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

Trial record **1 of 1** for: CQAB149B2338

Previous Study | Return to List | Next Study

# Safety of Indacaterol in Patients (≥ 12 Years) With Moderate to Severe Persistent Asthma

**This study has been completed.**

**Sponsor:**
Novartis Pharmaceuticals

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

**ClinicalTrials.gov Identifier:**
NCT00529529

First received: September 12, 2007
Last updated: August 25, 2011
Last verified: August 2011
History of Changes



Results First Received: July 22, 2011

| | |
|---|---|
| **Study Type:** | Interventional |
| **Study Design:** | Allocation: Randomized; Endpoint Classification: Safety Study;<br>Intervention Model: Parallel Assignment;<br>Masking: Double Blind (Subject, Caregiver, Investigator, Outcomes Assessor);<br>Primary Purpose: Treatment |
| **Condition:** | Asthma |
| **Interventions:** | Drug: Indacaterol 300 µg<br>Drug: Salmeterol 50 µg<br>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 |
|---|
| No text entered. |

### Pre-Assignment Details

| Significant events and approaches for the overall study following participant enrollment, but prior to group assignment |
|---|
| No text entered. |

### Reporting Groups

| | Description |
|---|---|
| **Indacaterol 300 µg** | Patients received indacaterol 300 µg delivered via a single dose dry powder inhaler (SDDPI) once daily (od) in the morning (between 7:00 and 11:00 AM). In addition to indacaterol 300 µg, patients received indacaterol and salmeterol placebo inhalations in the morning and salmeterol placebo inhalation in the evening (between 7:00 and 11:00 PM). Daily inhaled corticosteroid treatment (if applicable) was to remain stable throughout the study. The short-acting β2-agonist salbutamol/albuterol was available for rescue use throughout the study. |
| **Indacaterol 600 µg** | Patients received indacaterol 600 µg (2 x 300 µg capsules) delivered via single dose dry powder inhalers (SDDPI) once daily (od) in the morning (between 7:00 and 11:00 AM). In addition to indacaterol 600 µg, patients received salmeterol placebo inhalation in the morning and the evening (between 7:00 and 11:00 PM). Daily inhaled corticosteroid treatment (if applicable) was to remain stable throughout the study. The short-acting β2-agonist salbutamol/albuterol was available for rescue use throughout the study. |
| **Salmeterol 50 µg** | Patients received salmeterol 50 µg delivered via the salmeterol proprietary dry powder inhalation device bis in die (bid, twice daily), once in the morning (between 7:00 and 11:00 AM) and once in the evening (between 7:00 and 11:00 PM). In addition to salmeterol 50 µg, patients received 2 indacaterol placebo inhalations in the morning. Daily inhaled corticosteroid treatment (if applicable) was to remain stable throughout the study. The short-acting β2-agonist salbutamol/albuterol was available for rescue use throughout the study. |

**Participant Flow: Overall Study**

| | Indacaterol 300 µg | Indacaterol 600 µg | Salmeterol 50 µg |
|---|---|---|---|
| STARTED | 268 | 268 | 269 |
| COMPLETED | 225 | 225 | 238 |
| NOT COMPLETED | 43 | 43 | 31 |
| Adverse Event | 12 | 17 | 8 |
| Subject withdrew consent | 12 | 9 | 12 |
| Protocol deviation | 8 | 12 | 5 |
| Lost to Follow-up | 5 | 3 | 1 |
| Unsatisfactory therapeutic effect | 2 | 2 | 2 |
| Death | 2 | 0 | 0 |
| Abnormal test procedure result(s) | 1 | 0 | 0 |
| Administrative problems | 1 | 0 | 3 |

## 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 300 µg** | Patients received indacaterol 300 µg delivered via a single dose dry powder inhaler (SDDPI) once daily (od) in the morning (between 7:00 and 11:00 AM). In addition to indacaterol 300 µg, patients received indacaterol and salmeterol placebo inhalations in the morning and salmeterol placebo inhalation in the evening (between 7:00 and 11:00 PM). Daily inhaled corticosteroid treatment (if applicable) was to remain stable throughout the study. The short-acting β2-agonist salbutamol/albuterol was available for rescue use throughout the study. |
| **Indacaterol 600 µg** | Patients received indacaterol 600 µg (2 x 300 µg capsules) delivered via single dose dry powder inhalers (SDDPI) once daily (od) in the morning (between 7:00 and 11:00 AM). In addition to indacaterol 600 µg, patients received salmeterol placebo inhalation in the morning and the evening (between 7:00 and 11:00 PM). Daily inhaled corticosteroid treatment (if applicable) was to remain stable throughout the study. The short-acting β2-agonist salbutamol/albuterol was available for rescue use throughout the study. |
| **Salmeterol 50 µg** | Patients received salmeterol 50 µg delivered via the salmeterol proprietary dry powder inhalation device bis in die (bid, twice daily), once in the morning (between 7:00 and 11:00 AM) and once in the evening (between 7:00 and 11:00 PM). In addition to salmeterol 50 µg, patients received 2 indacaterol placebo inhalations in the morning. Daily inhaled corticosteroid treatment (if applicable) was to remain stable throughout the study. The short-acting β2-agonist salbutamol/albuterol was available for rescue use throughout the study. |
| **Total** | Total of all reporting groups |

### Baseline Measures

| | Indacaterol 300 µg | Indacaterol 600 µg | Salmeterol 50 µg | Total |
|---|---|---|---|---|
| **Number of Participants [units: participants]** | **268** | **268** | **269** | **805** |
| **Age [units: years] Mean (Standard Deviation)** | **43.5 (15.84)** | **44.5 (15.19)** | **42.5 (15.24)** | **43.5 (15.43)** |
| **Gender [units: participants]** | | | | |
| **Female** | **151** | **175** | **164** | **490** |
| **Male** | **117** | **93** | **105** | **315** |

## Outcome Measures

Hide All Outcome Measures

1. Primary: Percentage of Patients With at Least 1 Adverse Event During the 26 Weeks of the Study [ Time Frame: Baseline (Day 1) to end of study (Week 26) ]

| | |
|---|---|
| **Measure Type** | Primary |
| **Measure Title** | Percentage of Patients With at Least 1 Adverse Event During the 26 Weeks of the Study |
| **Measure Description** | Adverse events include asthma exacerbations. An asthma exacerbation was defined as a worsening of asthma as judged clinically significant by the physician, requiring treatment with rescue oral or intravenous (IV) corticosteroids. Asthma worsening that required treatment with inhaled or nebulized short-acting β2-agonists or an increase in inhaled corticosteroids only was not considered an asthma exacerbation. |
| **Time Frame** | Baseline (Day 1) to end of study (Week 26) |
| **Safety Issue** | Yes |

**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.** |
| Safety population: All patients who received at least one dose of study drug. |

**Reporting Groups**

| | Description |
|---|---|
| **Indacaterol 300 µg** | Patients received indacaterol 300 µg delivered via a single dose dry powder inhaler (SDDPI) once daily (od) in the morning (between 7:00 and 11:00 AM). In addition to indacaterol 300 µg, patients received indacaterol and salmeterol placebo inhalations in the morning and salmeterol placebo inhalation in the evening (between 7:00 and 11:00 PM). Daily inhaled corticosteroid treatment (if applicable) was to remain stable throughout the study. The short-acting β2-agonist salbutamol/albuterol was available for rescue use throughout the study. |
| **Indacaterol 600 µg** | Patients received indacaterol 600 µg (2 x 300 µg capsules) delivered via single dose dry powder inhalers (SDDPI) once daily (od) in the morning (between 7:00 and 11:00 AM). In addition to indacaterol 600 µg, patients received salmeterol placebo inhalation in the morning and the evening (between 7:00 and 11:00 PM). Daily inhaled corticosteroid treatment |

| | |
|---|---|
| | (if applicable) was to remain stable throughout the study. The short-acting β2-agonist salbutamol/albuterol was available for rescue use throughout the study. |
| **Salmeterol 50 µg** | Patients received salmeterol 50 µg delivered via the salmeterol proprietary dry powder inhalation device bis in die (bid, twice daily), once in the morning (between 7:00 and 11:00 AM) and once in the evening (between 7:00 and 11:00 PM). In addition to salmeterol 50 µg, patients received 2 indacaterol placebo inhalations in the morning. Daily inhaled corticosteroid treatment (if applicable) was to remain stable throughout the study. The short-acting β2-agonist salbutamol/albuterol was available for rescue use throughout the study. |

**Measured Values**

| | Indacaterol 300 µg | Indacaterol 600 µg | Salmeterol 50 µg |
|---|---|---|---|
| **Number of Participants Analyzed [units: participants]** | **268** | **268** | **269** |
| **Percentage of Patients With at Least 1 Adverse Event During the 26 Weeks of the Study [units: Percentage of patients]** | **54.9** | **66.4** | **67.3** |

**No statistical analysis provided for Percentage of Patients With at Least 1 Adverse Event During the 26 Weeks of the Study**

