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Trial record **1 of 1** for: CQAB149B2336

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Efficacy and Safety of Indacaterol in Patients With Chronic Obstructive Pulmonary Disease (COPD) Using Salmeterol as Active Control

This study has been completed.

Sponsor:
Novartis

Information provided by:
Novartis

ClinicalTrials.gov Identifier:
NCT00567996

First received: December 4, 2007
Last updated: July 22, 2011
Last verified: July 2011
History of Changes

Full Text View | Tabular View | **Study Results** | Disclaimer | How to Read a Study Record

Results First Received: July 22, 2011

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Investigator, Outcomes Assessor); Primary Purpose: Treatment
Condition:	Chronic Obstructive Pulmonary Disease (COPD)
	Drug: Indacaterol 150 µg Drug: Salmeterol 50 µg

Interventions:	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
1002 participants were randomized. 3 randomized participants in the Indacaterol group and 1 randomized participant in the Salmeterol group did not receive study medication and were not included in the intent-to-treat milestone.

Reporting Groups

	Description
Indacaterol 150 µg	Indacaterol 150 µg once daily in the morning, inhaled via a single dose dry powder inhaler (SDDPI). Placebo to Salmeterol delivered twice daily via a proprietary dry powder inhaler in the morning and in the evening. Daily inhaled corticosteroid treatment (if applicable) was allowed to remain stable throughout the study. The short acting (beta) β2-agonist (SABA) salbutamol/albuterol was available for rescue use throughout the study.
Salmeterol 50 µg	Salmeterol 50 µg twice daily delivered via a proprietary dry powder inhaler in the morning and in the evening. Placebo to Indacaterol daily in the morning, inhaled via a single dose dry powder inhaler (SDDPI). Daily inhaled corticosteroid treatment (if applicable) was allowed to remain stable throughout the study. The short acting (beta) β2-agonist (SABA) salbutamol/albuterol was available for rescue use throughout the study.
Placebo	Placebo to indacaterol inhaled via SDDPI. Placebo to salmeterol delivered twice daily via a proprietary dry powder inhaler in the morning and in the evening. Daily inhaled corticosteroid treatment (if applicable) was allowed to remain stable throughout the study. The short acting (beta) β2-agonist (SABA) salbutamol/albuterol was available for rescue use throughout the study.

Participant Flow: Overall Study

	Indacaterol 150 µg	Salmeterol 50 µg	Placebo
STARTED	333 [1]	334	335
Intent-to-treat: Received Study Drug	330	333	335
COMPLETED	289	284	265
NOT COMPLETED	44	50	70
Adverse Event	18	16	13
Protocol Deviation	9	11	13
Withdrawal by Subject	8	12	22
Abnormal Lab value(s)	2	1	2
Abnormal test procedure result(s)	2	1	1
Lost to Follow-up	2	5	2
Unsatisfactory therapeutic effect	1	2	15
Administrative problems	1	1	0
Death	1	0	2
Patient's inability to use the device	0	1	0

[1] Randomized participants

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 150 µg	Indacaterol 150 µg once daily in the morning, inhaled via a single dose dry powder inhaler (SDDPI). Placebo to Salmeterol delivered twice daily via a proprietary dry powder inhaler in the morning and in the evening. Daily inhaled corticosteroid treatment (if applicable) was allowed to remain stable throughout the study. The short acting (beta) β2-agonist (SABA) salbutamol/albuterol was available for rescue use throughout the study.
Salmeterol 50 µg	Salmeterol 50 µg twice daily delivered via a proprietary dry powder inhaler in the morning and in the evening. Placebo to Indacaterol daily in the morning, inhaled via a single dose dry powder inhaler (SDDPI). Daily inhaled corticosteroid treatment (if applicable) was allowed to remain stable throughout the study. The short acting (beta) β2-agonist (SABA) salbutamol/albuterol was available for rescue use throughout the study.
Placebo	Placebo to indacaterol inhaled via SDDPI. Placebo to salmeterol delivered twice daily via a proprietary dry powder inhaler in the morning and in the evening. Daily inhaled corticosteroid treatment (if applicable) was allowed to remain stable throughout 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 150 µg	Salmeterol 50 µg	Placebo	Total
Number of Participants [units: participants]	**330**	**333**	**335**	**998**
Age [1] [units: years] Mean (Standard Deviation)	**63.2 (8.67)**	**63.4 (9.19)**	**63.9 (8.56)**	**63.5 (8.81)**
Gender [units: participants]				
Female	**92**	**84**	**77**	**253**

Male	**238**	**249**	**258**	**745**

[1] All baseline measures are based on the intent-to-treat population that included all randomized participants who received at least one dose of study medication.

