseline in the Forced Expiratory Volume in 1 Second Standardized (With Respect to Time) Area Under the Curve (AUC) From 0 to 48 Hours (FEV1 AUC 0-48h) After Two Weeks of Treatment [ Time Frame: Baseline, 0 to 48 hours post dose week 2 ]

| | |
|---|---|
| **Measure Type** | Primary |
| **Measure Title** | Change From Baseline in the Forced Expiratory Volume in 1 Second Standardized (With Respect to Time) Area Under the Curve (AUC) From 0 to 48 Hours (FEV1 AUC 0-48h) After Two Weeks of Treatment |
| **Measure Description** | Spirometry was conducted according to internationally accepted standards. Standardized area under the curve (AUC 0-48 hours) of FEV1 measurements taken at pre-dose to 48 hours post-dose was calculated based on the trapezoidal rule and was adjusted for the area per time unit by using the scheduled time of measurements for FEV1. Analysis of covariance model was used with baseline FEV1 as a continuous covariate. |
| **Time Frame** | Baseline, 0 to 48 hours post dose week 2 |
| **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.** |
|---|
| Pharmacodynamic (PD) Analysis Set included all randomized participants who received at least one dose of study drug and who had evaluable PD data. |

**Reporting Groups**

| | **Description** |
|---|---|
| **Indacaterol 75 µg (Once a Day)** | Indacaterol 75 µg once a day (qd) inhaled via Concept1, a single dose dry powder inhaler (SDDPI), in the morning and Placebo to Indacaterol inhaled once daily via Concept1 in the evening for 16 days. All patients had to receive daily treatment with inhaled corticosteroid up to the maximum dose per day in a stable regimen for at least 4-weeks prior to screening and remain stable through out the study. The short acting (beta) β2-agonist (SABA) salbutamol/albuterol was available for rescue use throughout the study. |
| **Indacaterol 150 µg (Every Other Day)** | Indacaterol 150 µg every other day (qod) inhaled via Concept1, a single dose dry powder inhaler (SDDPI) for a total of 16 days. Indacaterol 150 µg inhaled via Concept1, a SDDPI, in the morning and Placebo to Indacaterol inhaled via Concept1 in the evening on odd days; and Placebo to Indacaterol inhaled via Concept1 in the morning and in the evening on even days. All patients had to receive daily treatment with inhaled corticosteroid up to the maximum dose per day in a stable regimen for at least 4-weeks prior to screening and remain stable through out the study. The short acting (beta) β2-agonist (SABA) salbutamol/albuterol was available for rescue use throughout the study. |
| **Placebo** | Placebo to Indacaterol twice daily (bid) inhaled via Concept1, a single dose dry powder inhaler (SDDPI), in the morning and in the evening for 16 days. All patients had to receive daily treatment with inhaled corticosteroid up to the maximum dose per day in a stable regimen for at least 4-weeks prior to screening and remain stable through out the study. The short acting (beta) β2-agonist (SABA) such as salbutamol/albuterol was available for rescue use throughout the study. |

**Measured Values**

| | **Indacaterol 75 µg (Once a Day)** | **Indacaterol 150 µg (Every Other Day)** | **Placebo** |
|---|---|---|---|
| **Number of Participants Analyzed** | **47** | **48** | **46** |

| | | | |
|---|---|---|---|
| **[units: participants]** | | | |
| **Change From Baseline in the Forced Expiratory Volume in 1 Second Standardized (With Respect to Time) Area Under the Curve (AUC) From 0 to 48 Hours (FEV1 AUC 0-48h) After Two Weeks of Treatment<br>[units: Liters]<br>Least Squares Mean (90% Confidence Interval)** | **0.218<br>(0.148 to 0.288)** | **0.198<br>(0.135 to 0.260)** | **0.059<br>(-0.012 to 0.129)** |

**No statistical analysis provided for Change From Baseline in the Forced Expiratory Volume in 1 Second Standardized (With Respect to Time) Area Under the Curve (AUC) From 0 to 48 Hours (FEV1 AUC 0-48h) After Two Weeks of Treatment**