2. Primary: Systolic Blood Pressure 1 Hour Post-dose at Day 1 [ Time Frame: Day 1 ]

| | |
|---|---|
| **Measure Type** | Primary |
| **Measure Title** | Systolic Blood Pressure 1 Hour Post-dose at Day 1 |
| **Measure Description** | Systolic blood pressure measurements (in millimeters of mercury, mmHg) were made 1 hour post-dose after the patient had rested in the sitting position for at least 10 minutes. Measurements were made using an inflatable cuff around the upper arm. The analysis included baseline systolic blood pressure and forced expiratory volume in 1 second (FEV1) pre-dose and 30 minutes post-dose of salbutamol/albuterol during screening as covariates. |
| **Time Frame** | Day 1 |
| **Safety Issue** | Yes |

**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.** |
|---|
| Safety population: All patients who received at least one dose of study drug. Participants with observations at Day 1 were included in the analysis. |

**Reporting Groups**

| | **Description** |
|---|---|
| **Indacaterol 300 µg** | Patients received indacaterol 300 µg delivered via a single dose dry powder inhaler (SDDPI) once daily (od) in the morning (between 7:00 and 11:00 AM). In addition to indacaterol 300 µg, patients received indacaterol and salmeterol placebo inhalations in the morning and salmeterol placebo inhalation in the evening (between 7:00 and 11:00 PM). Daily inhaled corticosteroid treatment (if applicable) was to remain stable throughout the study. The short-acting β2-agonist salbutamol/albuterol was available for rescue use throughout the study. |
| **Indacaterol 600 µg** | Patients received indacaterol 600 µg (2 x 300 µg capsules) delivered via single dose dry powder inhalers (SDDPI) once daily (od) in the morning (between 7:00 and 11:00 AM). In addition to indacaterol 600 µg, patients received salmeterol placebo inhalation in the morning and the evening (between 7:00 and 11:00 PM). Daily inhaled corticosteroid treatment (if applicable) was to remain stable throughout the study. The short-acting β2-agonist salbutamol/albuterol was available for rescue use throughout the study. |
| **Salmeterol 50 µg** | Patients received salmeterol 50 µg delivered via the salmeterol proprietary dry powder inhalation device bis in die (bid, twice daily), once in the morning (between 7:00 and 11:00 AM) and once in the evening (between 7:00 and 11:00 PM). In addition to salmeterol 50 µg, patients received 2 indacaterol placebo inhalations in the morning. Daily inhaled corticosteroid treatment (if applicable) was to remain stable throughout the study. The short-acting β2-agonist salbutamol/albuterol was available for rescue use throughout the study. |

**Measured Values**

| | **Indacaterol 300 µg** | **Indacaterol 600 µg** | **Salmeterol 50 µg** |
|---|---|---|---|
| **Number of Participants Analyzed [units: participants]** | **263** | **264** | **264** |
| **Systolic Blood Pressure 1 Hour Post-dose at Day 1** | | | |

| | | | |
|---|---|---|---|
| **[units: mmHg]<br>Least Squares Mean (Standard Error)** | **122.79 (0.605)** | **122.60 (0.605)** | **122.56 (0.606)** |

**No statistical analysis provided for Systolic Blood Pressure 1 Hour Post-dose at Day 1**

3. Primary: Systolic Blood Pressure 1 Hour Post-dose at Week 12 [ Time Frame: Week 12 ]

| | |
|---|---|
| **Measure Type** | Primary |
| **Measure Title** | Systolic Blood Pressure 1 Hour Post-dose at Week 12 |
| **Measure Description** | Systolic blood pressure measurements (in millimeters of mercury, mmHg) were made 1 hour post-dose after the patient had rested in the sitting position for at least 10 minutes. Measurements were made using an inflatable cuff around the upper arm. The analysis included baseline systolic blood pressure and FEV1 pre-dose and 30 minutes post-dose of salbutamol/albuterol during screening as covariates. |
| **Time Frame** | Week 12 |
| **Safety Issue** | Yes |

**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.** |
| Safety population: All patients who received at least one dose of study drug. Participants with observations at week 12 were included in the analysis. |

**Reporting Groups**

| | **Description** |
|---|---|
| **Indacaterol 300 µg** | Patients received indacaterol 300 µg delivered via a single dose dry powder inhaler (SDDPI) once daily (od) in the morning (between 7:00 and 11:00 AM). In addition to indacaterol 300 µg, patients received indacaterol and salmeterol placebo inhalations in the morning and salmeterol placebo inhalation in the evening (between 7:00 and 11:00 PM). Daily inhaled corticosteroid treatment (if applicable) was to remain stable throughout the study. The short-acting β2-agonist salbutamol/albuterol was available for rescue use throughout the study. |

| | |
|---|---|
| **Indacaterol 600 µg** | Patients received indacaterol 600 µg (2 x 300 µg capsules) delivered via single dose dry powder inhalers (SDDPI) once daily (od) in the morning (between 7:00 and 11:00 AM). In addition to indacaterol 600 µg, patients received salmeterol placebo inhalation in the morning and the evening (between 7:00 and 11:00 PM). Daily inhaled corticosteroid treatment (if applicable) was to remain stable throughout the study. The short-acting β2-agonist salbutamol/albuterol was available for rescue use throughout the study. |
| **Salmeterol 50 µg** | Patients received salmeterol 50 µg delivered via the salmeterol proprietary dry powder inhalation device bis in die (bid, twice daily), once in the morning (between 7:00 and 11:00 AM) and once in the evening (between 7:00 and 11:00 PM). In addition to salmeterol 50 µg, patients received 2 indacaterol placebo inhalations in the morning. Daily inhaled corticosteroid treatment (if applicable) was to remain stable throughout the study. The short-acting β2-agonist salbutamol/albuterol was available for rescue use throughout the study. |

**Measured Values**

| | Indacaterol 300 µg | Indacaterol 600 µg | Salmeterol 50 µg |
|---|---|---|---|
| **Number of Participants Analyzed [units: participants]** | **238** | **237** | **244** |
| **Systolic Blood Pressure 1 Hour Post-dose at Week 12 [units: mmHg] Least Squares Mean (Standard Error)** | **120.29 (0.802)** | **121.98 (0.809)** | **122.02 (0.801)** |

**No statistical analysis provided for Systolic Blood Pressure 1 Hour Post-dose at Week 12**

4. Primary: Diastolic Blood Pressure 1 Hour Post-dose at Day 1 [ Time Frame: Day 1 ]

| | |
|---|---|
| **Measure Type** | Primary |
| **Measure Title** | Diastolic Blood Pressure 1 Hour Post-dose at Day 1 |
| **Measure Description** | Diastolic blood pressure measurements (in millimeters of mercury, mmHg) were made 1 hour post-dose after the patient had rested in the sitting position for at least 10 minutes. Measurements were made using an inflatable cuff around the upper arm. Phase V Korotkoff sounds were used for determination of diastolic pressure. The analysis included baseline diastolic blood pressure and FEV1 pre-dose and 30 minutes post-dose of salbutamol/albuterol during screening as covariates. |

| | |
|---|---|
| **Time Frame** | Day 1 |
| **Safety Issue** | Yes |

**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.** |
|---|
| Safety population: All patients who received at least one dose of study drug. Participants with observations at Day 1 were included in this analysis. |

**Reporting Groups**

| | **Description** |
|---|---|
| **Indacaterol 300 µg** | Patients received indacaterol 300 µg delivered via a single dose dry powder inhaler (SDDPI) once daily (od) in the morning (between 7:00 and 11:00 AM). In addition to indacaterol 300 µg, patients received indacaterol and salmeterol placebo inhalations in the morning and salmeterol placebo inhalation in the evening (between 7:00 and 11:00 PM). Daily inhaled corticosteroid treatment (if applicable) was to remain stable throughout the study. The short-acting β2-agonist salbutamol/albuterol was available for rescue use throughout the study. |
| **Indacaterol 600 µg** | Patients received indacaterol 600 µg (2 x 300 µg capsules) delivered via single dose dry powder inhalers (SDDPI) once daily (od) in the morning (between 7:00 and 11:00 AM). In addition to indacaterol 600 µg, patients received salmeterol placebo inhalation in the morning and the evening (between 7:00 and 11:00 PM). Daily inhaled corticosteroid treatment (if applicable) was to remain stable throughout the study. The short-acting β2-agonist salbutamol/albuterol was available for rescue use throughout the study. |
| **Salmeterol 50 µg** | Patients received salmeterol 50 µg delivered via the salmeterol proprietary dry powder inhalation device bis in die (bid, twice daily), once in the morning (between 7:00 and 11:00 AM) and once in the evening (between 7:00 and 11:00 PM). In addition to salmeterol 50 µg, patients received 2 indacaterol placebo inhalations in the morning. Daily inhaled corticosteroid treatment (if applicable) was to remain stable throughout the study. The short-acting β2-agonist salbutamol/albuterol was available for rescue use throughout the study. |