Outcome Measures

Hide All Outcome Measures

1. Primary: Trough Forced Expiratory Volume in 1 Second (FEV1) After 12 Weeks of Treatment [Time Frame: Week 12]

Measure Type	Primary
Measure Title	Trough Forced Expiratory Volume in 1 Second (FEV1) After 12 Weeks of Treatment
Measure Description	Spirometry was conducted according to internationally accepted standards. Trough FEV1 was defined as the average of the 23 hour 10 minute and 23 hour 45 minute post-dose FEV1 readings. Mixed model used baseline FEV1, FEV1 prior to and 10-15 minutes post inhalation of salbutamol/albuterol, and FEV1 prior to and 1 hour post inhalation of ipratropium as covariates.
Time Frame	Week 12
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 population included all randomized participants who received at least one dose of study medication. The end point was analyzed only for those participants who had Trough FEV1 data at week 12. Missing data were imputed using Last Observation carried Forward (LOCF).

Reporting Groups

	Description
Indacaterol 150 µg	Indacaterol 150 µg once daily in the morning, inhaled via a single dose dry powder inhaler (SDDPI). Placebo to

	Salmeterol delivered twice daily via a proprietary dry powder inhaler in the morning and in the evening. Daily inhaled corticosteroid treatment (if applicable) was allowed to remain stable throughout the study. The short acting (beta) β2-agonist (SABA) salbutamol/albuterol was available for rescue use throughout the study.
Salmeterol 50 µg	Salmeterol 50 µg twice daily delivered via a proprietary dry powder inhaler in the morning and in the evening. Placebo to Indacaterol daily in the morning, inhaled via a single dose dry powder inhaler (SDDPI). Daily inhaled corticosteroid treatment (if applicable) was allowed to remain stable throughout the study. The short acting (beta) β2-agonist (SABA) salbutamol/albuterol was available for rescue use throughout the study.
Placebo	Placebo to indacaterol inhaled via SDDPI. Placebo to salmeterol delivered twice daily via a proprietary dry powder inhaler in the morning and in the evening. Daily inhaled corticosteroid treatment (if applicable) was allowed to remain stable throughout the study. The short acting (beta) β2-agonist (SABA) salbutamol/albuterol was available for rescue use throughout the study.

Measured Values

	Indacaterol 150 µg	Salmeterol 50 µg	Placebo
Number of Participants Analyzed [units: participants]	**320**	**317**	**316**
Trough Forced Expiratory Volume in 1 Second (FEV1) After 12 Weeks of Treatment [units: Liters] Least Squares Mean (Standard Error)	**1.45 (0.018)**	**1.39 (0.018)**	**1.28 (0.019)**

No statistical analysis provided for Trough Forced Expiratory Volume in 1 Second (FEV1) After 12 Weeks of Treatment

2. Secondary: St. George's Respiratory Questionnaire (SGRQ) Total Score After 12 Weeks of Treatment [Time Frame: Week 12]

Measure Type	Secondary
Measure Title	St. George's Respiratory Questionnaire (SGRQ) Total Score After 12 Weeks of Treatment
Measure Description	SGRQ is a health related quality of life questionnaire consisting of 76 items in three sections: symptoms, activity and

	impacts. The total score is 0 to 100 with a higher score indicating poorer health status. The mixed model used baseline SGRQ total score, FEV1 prior to and 30 minutes post inhalation of salbutamol/albuterol, and FEV1 prior to and one hour post inhalation of ipratropium as covariates.
Time Frame	Week 12
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 population included all randomized participants who received at least one dose of study medication. The endpoint was analyzed only for those participants who had SGRQ data at week 12. Missing data were imputed using Last Observation carried Forward (LOCF).

Reporting Groups

	Description
Indacaterol 150 µg	Indacaterol 150 µg once daily in the morning, inhaled via a single dose dry powder inhaler (SDDPI). Placebo to Salmeterol delivered twice daily via a proprietary dry powder inhaler in the morning and in the evening. Daily inhaled corticosteroid treatment (if applicable) was allowed to remain stable throughout the study. The short acting (beta) β2-agonist (SABA) salbutamol/albuterol was available for rescue use throughout the study.
Salmeterol 50 µg	Salmeterol 50 µg twice daily delivered via a proprietary dry powder inhaler in the morning and in the evening. Placebo to Indacaterol daily in the morning, inhaled via a single dose dry powder inhaler (SDDPI). Daily inhaled corticosteroid treatment (if applicable) was allowed to remain stable throughout the study. The short acting (beta) β2-agonist (SABA) salbutamol/albuterol was available for rescue use throughout the study.
Placebo	Placebo to indacaterol inhaled via SDDPI. Placebo to salmeterol delivered twice daily via a proprietary dry powder inhaler in the morning and in the evening. Daily inhaled corticosteroid treatment (if applicable) was allowed to remain stable throughout the study. The short acting (beta) β2-agonist (SABA) salbutamol/albuterol was available for rescue use throughout the study.