4. Secondary: Change From Baseline in the Forced Expiratory Volume in 1 Second Standardized (With Respect to Time) Area Under the Curve (AUC) From 0 to 12 Hours (FEV1 AUC 0-12h) After Two Weeks of Treatment [ Time Frame: Baseline, 0 to 12 hours post dose week 2 ]

| | |
|---|---|
| **Measure Type** | Secondary |
| **Measure Title** | Change From Baseline in the Forced Expiratory Volume in 1 Second Standardized (With Respect to Time) Area Under the Curve (AUC) From 0 to 12 Hours (FEV1 AUC 0-12h) After Two Weeks of Treatment |
| **Measure Description** | Spirometry was conducted according to internationally accepted standards. Standardized area under the curve (AUC 0-12 hours) of FEV1 measurements taken at pre-dose to 12 hours post-dose was calculated based on the trapezoidal rule and was adjusted for the area per time unit by using the scheduled time of measurements for FEV1. Analysis of covariance model was used with baseline FEV1 as a continuous covariate. |
| **Time Frame** | Baseline, 0 to 12 hours post dose week 2 |
| **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.** |
| Pharmacodynamic (PD) Analysis Set included all randomized participants who received at least one dose of study drug and who had evaluable PD data. |

**Reporting Groups**

| | Description |
|---|---|
| **Indacaterol 37.5 µg (Twice a Day)** | Indacaterol 37.5 µg twice a day (bid) inhaled via Concept1, a single dose dry powder inhaler (SDDPI), in the morning and in the evening for 16 days. All patients had to receive daily treatment with inhaled corticosteroid up to the maximum dose per day in a stable regimen for at least 4-weeks prior to screening and remain stable through out the study. The short acting (beta) β2-agonist (SABA) salbutamol/albuterol was available for rescue use throughout the study. |
| **Indacaterol 75 µg (Once a Day)** | Indacaterol 75 µg once a day (qd) inhaled via Concept1, a single dose dry powder inhaler (SDDPI), in the morning and Placebo to Indacaterol inhaled once daily via Concept1 in the evening for 16 days. All patients had to receive daily treatment with inhaled corticosteroid up to the maximum dose per day in a stable regimen for at least 4-weeks prior to screening and remain stable through out the study. The short acting (beta) β2-agonist (SABA) salbutamol/albuterol was available for rescue use throughout the study. |
| **Placebo** | Placebo to Indacaterol twice daily (bid) inhaled via Concept1, a single dose dry powder inhaler (SDDPI), in the morning and in the evening for 16 days. All patients had to receive daily treatment with inhaled corticosteroid up to the maximum dose per day in a stable regimen for at least 4-weeks prior to screening and remain stable through out the study. The short acting (beta) β2-agonist (SABA) such as salbutamol/albuterol was available for rescue use throughout the study. |

**Measured Values**

| | Indacaterol 37.5 µg (Twice a Day) | Indacaterol 75 µg (Once a Day) | Placebo |
|---|---|---|---|
| **Number of Participants Analyzed [units: participants]** | **48** | **47** | **46** |
| **Change From Baseline in the Forced Expiratory Volume in 1 Second Standardized (With Respect to Time) Area Under the Curve (AUC) From 0 to 12 Hours (FEV1 AUC 0-12h) After Two Weeks of Treatment [units: Liters] Least Squares Mean (90% Confidence Interval)** | **0.245 (0.170 to 0.319)** | **0.243 (0.163 to 0.317)** | **0.059 (-0.018 to 0.137)** |

**No statistical analysis provided for Change From Baseline in the Forced Expiratory Volume in 1 Second Standardized (With Respect to Time) Area**

**Under the Curve (AUC) From 0 to 12 Hours (FEV1 AUC 0-12h) After Two Weeks of Treatment**

## Serious Adverse Events

Hide Serious Adverse Events

| | |
|---|---|
| **Time Frame** | No text entered. |
| **Additional Description** | Safety population. |