**Measured Values**

| | **Indacaterol 300 µg** | **Indacaterol 600 µg** | **Salmeterol 50 µg** |
|---|---|---|---|
| **Number of Participants Analyzed** | | | |

| | | | |
|---|---|---|---|
| **[units: participants]** | **263** | **264** | **264** |
| **Diastolic Blood Pressure 1 Hour Post-dose at Day 1 [units: mmHg] Least Squares Mean (Standard Error)** | **76.67 (0.484)** | **76.55 (0.484)** | **77.08 (0.485)** |

**No statistical analysis provided for Diastolic Blood Pressure 1 Hour Post-dose at Day 1**

5. Primary: Diastolic Blood Pressure 1 Hour Post-dose at Week 12 [ Time Frame: Week 12 ]

| | |
|---|---|
| **Measure Type** | Primary |
| **Measure Title** | Diastolic Blood Pressure 1 Hour Post-dose at Week 12 |
| **Measure Description** | Diastolic blood pressure measurements (in millimeters of mercury, mmHg) were made 1 hour post-dose after the patient had rested in the sitting position for at least 10 minutes. Measurements were made using an inflatable cuff around the upper arm. Phase V Korotkoff sounds were used for determination of diastolic pressure. The analysis included baseline diastolic blood pressure and FEV1 pre-dose and 30 minutes post-dose of salbutamol/albuterol during screening as covariates. |
| **Time Frame** | Week 12 |
| **Safety Issue** | Yes |

**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.** |
| Safety population: All patients who received at least one dose of study drug. Participants with observations at week 12 were included in the analysis. |

**Reporting Groups**

| | **Description** |
|---|---|
| | |

| | |
|---|---|
| **Indacaterol 300 µg** | Patients received indacaterol 300 µg delivered via a single dose dry powder inhaler (SDDPI) once daily (od) in the morning (between 7:00 and 11:00 AM). In addition to indacaterol 300 µg, patients received indacaterol and salmeterol placebo inhalations in the morning and salmeterol placebo inhalation in the evening (between 7:00 and 11:00 PM). Daily inhaled corticosteroid treatment (if applicable) was to remain stable throughout the study. The short-acting β2-agonist salbutamol/albuterol was available for rescue use throughout the study. |
| **Indacaterol 600 µg** | Patients received indacaterol 600 µg (2 x 300 µg capsules) delivered via single dose dry powder inhalers (SDDPI) once daily (od) in the morning (between 7:00 and 11:00 AM). In addition to indacaterol 600 µg, patients received salmeterol placebo inhalation in the morning and the evening (between 7:00 and 11:00 PM). Daily inhaled corticosteroid treatment (if applicable) was to remain stable throughout the study. The short-acting β2-agonist salbutamol/albuterol was available for rescue use throughout the study. |
| **Salmeterol 50 µg** | Patients received salmeterol 50 µg delivered via the salmeterol proprietary dry powder inhalation device bis in die (bid, twice daily), once in the morning (between 7:00 and 11:00 AM) and once in the evening (between 7:00 and 11:00 PM). In addition to salmeterol 50 µg, patients received 2 indacaterol placebo inhalations in the morning. Daily inhaled corticosteroid treatment (if applicable) was to remain stable throughout the study. The short-acting β2-agonist salbutamol/albuterol was available for rescue use throughout the study. |

**Measured Values**

| | Indacaterol 300 µg | Indacaterol 600 µg | Salmeterol 50 µg |
|---|---|---|---|
| **Number of Participants Analyzed [units: participants]** | **238** | **237** | **244** |
| **Diastolic Blood Pressure 1 Hour Post-dose at Week 12 [units: mmHg] Least Squares Mean (Standard Error)** | **75.38 (0.576)** | **76.11 (0.580)** | **76.96 (0.575)** |

**No statistical analysis provided for Diastolic Blood Pressure 1 Hour Post-dose at Week 12**

6. Primary: Corrected QT (QTc) Interval Using Fridericia's Formula Measured 1 Hour Post-dose at Day 1 [ Time Frame: Day 1 ]

| | |
|---|---|
| **Measure Type** | Primary |
| **Measure Title** | Corrected QT (QTc) Interval Using Fridericia's Formula Measured 1 Hour Post-dose at Day 1 |

| | |
|---|---|
| **Measure Description** | The QTc interval (in milliseconds, ms) is calculated from electrocardiogram (ECG) data collected 1 hour post-dose using Fridericia's formula: QTc = QT/RR^0.33. QTc is the interval between the Q and T waves corrected for heart rate and RR is the interval between two R waves. ECGs included all 12 standard leads and a Lead II rhythm strip of at least 10-second duration. All results were sent to a central laboratory for review by a cardiologist. The analysis included baseline QTc interval and FEV1 pre-dose and 30 minutes post-dose of salbutamol/albuterol during screening as covariates. |
| **Time Frame** | Day 1 |
| **Safety Issue** | Yes |

**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.** |
|---|
| Safety population: All patients who received at least one dose of study drug. Participants with observations at Day 1 were included in the analysis. |

**Reporting Groups**

| | **Description** |
|---|---|
| **Indacaterol 300 µg** | Patients received indacaterol 300 µg delivered via a single dose dry powder inhaler (SDDPI) once daily (od) in the morning (between 7:00 and 11:00 AM). In addition to indacaterol 300 µg, patients received indacaterol and salmeterol placebo inhalations in the morning and salmeterol placebo inhalation in the evening (between 7:00 and 11:00 PM). Daily inhaled corticosteroid treatment (if applicable) was to remain stable throughout the study. The short-acting β2-agonist salbutamol/albuterol was available for rescue use throughout the study. |
| **Indacaterol 600 µg** | Patients received indacaterol 600 µg (2 x 300 µg capsules) delivered via single dose dry powder inhalers (SDDPI) once daily (od) in the morning (between 7:00 and 11:00 AM). In addition to indacaterol 600 µg, patients received salmeterol placebo inhalation in the morning and the evening (between 7:00 and 11:00 PM). Daily inhaled corticosteroid treatment (if applicable) was to remain stable throughout the study. The short-acting β2-agonist salbutamol/albuterol was available for rescue use throughout the study. |
| **Salmeterol 50 µg** | Patients received salmeterol 50 µg delivered via the salmeterol proprietary dry powder inhalation device bis in die (bid, twice daily), once in the morning (between 7:00 and 11:00 AM) and once in the evening (between 7:00 and 11:00 PM). In addition to salmeterol 50 µg, patients received 2 indacaterol placebo inhalations in the morning. Daily inhaled corticosteroid treatment (if applicable) was to remain stable throughout the study. The short-acting β2-agonist salbutamol/albuterol was available for rescue use throughout the study. |

**Measured Values**

| | Indacaterol 300 µg | Indacaterol 600 µg | Salmeterol 50 µg |
|---|---|---|---|
| **Number of Participants Analyzed [units: participants]** | **265** | **265** | **265** |
| **Corrected QT (QTc) Interval Using Fridericia's Formula Measured 1 Hour Post-dose at Day 1 [units: ms] Least Squares Mean (Standard Error)** | **404.46 (0.706)** | **404.97 (0.704)** | **405.05 (0.706)** |

**No statistical analysis provided for Corrected QT (QTc) Interval Using Fridericia's Formula Measured 1 Hour Post-dose at Day 1**

7. Primary: Corrected QT (QTc) Interval Using Fridericia's Formula Measured 1 Hour Post-dose at Week 12 [ Time Frame: Week 12 ]

| | |
|---|---|
| **Measure Type** | Primary |
| **Measure Title** | Corrected QT (QTc) Interval Using Fridericia's Formula Measured 1 Hour Post-dose at Week 12 |
| **Measure Description** | The QTc interval (in milliseconds, ms) is calculated from electrocardiogram (ECG) data collected 1 hour post-dose using Fridericia's formula: QTc = QT/RR^0.33. QTc is the interval between the Q and T waves corrected for heart rate and RR is the interval between two R waves. ECGs included all 12 standard leads and a Lead II rhythm strip of at least 10-second duration. All results were sent to a central laboratory for review by a cardiologist. The analysis included baseline QTc interval and FEV1 pre-dose and 30 minutes post-dose of salbutamol/albuterol during screening as covariates. |
| **Time Frame** | Week 12 |
| **Safety Issue** | Yes |

**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.**

Safety population: All patients who received at least one dose of study drug. Participants with observations at week 12 were included in the analysis.

**Reporting Groups**

| | Description |
|---|---|
| **Indacaterol 300 µg** | Patients received indacaterol 300 µg delivered via a single dose dry powder inhaler (SDDPI) once daily (od) in the morning (between 7:00 and 11:00 AM). In addition to indacaterol 300 µg, patients received indacaterol and salmeterol placebo inhalations in the morning and salmeterol placebo inhalation in the evening (between 7:00 and 11:00 PM). Daily inhaled corticosteroid treatment (if applicable) was to remain stable throughout the study. The short-acting β2-agonist salbutamol/albuterol was available for rescue use throughout the study. |
| **Indacaterol 600 µg** | Patients received indacaterol 600 µg (2 x 300 µg capsules) delivered via single dose dry powder inhalers (SDDPI) once daily (od) in the morning (between 7:00 and 11:00 AM). In addition to indacaterol 600 µg, patients received salmeterol placebo inhalation in the morning and the evening (between 7:00 and 11:00 PM). Daily inhaled corticosteroid treatment (if applicable) was to remain stable throughout the study. The short-acting β2-agonist salbutamol/albuterol was available for rescue use throughout the study. |
| **Salmeterol 50 µg** | Patients received salmeterol 50 µg delivered via the salmeterol proprietary dry powder inhalation device bis in die (bid, twice daily), once in the morning (between 7:00 and 11:00 AM) and once in the evening (between 7:00 and 11:00 PM). In addition to salmeterol 50 µg, patients received 2 indacaterol placebo inhalations in the morning. Daily inhaled corticosteroid treatment (if applicable) was to remain stable throughout the study. The short-acting β2-agonist salbutamol/albuterol was available for rescue use throughout the study. |

**Measured Values**

| | Indacaterol 300 µg | Indacaterol 600 µg | Salmeterol 50 µg |
|---|---|---|---|
| **Number of Participants Analyzed [units: participants]** | **238** | **236** | **242** |
| **Corrected QT (QTc) Interval Using Fridericia's Formula Measured 1 Hour Post-dose at Week 12 [units: ms] Least Squares Mean (Standard Error)** | **404.93 (0.970)** | **407.78 (0.979)** | **406.98 (0.967)** |

**No statistical analysis provided for Corrected QT (QTc) Interval Using Fridericia's Formula Measured 1 Hour Post-dose at Week 12**

8. Primary: Corrected QT (QTc) Interval Using Fridericia's Formula Measured 1 Hour Post-dose at Week 21 [ Time Frame: Week 21 ]

| | |
|---|---|
| **Measure Type** | Primary |
| **Measure Title** | Corrected QT (QTc) Interval Using Fridericia's Formula Measured 1 Hour Post-dose at Week 21 |
| **Measure Description** | The QTc interval (in milliseconds, ms) is calculated from electrocardiogram (ECG) data collected 1 hour post-dose using Fridericia's formula: QTc = QT/RR^0.33. QTc is the interval between the Q and T waves corrected for heart rate and RR is the interval between two R waves. ECGs included all 12 standard leads and a Lead II rhythm strip of at least 10-second duration. All results were sent to a central laboratory for review by a cardiologist. The analysis included baseline QTc interval and FEV1 pre-dose and 30 minutes post-dose of salbutamol/albuterol during screening as covariates. |
| **Time Frame** | Week 21 |
| **Safety Issue** | Yes |

**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.** |
|---|
| Safety population: All patients who received at least one dose of study drug. Participants with observations at week 21 were included in the analysis. |

**Reporting Groups**

| | **Description** |
|---|---|
| **Indacaterol 300 µg** | Patients received indacaterol 300 µg delivered via a single dose dry powder inhaler (SDDPI) once daily (od) in the morning (between 7:00 and 11:00 AM). In addition to indacaterol 300 µg, patients received indacaterol and salmeterol placebo inhalations in the morning and salmeterol placebo inhalation in the evening (between 7:00 and 11:00 PM). Daily inhaled corticosteroid treatment (if applicable) was to remain stable throughout the study. The short-acting β2-agonist salbutamol/albuterol was available for rescue use throughout the study. |
| **Indacaterol 600 µg** | Patients received indacaterol 600 µg (2 x 300 µg capsules) delivered via single dose dry powder inhalers (SDDPI) once |

| | |
|---|---|
| | daily (od) in the morning (between 7:00 and 11:00 AM). In addition to indacaterol 600 µg, patients received salmeterol placebo inhalation in the morning and the evening (between 7:00 and 11:00 PM). Daily inhaled corticosteroid treatment (if applicable) was to remain stable throughout the study. The short-acting β2-agonist salbutamol/albuterol was available for rescue use throughout the study. |
| **Salmeterol 50 µg** | Patients received salmeterol 50 µg delivered via the salmeterol proprietary dry powder inhalation device bis in die (bid, twice daily), once in the morning (between 7:00 and 11:00 AM) and once in the evening (between 7:00 and 11:00 PM). In addition to salmeterol 50 µg, patients received 2 indacaterol placebo inhalations in the morning. Daily inhaled corticosteroid treatment (if applicable) was to remain stable throughout the study. The short-acting β2-agonist salbutamol/albuterol was available for rescue use throughout the study. |

**Measured Values**

| | Indacaterol 300 µg | Indacaterol 600 µg | Salmeterol 50 µg |
|---|---|---|---|
| **Number of Participants Analyzed [units: participants]** | **227** | **228** | **237** |
| **Corrected QT (QTc) Interval Using Fridericia's Formula Measured 1 Hour Post-dose at Week 21 [units: ms] Least Squares Mean (Standard Error)** | **406.41 (1.005)** | **407.49 (1.014)** | **407.23 (0.995)** |

**No statistical analysis provided for Corrected QT (QTc) Interval Using Fridericia's Formula Measured 1 Hour Post-dose at Week 21**

9. Primary: 24 Hour Mean Heart Rate Determined From ECG Holter Monitoring at Week 12 [ Time Frame: Week 12 ]

| | |
|---|---|
| **Measure Type** | Primary |
| **Measure Title** | 24 Hour Mean Heart Rate Determined From ECG Holter Monitoring at Week 12 |
| **Measure Description** | Continuous 24 hour electrocardiography (Holter monitoring) was conducted in a subset of patients at designated study centers, and was used to calculate the mean heart rate (in beats per minute, bpm). Patients returned the Holter monitor recorder to the clinic the morning after the 24 hour recording was complete. The results of Holter monitoring were processed centrally. The analysis included baseline 24 hour mean heart rate and FEV1 pre-dose and 30 minutes |

| | |
|---|---|
| | post-dose of salbutamol/albuterol during screening as covariates. |
| **Time Frame** | Week 12 |
| **Safety Issue** | Yes |

**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.** |
|---|
| Safety population: All patients who received at least one dose of study drug. Participants with observations at week 12 were included in the analysis. |

**Reporting Groups**

| | **Description** |
|---|---|
| **Indacaterol 300 µg** | Patients received indacaterol 300 µg delivered via a single dose dry powder inhaler (SDDPI) once daily (od) in the morning (between 7:00 and 11:00 AM). In addition to indacaterol 300 µg, patients received indacaterol and salmeterol placebo inhalations in the morning and salmeterol placebo inhalation in the evening (between 7:00 and 11:00 PM). Daily inhaled corticosteroid treatment (if applicable) was to remain stable throughout the study. The short-acting β2-agonist salbutamol/albuterol was available for rescue use throughout the study. |
| **Indacaterol 600 µg** | Patients received indacaterol 600 µg (2 x 300 µg capsules) delivered via single dose dry powder inhalers (SDDPI) once daily (od) in the morning (between 7:00 and 11:00 AM). In addition to indacaterol 600 µg, patients received salmeterol placebo inhalation in the morning and the evening (between 7:00 and 11:00 PM). Daily inhaled corticosteroid treatment (if applicable) was to remain stable throughout the study. The short-acting β2-agonist salbutamol/albuterol was available for rescue use throughout the study. |
| **Salmeterol 50 µg** | Patients received salmeterol 50 µg delivered via the salmeterol proprietary dry powder inhalation device bis in die (bid, twice daily), once in the morning (between 7:00 and 11:00 AM) and once in the evening (between 7:00 and 11:00 PM). In addition to salmeterol 50 µg, patients received 2 indacaterol placebo inhalations in the morning. Daily inhaled corticosteroid treatment (if applicable) was to remain stable throughout the study. The short-acting β2-agonist salbutamol/albuterol was available for rescue use throughout the study. |

**Measured Values**

| | **Indacaterol 300 µg** | **Indacaterol 600 µg** | **Salmeterol 50 µg** |
|---|---|---|---|

| | | | |
|---|---|---|---|
| **Number of Participants Analyzed [units: participants]** | **74** | **75** | **69** |
| **24 Hour Mean Heart Rate Determined From ECG Holter Monitoring at Week 12 [units: bpm] Least Squares Mean (Standard Error)** | **81.0 (1.10)** | **81.7 (1.11)** | **80.4 (1.05)** |

**No statistical analysis provided for 24 Hour Mean Heart Rate Determined From ECG Holter Monitoring at Week 12**

10. Primary: 24 Hour Mean Heart Rate Determined From ECG Holter Monitoring at Week 26 [ Time Frame: Week 26 ]

| | |
|---|---|
| **Measure Type** | Primary |
| **Measure Title** | 24 Hour Mean Heart Rate Determined From ECG Holter Monitoring at Week 26 |
| **Measure Description** | Continuous 24 hour electrocardiography (Holter monitoring) was conducted in a subset of patients at designated study centers, and was used to calculate the mean heart rate (in beats per minute, bpm). Patients returned the Holter monitor recorder to the clinic the morning after the 24 hour recording was complete. The results of Holter monitoring were processed centrally. The analysis included baseline 24 hour mean heart rate and FEV1 pre-dose and 30 minutes post-dose of salbutamol/albuterol during screening as covariates. |
| **Time Frame** | Week 26 |
| **Safety Issue** | Yes |