### Reporting Groups

| | Description |
|---|---|
| **Indacaterol 37.5 ug (Twice a Day)** | Indacaterol 37.5 µg twice a day (bid) inhaled via Concept1, a single dose dry powder inhaler (SDDPI), in the morning and in the evening for 16 days. All patients had to receive daily treatment with inhaled corticosteroid up to the maximum dose per day in a stable regimen for at least 4-weeks prior to screening and remain stable through out the study. The short acting (beta) β2-agonist (SABA) salbutamol/albuterol was available for rescue use throughout the study. |
| **Indacaterol 75 ug (Once a Day)** | Indacaterol 75 µg once a day (qd) inhaled via Concept1, a single dose dry powder inhaler (SDDPI), in the morning and Placebo to Indacaterol inhaled once daily via Concept1 in the evening for 16 days. All patients had to receive daily treatment with inhaled corticosteroid up to the maximum dose per day in a stable regimen for at least 4-weeks prior to screening and remain stable through out the study. The short acting (beta) β2-agonist (SABA) salbutamol/albuterol was available for rescue use throughout the study. |
| **Indacaterol 150 ug (Every Other Day)** | Indacaterol 150 µg every other day (qod) inhaled via Concept1, a single dose dry powder inhaler (SDDPI) for a total of 16 days. Indacaterol 150 µg inhaled via Concept1, a SDDPI, in the morning and Placebo to Indacaterol inhaled via Concept1 in the evening on odd days; and Placebo to Indacaterol inhaled via Concept1 in the morning and in the evening on even days. All patients had to receive daily treatment with inhaled corticosteroid up to the maximum dose per day in a stable regimen for at least 4-weeks prior to screening and remain stable through out the study. The short acting (beta) β2-agonist (SABA) salbutamol/albuterol was available for rescue use throughout the study. |
| **Placebo** | Placebo to Indacaterol twice daily (bid) inhaled via Concept1, a single dose dry powder inhaler (SDDPI), in the morning and in the evening for 16 days. All patients had to receive daily treatment with |

| | |
|---|---|
| | inhaled corticosteroid up to the maximum dose per day in a stable regimen for at least 4-weeks prior to screening and remain stable through out the study. The short acting (beta) β2-agonist (SABA) salbutamol/albuterol was available for rescue use throughout the study. |

### Serious Adverse Events

| | Indacaterol 37.5 ug (Twice a Day) | Indacaterol 75 ug (Once a Day) | Indacaterol 150 ug (Every Other Day) | Placebo |
|---|---|---|---|---|
| **Total, serious adverse events** | | | | |
| **# participants affected / at risk** | **0/48 (0.00%)** | **0/47 (0.00%)** | **1/48 (2.08%)** | **0/46 (0.00%)** |
| **Respiratory, thoracic and mediastinal disorders** | | | | |
| **Asthma † 1** | | | | |
| **# participants affected / at risk** | **0/48 (0.00%)** | **0/47 (0.00%)** | **1/48 (2.08%)** | **0/46 (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** | Safety population. |

### Frequency Threshold

| | |
|---|---|
| **Threshold above which other adverse events are reported** | 4% |