**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.** |
| Safety population: All patients who received at least one dose of study drug. Participants with observations at week 26 were included in the analysis. |

**Reporting Groups**

| | Description |
|---|---|
| **Indacaterol 300 µg** | Patients received indacaterol 300 µg delivered via a single dose dry powder inhaler (SDDPI) once daily (od) in the morning (between 7:00 and 11:00 AM). In addition to indacaterol 300 µg, patients received indacaterol and salmeterol placebo inhalations in the morning and salmeterol placebo inhalation in the evening (between 7:00 and 11:00 PM). Daily inhaled corticosteroid treatment (if applicable) was to remain stable throughout the study. The short-acting β2-agonist salbutamol/albuterol was available for rescue use throughout the study. |
| **Indacaterol 600 µg** | Patients received indacaterol 600 µg (2 x 300 µg capsules) delivered via single dose dry powder inhalers (SDDPI) once daily (od) in the morning (between 7:00 and 11:00 AM). In addition to indacaterol 600 µg, patients received salmeterol placebo inhalation in the morning and the evening (between 7:00 and 11:00 PM). Daily inhaled corticosteroid treatment (if applicable) was to remain stable throughout the study. The short-acting β2-agonist salbutamol/albuterol was available for rescue use throughout the study. |
| **Salmeterol 50 µg** | Patients received salmeterol 50 µg delivered via the salmeterol proprietary dry powder inhalation device bis in die (bid, twice daily), once in the morning (between 7:00 and 11:00 AM) and once in the evening (between 7:00 and 11:00 PM). In addition to salmeterol 50 µg, patients received 2 indacaterol placebo inhalations in the morning. Daily inhaled corticosteroid treatment (if applicable) was to remain stable throughout the study. The short-acting β2-agonist salbutamol/albuterol was available for rescue use throughout the study. |

**Measured Values**

| | Indacaterol 300 µg | Indacaterol 600 µg | Salmeterol 50 µg |
|---|---|---|---|
| **Number of Participants Analyzed [units: participants]** | **64** | **65** | **63** |
| **24 Hour Mean Heart Rate Determined From ECG Holter Monitoring at Week 26 [units: bpm] Least Squares Mean (Standard Error)** | **79.4 (0.96)** | **81.0 (0.96)** | **79.2 (0.96)** |

**No statistical analysis provided for 24 Hour Mean Heart Rate Determined From ECG Holter Monitoring at Week 26**

11. Primary: Serum Potassium 1 Hour Post-dose at Day 1 [ Time Frame: Day 1 ]

| | |
|---|---|
| **Measure Type** | Primary |
| **Measure Title** | Serum Potassium 1 Hour Post-dose at Day 1 |
| **Measure Description** | Serum potassium (in millimoles per liter, mmol/L) was measured from venous blood samples. Samples were sent to a central laboratory for analysis. The analysis included baseline serum potassium and FEV1 pre-dose and 30 minutes post-dose of salbutamol/albuterol during screening as covariates. |
| **Time Frame** | Day 1 |
| **Safety Issue** | Yes |

**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.** |
|---|
| Safety population: All patients who received at least one dose of study drug. Participants with observations at Day 1 were included in the analysis. |

**Reporting Groups**

| | **Description** |
|---|---|
| **Indacaterol 300 µg** | Patients received indacaterol 300 µg delivered via a single dose dry powder inhaler (SDDPI) once daily (od) in the morning (between 7:00 and 11:00 AM). In addition to indacaterol 300 µg, patients received indacaterol and salmeterol placebo inhalations in the morning and salmeterol placebo inhalation in the evening (between 7:00 and 11:00 PM). Daily inhaled corticosteroid treatment (if applicable) was to remain stable throughout the study. The short-acting β2-agonist salbutamol/albuterol was available for rescue use throughout the study. |
| **Indacaterol 600 µg** | Patients received indacaterol 600 µg (2 x 300 µg capsules) delivered via single dose dry powder inhalers (SDDPI) once daily (od) in the morning (between 7:00 and 11:00 AM). In addition to indacaterol 600 µg, patients received salmeterol placebo inhalation in the morning and the evening (between 7:00 and 11:00 PM). Daily inhaled corticosteroid treatment (if applicable) was to remain stable throughout the study. The short-acting β2-agonist salbutamol/albuterol was available for rescue use throughout the study. |
| **Salmeterol 50 µg** | Patients received salmeterol 50 µg delivered via the salmeterol proprietary dry powder inhalation device bis in die (bid, twice daily), once in the morning (between 7:00 and 11:00 AM) and once in the evening (between 7:00 and 11:00 PM). In addition to salmeterol 50 µg, patients received 2 indacaterol placebo inhalations in the morning. Daily inhaled corticosteroid treatment (if applicable) was to remain stable throughout the study. The short-acting β2-agonist |

| | |
|---|---|
| | salbutamol/albuterol was available for rescue use throughout the study. |

**Measured Values**

| | Indacaterol 300 µg | Indacaterol 600 µg | Salmeterol 50 µg |
|---|---|---|---|
| **Number of Participants Analyzed [units: participants]** | **266** | **262** | **257** |
| **Serum Potassium 1 Hour Post-dose at Day 1 [units: mmol/L] Least Squares Mean (Standard Error)** | **4.30 (0.022)** | **4.24 (0.023)** | **4.32 (0.023)** |

**No statistical analysis provided for Serum Potassium 1 Hour Post-dose at Day 1**

12. Primary: Serum Potassium 1 Hour Post-dose at Week 12 [ Time Frame: Week 12 ]

| | |
|---|---|
| **Measure Type** | Primary |
| **Measure Title** | Serum Potassium 1 Hour Post-dose at Week 12 |
| **Measure Description** | Serum potassium (in millimoles per liter, mmol/L) was measured from venous blood samples. Samples were sent to a central laboratory for analysis. The analysis included baseline serum potassium and FEV1 pre-dose and 30 minutes post-dose of salbutamol/albuterol during screening as covariates. |
| **Time Frame** | Week 12 |
| **Safety Issue** | Yes |

**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.** |
|---|
| Safety population: All patients who received at least one dose of study drug. Participants with observations at week 12 were included in the analysis. |

**Reporting Groups**

| | Description |
|---|---|
| **Indacaterol 300 µg** | Patients received indacaterol 300 µg delivered via a single dose dry powder inhaler (SDDPI) once daily (od) in the morning (between 7:00 and 11:00 AM). In addition to indacaterol 300 µg, patients received indacaterol and salmeterol placebo inhalations in the morning and salmeterol placebo inhalation in the evening (between 7:00 and 11:00 PM). Daily inhaled corticosteroid treatment (if applicable) was to remain stable throughout the study. The short-acting β2-agonist salbutamol/albuterol was available for rescue use throughout the study. |
| **Indacaterol 600 µg** | Patients received indacaterol 600 µg (2 x 300 µg capsules) delivered via single dose dry powder inhalers (SDDPI) once daily (od) in the morning (between 7:00 and 11:00 AM). In addition to indacaterol 600 µg, patients received salmeterol placebo inhalation in the morning and the evening (between 7:00 and 11:00 PM). Daily inhaled corticosteroid treatment (if applicable) was to remain stable throughout the study. The short-acting β2-agonist salbutamol/albuterol was available for rescue use throughout the study. |
| **Salmeterol 50 µg** | Patients received salmeterol 50 µg delivered via the salmeterol proprietary dry powder inhalation device bis in die (bid, twice daily), once in the morning (between 7:00 and 11:00 AM) and once in the evening (between 7:00 and 11:00 PM). In addition to salmeterol 50 µg, patients received 2 indacaterol placebo inhalations in the morning. Daily inhaled corticosteroid treatment (if applicable) was to remain stable throughout the study. The short-acting β2-agonist salbutamol/albuterol was available for rescue use throughout the study. |

**Measured Values**

| | Indacaterol 300 µg | Indacaterol 600 µg | Salmeterol 50 µg |
|---|---|---|---|
| **Number of Participants Analyzed [units: participants]** | **235** | **233** | **241** |
| **Serum Potassium 1 Hour Post-dose at Week 12 [units: mmol/L] Least Squares Mean (Standard Error)** | **4.31 (0.025)** | **4.29 (0.025)** | **4.33 (0.025)** |

**No statistical analysis provided for Serum Potassium 1 Hour Post-dose at Week 12**

13. Primary: Blood Glucose 1 Hour Post-dose at Day 1 [ Time Frame: Day 1 ]

| | |
|---|---|
| **Measure Type** | Primary |
| **Measure Title** | Blood Glucose 1 Hour Post-dose at Day 1 |
| **Measure Description** | Blood glucose (in millimoles per liter, mmol/L) was measured from venous blood samples. Samples were sent to a central laboratory for analysis. The analysis included baseline blood glucose and FEV1 pre-dose and 30 minutes post-dose of salbutamol/albuterol during screening as covariates. |
| **Time Frame** | Day 1 |
| **Safety Issue** | Yes |

**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.** |
|---|
| Safety population: All patients who received at least one dose of study drug. Participants with observations at Day 1 were included in the analysis. |

**Reporting Groups**

| | **Description** |
|---|---|
| **Indacaterol 300 µg** | Patients received indacaterol 300 µg delivered via a single dose dry powder inhaler (SDDPI) once daily (od) in the morning (between 7:00 and 11:00 AM). In addition to indacaterol 300 µg, patients received indacaterol and salmeterol placebo inhalations in the morning and salmeterol placebo inhalation in the evening (between 7:00 and 11:00 PM). Daily inhaled corticosteroid treatment (if applicable) was to remain stable throughout the study. The short-acting β2-agonist salbutamol/albuterol was available for rescue use throughout the study. |
| **Indacaterol 600 µg** | Patients received indacaterol 600 µg (2 x 300 µg capsules) delivered via single dose dry powder inhalers (SDDPI) once daily (od) in the morning (between 7:00 and 11:00 AM). In addition to indacaterol 600 µg, patients received salmeterol placebo inhalation in the morning and the evening (between 7:00 and 11:00 PM). Daily inhaled corticosteroid treatment (if applicable) was to remain stable throughout the study. The short-acting β2-agonist salbutamol/albuterol was available for rescue use throughout the study. |
| **Salmeterol 50 µg** | Patients received salmeterol 50 µg delivered via the salmeterol proprietary dry powder inhalation device bis in die (bid, twice daily), once in the morning (between 7:00 and 11:00 AM) and once in the evening (between 7:00 and 11:00 PM). In addition to salmeterol 50 µg, patients received 2 indacaterol placebo inhalations in the morning. Daily inhaled corticosteroid treatment (if applicable) was to remain stable throughout the study. The short-acting β2-agonist |

| | |
|---|---|
| | salbutamol/albuterol was available for rescue use throughout the study. |

**Measured Values**

| | Indacaterol 300 µg | Indacaterol 600 µg | Salmeterol 50 µg |
|---|---|---|---|
| **Number of Participants Analyzed [units: participants]** | **266** | **265** | **258** |
| **Blood Glucose 1 Hour Post-dose at Day 1 [units: mmol/L] Least Squares Mean (Standard Error)** | **5.24 (0.061)** | **5.45 (0.061)** | **5.21 (0.062)** |

**No statistical analysis provided for Blood Glucose 1 Hour Post-dose at Day 1**

14. Primary: Blood Glucose 1 Hour Post-dose at Week 12 [ Time Frame: Week 12 ]

| | |
|---|---|
| **Measure Type** | Primary |
| **Measure Title** | Blood Glucose 1 Hour Post-dose at Week 12 |
| **Measure Description** | Blood glucose (in millimoles per liter, mmol/L) was measured from venous blood samples. Samples were sent to a central laboratory for analysis. The analysis included baseline blood glucose and FEV1 pre-dose and 30 minutes post-dose of salbutamol/albuterol during screening as covariates. |
| **Time Frame** | Week 12 |
| **Safety Issue** | Yes |

**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.** |
|---|
| Safety population: All patients who received at least one dose of study drug. Participants with observations at week 12 were included in the analysis. |

**Reporting Groups**

| | Description |
|---|---|
| **Indacaterol 300 µg** | Patients received indacaterol 300 µg delivered via a single dose dry powder inhaler (SDDPI) once daily (od) in the morning (between 7:00 and 11:00 AM). In addition to indacaterol 300 µg, patients received indacaterol and salmeterol placebo inhalations in the morning and salmeterol placebo inhalation in the evening (between 7:00 and 11:00 PM). Daily inhaled corticosteroid treatment (if applicable) was to remain stable throughout the study. The short-acting β2-agonist salbutamol/albuterol was available for rescue use throughout the study. |
| **Indacaterol 600 µg** | Patients received indacaterol 600 µg (2 x 300 µg capsules) delivered via single dose dry powder inhalers (SDDPI) once daily (od) in the morning (between 7:00 and 11:00 AM). In addition to indacaterol 600 µg, patients received salmeterol placebo inhalation in the morning and the evening (between 7:00 and 11:00 PM). Daily inhaled corticosteroid treatment (if applicable) was to remain stable throughout the study. The short-acting β2-agonist salbutamol/albuterol was available for rescue use throughout the study. |
| **Salmeterol 50 µg** | Patients received salmeterol 50 µg delivered via the salmeterol proprietary dry powder inhalation device bis in die (bid, twice daily), once in the morning (between 7:00 and 11:00 AM) and once in the evening (between 7:00 and 11:00 PM). In addition to salmeterol 50 µg, patients received 2 indacaterol placebo inhalations in the morning. Daily inhaled corticosteroid treatment (if applicable) was to remain stable throughout the study. The short-acting β2-agonist salbutamol/albuterol was available for rescue use throughout the study. |

**Measured Values**

| | Indacaterol 300 µg | Indacaterol 600 µg | Salmeterol 50 µg |
|---|---|---|---|
| **Number of Participants Analyzed [units: participants]** | **235** | **234** | **241** |
| **Blood Glucose 1 Hour Post-dose at Week 12 [units: mmol/L] Least Squares Mean (Standard Error)** | **5.27 (0.068)** | **5.38 (0.069)** | **5.23 (0.068)** |

**No statistical analysis provided for Blood Glucose 1 Hour Post-dose at Week 12**

15. Primary: Percentage of Patients With Clinically Significant Asthma Exacerbations During the 26 Weeks of the Study [ Time Frame: Baseline (Day 1) to end of study (Week 26) ]

| | |
|---|---|
| **Measure Type** | Primary |
| **Measure Title** | Percentage of Patients With Clinically Significant Asthma Exacerbations During the 26 Weeks of the Study |
| **Measure Description** | A clinically significant asthma exacerbation was defined as a worsening of asthma as judged clinically significant by the physician, requiring treatment with systemic corticosteroids. This includes events recorded on the asthma exacerbation clinical report form (CRF) page and events recorded on the adverse events CRF page with “asthma” as a key word in the preferred term. |
| **Time Frame** | Baseline (Day 1) to end of study (Week 26) |
| **Safety Issue** | Yes |

**Population Description**

| **Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.** |
|---|
| Intent-to-treat (ITT) population: All randomized patients who received at least 1 dose of study drug. |

**Reporting Groups**

| | **Description** |
|---|---|
| **Indacaterol 300 µg** | Patients received indacaterol 300 µg delivered via a single dose dry powder inhaler (SDDPI) once daily (od) in the morning (between 7:00 and 11:00 AM). In addition to indacaterol 300 µg, patients received indacaterol and salmeterol placebo inhalations in the morning and salmeterol placebo inhalation in the evening (between 7:00 and 11:00 PM). Daily inhaled corticosteroid treatment (if applicable) was to remain stable throughout the study. The short-acting β2-agonist salbutamol/albuterol was available for rescue use throughout the study. |
| **Indacaterol 600 µg** | Patients received indacaterol 600 µg (2 x 300 µg capsules) delivered via single dose dry powder inhalers (SDDPI) once daily (od) in the morning (between 7:00 and 11:00 AM). In addition to indacaterol 600 µg, patients received salmeterol placebo inhalation in the morning and the evening (between 7:00 and 11:00 PM). Daily inhaled corticosteroid treatment (if applicable) was to remain stable throughout the study. The short-acting β2-agonist salbutamol/albuterol was available for rescue use throughout the study. |
| **Salmeterol 50 µg** | Patients received salmeterol 50 µg delivered via the salmeterol proprietary dry powder inhalation device bis in die (bid, twice daily), once in the morning (between 7:00 and 11:00 AM) and once in the evening (between 7:00 and 11:00 PM). In addition to salmeterol 50 µg, patients received 2 indacaterol placebo inhalations in the morning. Daily inhaled |

| | |
|---|---|
| | corticosteroid treatment (if applicable) was to remain stable throughout the study. The short-acting β2-agonist salbutamol/albuterol was available for rescue use throughout the study. |

**Measured Values**

| | Indacaterol 300 µg | Indacaterol 600 µg | Salmeterol 50 µg |
|---|---|---|---|
| **Number of Participants Analyzed [units: participants]** | **268** | **268** | **269** |
| **Percentage of Patients With Clinically Significant Asthma Exacerbations During the 26 Weeks of the Study [units: Percentage of patients]** | | | |
| **0 exacerbations** | **92.9** | **89.9** | **90.0** |
| **1 exacerbation** | **5.6** | **9.3** | **8.6** |
| **2 exacerbations** | **0.7** | **0.7** | **1.5** |
| **3 exacerbations** | **0.7** | **0.0** | **0.0** |

**No statistical analysis provided for Percentage of Patients With Clinically Significant Asthma Exacerbations During the 26 Weeks of the Study**