**Reporting Groups**

| | Description |
|---|---|
| **Indacaterol 37.5 ug (Twice a Day)** | Indacaterol 37.5 µg twice a day (bid) inhaled via Concept1, a single dose dry powder inhaler (SDDPI), in the morning and in the evening for 16 days. All patients had to receive daily treatment with inhaled corticosteroid up to the maximum dose per day in a stable regimen for at least 4-weeks prior to screening and remain stable through out the study. The short acting (beta) β2-agonist (SABA) salbutamol/albuterol was available for rescue use throughout the study. |
| **Indacaterol 75 ug (Once a Day)** | Indacaterol 75 µg once a day (qd) inhaled via Concept1, a single dose dry powder inhaler (SDDPI), in the morning and Placebo to Indacaterol inhaled once daily via Concept1 in the evening for 16 days. All patients had to receive daily treatment with inhaled corticosteroid up to the maximum dose per day in a stable regimen for at least 4-weeks prior to screening and remain stable through out the study. The short acting (beta) β2-agonist (SABA) salbutamol/albuterol was available for rescue use throughout the study. |
| **Indacaterol 150 ug (Every Other Day)** | Indacaterol 150 µg every other day (qod) inhaled via Concept1, a single dose dry powder inhaler (SDDPI) for a total of 16 days. Indacaterol 150 µg inhaled via Concept1, a SDDPI, in the morning and Placebo to Indacaterol inhaled via Concept1 in the evening on odd days; and Placebo to Indacaterol inhaled via Concept1 in the morning and in the evening on even days. All patients had to receive daily treatment with inhaled corticosteroid up to the maximum dose per day in a stable regimen for at least 4-weeks prior to screening and remain stable through out the study. The short acting (beta) β2-agonist (SABA) salbutamol/albuterol was available for rescue use throughout the study. |
| **Placebo** | Placebo to Indacaterol twice daily (bid) inhaled via Concept1, a single dose dry powder inhaler (SDDPI), in the morning and in the evening for 16 days. All patients had to receive daily treatment with inhaled corticosteroid up to the maximum dose per day in a stable regimen for at least 4-weeks prior to screening and remain stable through out the study. The short acting (beta) β2-agonist (SABA) salbutamol/albuterol was available for rescue use throughout the study. |

## Other Adverse Events

| | Indacaterol 37.5 ug (Twice a Day) | Indacaterol 75 ug (Once a Day) | Indacaterol 150 ug (Every Other Day) | Placebo |
|---|---|---|---|---|
| **Total, other (not including serious) adverse events** | | | | |
| | | | | |

| | | | | |
|---|---|---|---|---|
| **# participants affected / at risk** | **7/48 (14.58%)** | **8/47 (17.02%)** | **11/48 (22.92%)** | **8/46 (17.39%)** |
| **Gastrointestinal disorders** | | | | |
| **Vomiting † 1** | | | | |
| **# participants affected / at risk** | **0/48 (0.00%)** | **1/47 (2.13%)** | **2/48 (4.17%)** | **0/46 (0.00%)** |
| **Infections and infestations** | | | | |
| **Nasopharyngitis † 1** | | | | |
| **# participants affected / at risk** | **1/48 (2.08%)** | **2/47 (4.26%)** | **0/48 (0.00%)** | **0/46 (0.00%)** |
| **Nervous system disorders** | | | | |
| **Dizziness † 1** | | | | |
| **# participants affected / at risk** | **0/48 (0.00%)** | **2/47 (4.26%)** | **1/48 (2.08%)** | **1/46 (2.17%)** |
| **Headache † 1** | | | | |
| **# participants affected / at risk** | **3/48 (6.25%)** | **2/47 (4.26%)** | **3/48 (6.25%)** | **6/46 (13.04%)** |
| **Respiratory, thoracic and mediastinal disorders** | | | | |
| **Cough † 1** | | | | |
| **# participants affected / at risk** | **3/48 (6.25%)** | **3/47 (6.38%)** | **7/48 (14.58%)** | **1/46 (2.17%)** |

† 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:<br>☐ 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.<br>☐ 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.<br>Other disclosure agreement that restricts the right of the PI to discuss or publish trial results after the trial is completed.<br>☑ **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**

| | |
|---|---|
| Responsible Party: | External Affairs, Novartis Pharmaceuticals |
| ClinicalTrials.gov Identifier: | NCT01156844 History of Changes |
| Other Study ID Numbers: | **CQAB149B2223** |
| | 2010-018481-22 ( EudraCT Number ) |
| Study First Received: | June 30, 2010 |
| Results First Received: | July 22, 2011 |
| Last Updated: | July 22, 2011 |
| Health Authority: | United States: Food and Drug Administration |
| | France: Afssaps - Agence française de sécurité sanitaire des produits de santé (Saint-Denis) |
| | Germany: Federal Institute for Drugs and Medical Devices |
| | Jordan: Jordanian FDA |
| | Netherlands: The Central Committee on Research Involving Human Subjects (CCMO) |
| | United Kingdom: Medicines and Healthcare Products Regulatory Agency |