16. Secondary: Trough Forced Expiratory Volume in 1 Second (FEV1) 24 Hours Post-dose at Week 12 + 1 Day, Day 85 [ Time Frame: 24 hours post-dose at Week 12 + 1 day, Day 85 ]

| | |
|---|---|
| **Measure Type** | Secondary |
| **Measure Title** | Trough Forced Expiratory Volume in 1 Second (FEV1) 24 Hours Post-dose at Week 12 + 1 Day, Day 85 |
| **Measure Description** | FEV1 (in liters, L) was measured with spirometry conducted according to internationally accepted standards. Trough FEV1 was defined as the average of measurements made 23 hours 10 minutes and 23 hours 45 minutes post-dose at Week 12, Day 85. The analysis included baseline FEV1 and FEV1 pre-dose and 30 minutes post-dose of salbutamol during screening as covariates. |
| **Time Frame** | 24 hours post-dose at Week 12 + 1 day, Day 85 |

| | |
|---|---|
| **Safety Issue** | No |

**Population Description**

| |
|---|
| **Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.** |
| Intent-to-treat (ITT) population: All randomized patients who received at least 1 dose of study drug. Participants with observations at Day 85 were included in the analysis. |

**Reporting Groups**

| | Description |
|---|---|
| **Indacaterol 300 µg** | Patients received indacaterol 300 µg delivered via a single dose dry powder inhaler (SDDPI) once daily (od) in the morning (between 7:00 and 11:00 AM). In addition to indacaterol 300 µg, patients received indacaterol and salmeterol placebo inhalations in the morning and salmeterol placebo inhalation in the evening (between 7:00 and 11:00 PM). Daily inhaled corticosteroid treatment (if applicable) was to remain stable throughout the study. The short-acting β2-agonist salbutamol/albuterol was available for rescue use throughout the study. |
| **Indacaterol 600 µg** | Patients received indacaterol 600 µg (2 x 300 µg capsules) delivered via single dose dry powder inhalers (SDDPI) once daily (od) in the morning (between 7:00 and 11:00 AM). In addition to indacaterol 600 µg, patients received salmeterol placebo inhalation in the morning and the evening (between 7:00 and 11:00 PM). Daily inhaled corticosteroid treatment (if applicable) was to remain stable throughout the study. The short-acting β2-agonist salbutamol/albuterol was available for rescue use throughout the study. |
| **Salmeterol 50 µg** | Patients received salmeterol 50 µg delivered via the salmeterol proprietary dry powder inhalation device bis in die (bid, twice daily), once in the morning (between 7:00 and 11:00 AM) and once in the evening (between 7:00 and 11:00 PM). In addition to salmeterol 50 µg, patients received 2 indacaterol placebo inhalations in the morning. Daily inhaled corticosteroid treatment (if applicable) was to remain stable throughout the study. The short-acting β2-agonist salbutamol/albuterol was available for rescue use throughout the study. |

**Measured Values**

| | Indacaterol 300 µg | Indacaterol 600 µg | Salmeterol 50 µg |
|---|---|---|---|
| **Number of Participants Analyzed [units: participants]** | **258** | **255** | **262** |

| | | | |
|---|---|---|---|
| **Trough Forced Expiratory Volume in 1 Second (FEV1) 24 Hours Post-dose at Week 12 + 1 Day, Day 85 [units: Liters] Least Squares Mean (Standard Error)** | **2.61 (0.023)** | **2.62 (0.023)** | **2.54 (0.023)** |

**No statistical analysis provided for Trough Forced Expiratory Volume in 1 Second (FEV1) 24 Hours Post-dose at Week 12 + 1 Day, Day 85**

17. Secondary: Number of Asthma Exacerbations Per Patient (Without Imputation) During the 26 Weeks of the Study [ Time Frame: Baseline (Day 1) to end of study (Week 26) ]

| | |
|---|---|
| **Measure Type** | Secondary |
| **Measure Title** | Number of Asthma Exacerbations Per Patient (Without Imputation) During the 26 Weeks of the Study |
| **Measure Description** | An asthma exacerbation was defined as a worsening of asthma as judged clinically significant by the physician, requiring treatment with rescue oral or intravenous (IV) corticosteroids. The number of asthma exacerbations includes events recorded on the asthma exacerbation clinical report form (CRF) page and events recorded on the adverse events CRF page with “asthma” as a key word in the preferred term. |
| **Time Frame** | Baseline (Day 1) to end of study (Week 26) |
| **Safety Issue** | No |

**Population Description**

| **Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.** |
|---|
| Intent-to-treat (ITT) population: All randomized patients who received at least 1 dose of study drug. |

**Reporting Groups**

| | **Description** |
|---|---|
| **Indacaterol 300 µg** | Patients received indacaterol 300 µg delivered via a single dose dry powder inhaler (SDDPI) once daily (od) in the morning (between 7:00 and 11:00 AM). In addition to indacaterol 300 µg, patients received indacaterol and salmeterol |

| | |
|---|---|
| | placebo inhalations in the morning and salmeterol placebo inhalation in the evening (between 7:00 and 11:00 PM). Daily inhaled corticosteroid treatment (if applicable) was to remain stable throughout the study. The short-acting β2-agonist salbutamol/albuterol was available for rescue use throughout the study. |
| **Indacaterol 600 µg** | Patients received indacaterol 600 µg (2 x 300 µg capsules) delivered via single dose dry powder inhalers (SDDPI) once daily (od) in the morning (between 7:00 and 11:00 AM). In addition to indacaterol 600 µg, patients received salmeterol placebo inhalation in the morning and the evening (between 7:00 and 11:00 PM). Daily inhaled corticosteroid treatment (if applicable) was to remain stable throughout the study. The short-acting β2-agonist salbutamol/albuterol was available for rescue use throughout the study. |
| **Salmeterol 50 µg** | Patients received salmeterol 50 µg delivered via the salmeterol proprietary dry powder inhalation device bis in die (bid, twice daily), once in the morning (between 7:00 and 11:00 AM) and once in the evening (between 7:00 and 11:00 PM). In addition to salmeterol 50 µg, patients received 2 indacaterol placebo inhalations in the morning. Daily inhaled corticosteroid treatment (if applicable) was to remain stable throughout the study. The short-acting β2-agonist salbutamol/albuterol was available for rescue use throughout the study. |

**Measured Values**

| | Indacaterol 300 µg | Indacaterol 600 µg | Salmeterol 50 µg |
|---|---|---|---|
| **Number of Participants Analyzed [units: participants]** | **268** | **268** | **269** |
| **Number of Asthma Exacerbations Per Patient (Without Imputation) During the 26 Weeks of the Study [units: Asthma exacerbations] Mean (Standard Deviation)** | **0.17 (0.561)** | **0.19 (0.512)** | **0.19 (0.494)** |

**No statistical analysis provided for Number of Asthma Exacerbations Per Patient (Without Imputation) During the 26 Weeks of the Study**

## Serious Adverse Events

Hide Serious Adverse Events

| | |
|---|---|
| **Time Frame** | Baseline to the end of the study (Week 26) |

| | |
|---|---|
| **Additional Description** | Safety population: All patients who received at least one dose of study drug. |

### Reporting Groups

| | Description |
|---|---|
| **Indacaterol 300 µg** | Patients received indacaterol 300 µg delivered via a single dose dry powder inhaler (SDDPI) once daily (od) in the morning (between 7:00 and 11:00 AM). In addition to indacaterol 300 µg, patients received indacaterol and salmeterol placebo inhalations in the morning and salmeterol placebo inhalation in the evening (between 7:00 and 11:00 PM). Daily inhaled corticosteroid treatment (if applicable) was to remain stable throughout the study. The short-acting β2-agonist salbutamol/albuterol was available for rescue use throughout the study. |
| **Indacaterol 600 µg** | Patients received indacaterol 600 µg (2 x 300 µg capsules) delivered via single dose dry powder inhalers (SDDPI) once daily (od) in the morning (between 7:00 and 11:00 AM). In addition to indacaterol 600 µg, patients received salmeterol placebo inhalation in the morning and the evening (between 7:00 and 11:00 PM). Daily inhaled corticosteroid treatment (if applicable) was to remain stable throughout the study. The short-acting β2-agonist salbutamol/albuterol was available for rescue use throughout the study. |
| **Salmeterol 50 µg** | Patients received salmeterol 50 µg delivered via the salmeterol proprietary dry powder inhalation device bis in die (bid, twice daily), once in the morning (between 7:00 and 11:00 AM) and once in the evening (between 7:00 and 11:00 PM). In addition to salmeterol 50 µg, patients received 2 indacaterol placebo inhalations in the morning. Daily inhaled corticosteroid treatment (if applicable) was to remain stable throughout the study. The short-acting β2-agonist salbutamol/albuterol was available for rescue use throughout the study. |

### Serious Adverse Events

| | Indacaterol 300 µg | Indacaterol 600 µg | Salmeterol 50 µg |
|---|---|---|---|
| **Total, serious adverse events** | | | |
| **# participants affected / at risk** | **5/268 (1.87%)** | **11/268 (4.10%)** | **8/269 (2.97%)** |
| **Blood and lymphatic system disorders** | | | |
| **Splenic cyst † [1]** | | | |
| **# participants affected / at risk** | **0/268 (0.00%)** | **1/268 (0.37%)** | **0/269 (0.00%)** |
| **Cardiac disorders** | | | |
| **Atrial fibrillation † [1]** | | | |

| | | | |
|---|---|---|---|
| # participants affected / at risk | 0/268 (0.00%) | 1/268 (0.37%) | 0/269 (0.00%) |
| Cardiac arrest † 1 | | | |
| # participants affected / at risk | 1/268 (0.37%) | 0/268 (0.00%) | 0/269 (0.00%) |
| Myocardial infarction † 1 | | | |
| # participants affected / at risk | 0/268 (0.00%) | 0/268 (0.00%) | 1/269 (0.37%) |
| General disorders | | | |
| Sudden death † 1 | | | |
| # participants affected / at risk | 1/268 (0.37%) | 0/268 (0.00%) | 0/269 (0.00%) |
| Hepatobiliary disorders | | | |
| Biliary colic † 1 | | | |
| # participants affected / at risk | 0/268 (0.00%) | 0/268 (0.00%) | 1/269 (0.37%) |
| Cholangitis † 1 | | | |
| # participants affected / at risk | 0/268 (0.00%) | 1/268 (0.37%) | 0/269 (0.00%) |
| Cholelithiasis † 1 | | | |
| # participants affected / at risk | 0/268 (0.00%) | 0/268 (0.00%) | 1/269 (0.37%) |
| Immune system disorders | | | |
| Drug hypersensitivity † 1 | | | |
| # participants affected / at risk | 0/268 (0.00%) | 0/268 (0.00%) | 1/269 (0.37%) |
| Food allergy † 1 | | | |
| # participants affected / at risk | 0/268 (0.00%) | 1/268 (0.37%) | 0/269 (0.00%) |
| Infections and infestations | | | |
| Abscess neck † 1 | | | |
| # participants affected / at risk | 1/268 (0.37%) | 0/268 (0.00%) | 0/269 (0.00%) |
| Pneumonia † 1 | | | |
| # participants affected / at risk | 0/268 (0.00%) | 1/268 (0.37%) | 1/269 (0.37%) |

| | | | |
|---|---|---|---|
| **Upper respiratory tract infection bacterial † 1** | | | |
| **# participants affected / at risk** | **1/268 (0.37%)** | **0/268 (0.00%)** | **0/269 (0.00%)** |
| **Injury, poisoning and procedural complications** | | | |
| **Fall † 1** | | | |
| **# participants affected / at risk** | **0/268 (0.00%)** | **2/268 (0.75%)** | **0/269 (0.00%)** |
| **Foot fracture † 1** | | | |
| **# participants affected / at risk** | **0/268 (0.00%)** | **0/268 (0.00%)** | **1/269 (0.37%)** |
| **Lumbar vertebral fracture † 1** | | | |
| **# participants affected / at risk** | **0/268 (0.00%)** | **1/268 (0.37%)** | **0/269 (0.00%)** |
| **Multiple fractures † 1** | | | |
| **# participants affected / at risk** | **0/268 (0.00%)** | **1/268 (0.37%)** | **0/269 (0.00%)** |
| **Nervous system disorders** | | | |
| **Facial paresis † 1** | | | |
| **# participants affected / at risk** | **0/268 (0.00%)** | **0/268 (0.00%)** | **1/269 (0.37%)** |
| **Pregnancy, puerperium and perinatal conditions** | | | |
| **Pregnancy † 1** | | | |
| **# participants affected / at risk** | **0/268 (0.00%)** | **2/268 (0.75%)** | **1/269 (0.37%)** |
| **Psychiatric disorders** | | | |
| **Stress † 1** | | | |
| **# participants affected / at risk** | **1/268 (0.37%)** | **0/268 (0.00%)** | **0/269 (0.00%)** |
| **Respiratory, thoracic and mediastinal disorders** | | | |
| **Analgesic asthma syndrome † 1** | | | |
| **# participants affected / at risk** | **0/268 (0.00%)** | **0/268 (0.00%)** | **1/269 (0.37%)** |
| **Asthma † 1** | | | |
| **# participants affected / at risk** | **2/268 (0.75%)** | **3/268 (1.12%)** | **0/269 (0.00%)** |

| | | | |
|---|---|---|---|
| **Skin and subcutaneous tissue disorders** | | | |
| **Angioedema † 1** | | | |
| **# participants affected / at risk** | **0/268 (0.00%)** | **0/268 (0.00%)** | **1/269 (0.37%)** |
| **Dermatitis allergic † 1** | | | |
| **# participants affected / at risk** | **0/268 (0.00%)** | **0/268 (0.00%)** | **1/269 (0.37%)** |

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

## Other Adverse Events

Hide Other Adverse Events

| | |
|---|---|
| **Time Frame** | Baseline to the end of the study (Week 26) |
| **Additional Description** | Safety population: All patients who received at least one dose of study drug. |

### Frequency Threshold

| | |
|---|---|
| **Threshold above which other adverse events are reported** | 5% |

### Reporting Groups

| | **Description** |
|---|---|
| **Indacaterol 300 µg** | Patients received indacaterol 300 µg delivered via a single dose dry powder inhaler (SDDPI) once daily (od) in the morning (between 7:00 and 11:00 AM). In addition to indacaterol 300 µg, patients received indacaterol and salmeterol placebo inhalations in the morning and salmeterol placebo inhalation in the evening (between 7:00 and 11:00 PM). Daily inhaled corticosteroid treatment (if applicable) was to remain stable throughout the study. The short-acting β2-agonist salbutamol/albuterol was available for rescue use throughout the study. |
| **Indacaterol 600 µg** | Patients received indacaterol 600 µg (2 x 300 µg capsules) delivered via single dose dry powder inhalers (SDDPI) once daily (od) in the morning (between 7:00 and 11:00 AM). In addition to indacaterol 600 µg, patients received salmeterol placebo inhalation in the morning and the evening (between 7:00 and 11:00 PM). Daily inhaled corticosteroid treatment (if applicable) was to remain stable throughout the study. The short-acting β2-agonist salbutamol/albuterol was available |

| | |
|---|---|
| | for rescue use throughout the study. |
| **Salmeterol 50 µg** | Patients received salmeterol 50 µg delivered via the salmeterol proprietary dry powder inhalation device bis in die (bid, twice daily), once in the morning (between 7:00 and 11:00 AM) and once in the evening (between 7:00 and 11:00 PM). In addition to salmeterol 50 µg, patients received 2 indacaterol placebo inhalations in the morning. Daily inhaled corticosteroid treatment (if applicable) was to remain stable throughout the study. The short-acting β2-agonist salbutamol/albuterol was available for rescue use throughout the study. |

## Other Adverse Events

| | Indacaterol 300 µg | Indacaterol 600 µg | Salmeterol 50 µg |
|---|---|---|---|
| **Total, other (not including serious) adverse events** | | | |
| **# participants affected / at risk** | **86/268 (32.09%)** | **105/268 (39.18%)** | **101/269 (37.55%)** |
| **Infections and infestations** | | | |
| **Bronchitis † [1]** | | | |
| **# participants affected / at risk** | **10/268 (3.73%)** | **13/268 (4.85%)** | **16/269 (5.95%)** |
| **Nasopharyngitis † [1]** | | | |
| **# participants affected / at risk** | **20/268 (7.46%)** | **22/268 (8.21%)** | **26/269 (9.67%)** |
| **Upper respiratory tract infection † [1]** | | | |
| **# participants affected / at risk** | **17/268 (6.34%)** | **27/268 (10.07%)** | **18/269 (6.69%)** |
| **Nervous system disorders** | | | |
| **Headache † [1]** | | | |
| **# participants affected / at risk** | **14/268 (5.22%)** | **18/268 (6.72%)** | **20/269 (7.43%)** |
| **Respiratory, thoracic and mediastinal disorders** | | | |
| **Asthma † [1]** | | | |
| **# participants affected / at risk** | **30/268 (11.19%)** | **39/268 (14.55%)** | **40/269 (14.87%)** |
| **Cough † [1]** | | | |
| **# participants affected / at risk** | **28/268 (10.45%)** | **29/268 (10.82%)** | **14/269 (5.20%)** |

† 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 (ie, data from all sites) in the clinical trial. |

**Results Point of Contact:**

Name/Title: Study Director
Organization: Novartis Pharmaceuticals
phone: 862 778-8300

**No publications provided**

| | |
|---|---|
| Responsible Party: | Novartis ( Novartis Pharmaceuticals ) |
| ClinicalTrials.gov Identifier: | NCT00529529 History of Changes |
| Other Study ID Numbers: | **CQAB149B2338** |
| Study First Received: | September 12, 2007 |
| Results First Received: | July 22, 2011 |
| Last Updated: | August 25, 2011 |
| Health Authority: | United States: Food and Drug Administration<br>Germany: Federal Institute for Drugs and Medical Devices<br>Argentina: Administracion Nacional de Medicamentos, Alimentos y Tecnologia Medica<br>Canada: Health Canada<br>Czech Republic: State Institute for Drug Control<br>France: Afssaps - Agence française de sécurité sanitaire des produits de santé (Saint-Denis)<br>Hungary: Ministry of Health, Social and Family Affairs<br>Italy: Ministry of Health<br>Peru: Ministry of Health<br>Slovakia: State Institute for Drug Control<br>Spain: Spanish Agency of Medicines<br>Turkey: Ministry of Health |