Measured Values

	Indacaterol 150 µg	**Salmeterol 50 µg**	**Placebo**

Number of Participants Analyzed [units: participants]	**309**	**301**	**294**
St. George's Respiratory Questionnaire (SGRQ) Total Score After 12 Weeks of Treatment [units: Score on a scale] Least Squares Mean (Standard Error)	**36.4 (1.04)**	**38.5 (1.04)**	**42.6 (1.05)**

No statistical analysis provided for St. George's Respiratory Questionnaire (SGRQ) Total Score After 12 Weeks of Treatment

3. Secondary: Percentage of COPD "Days of Poor Control" During 26 Weeks of Treatment [Time Frame: Up to 26 weeks]

Measure Type	Secondary
Measure Title	Percentage of COPD "Days of Poor Control" During 26 Weeks of Treatment
Measure Description	Participants rated their symptoms on a scale of 0=none to 3=severe. A Chronic Obstructive Pulmonary Disease (COPD) "day of poor control" was defined as any day in the participants diary with a score >=2 (moderate or severe) for at least 2 of 5 symptoms (cough, wheeze, production of sputum, color of sputum, breathlessness). The mixed model used baseline percentage of “days of poor control”, FEV1 prior to and 30 minutes post inhalation of salbutamol/albuterol, and FEV1 prior to and one hour post inhalation of ipratropium as covariates.
Time Frame	Up to 26 weeks
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 population included all randomized participants who received at least one dose of study medication. The endpoint was analyzed only for those participants who had data for this outcome measure.

Reporting Groups

	Description
Indacaterol 150 µg	Indacaterol 150 µg once daily in the morning, inhaled via a single dose dry powder inhaler (SDDPI). Placebo to Salmeterol delivered twice daily via a proprietary dry powder inhaler in the morning and in the evening. Daily inhaled corticosteroid treatment (if applicable) was allowed to remain stable throughout the study. The short acting (beta) β2-agonist (SABA) salbutamol/albuterol was available for rescue use throughout the study.
Salmeterol 50 µg	Salmeterol 50 µg twice daily delivered via a proprietary dry powder inhaler in the morning and in the evening. Placebo to Indacaterol daily in the morning, inhaled via a single dose dry powder inhaler (SDDPI). Daily inhaled corticosteroid treatment (if applicable) was allowed to remain stable throughout the study. The short acting (beta) β2-agonist (SABA) salbutamol/albuterol was available for rescue use throughout the study.
Placebo	Placebo to indacaterol inhaled via SDDPI. Placebo to salmeterol delivered twice daily via a proprietary dry powder inhaler in the morning and in the evening. Daily inhaled corticosteroid treatment (if applicable) was allowed to remain stable throughout the study. The short acting (beta) β2-agonist (SABA) salbutamol/albuterol was available for rescue use throughout the study.

Measured Values

	Indacaterol 150 µg	Salmeterol 50 µg	Placebo
Number of Participants Analyzed [units: participants]	**310**	**310**	**304**
Percentage of COPD "Days of Poor Control" During 26 Weeks of Treatment [units: Percentage of days] Least Squares Mean (Standard Error)	**34.1 (1.82)**	**34.1 (1.82)**	**38.1 (1.85)**

No statistical analysis provided for Percentage of COPD "Days of Poor Control" During 26 Weeks of Treatment

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	26 weeks

Additional Description	Safety population consisting of all participants who received at least one dose of study medication.

Reporting Groups

	Description
Indacaterol 150 µg	Indacaterol 150 µg once daily in the morning, inhaled via a single dose dry powder inhaler (SDDPI). Placebo to Salmeterol delivered twice daily via a proprietary dry powder inhaler in the morning and in the evening. Daily inhaled corticosteroid treatment (if applicable) was allowed to remain stable throughout the study. The short acting (beta) β2-agonist (SABA) salbutamol/albuterol was available for rescue use throughout the study.
Salmeterol 50 µg	Salmeterol 50 µg twice daily delivered via a proprietary dry powder inhaler in the morning and in the evening. Placebo to Indacaterol daily in the morning, inhaled via a single dose dry powder inhaler (SDDPI). Daily inhaled corticosteroid treatment (if applicable) was allowed to remain stable throughout the study. The short acting (beta) β2-agonist (SABA) salbutamol/albuterol was available for rescue use throughout the study.
Placebo	Placebo to Indacaterol once daily in the morning, inhaled via a single dose dry powder inhaler (SDDPI). Placebo to Salmeterol delivered twice daily via a proprietary dry powder inhaler in the morning and in the evening. Daily inhaled corticosteroid treatment (if applicable) was allowed to remain stable throughout the study. The short acting (beta) β2-agonist (SABA) salbutamol/albuterol was available for rescue use throughout the study.

Serious Adverse Events

	Indacaterol 150 µg	Salmeterol 50 µg	Placebo
Total, serious adverse events			
# participants affected / at risk	**29/330 (8.79%)**	**19/333 (5.71%)**	**26/335 (7.76%)**
Blood and lymphatic system disorders			
Anaemia † [1]			
# participants affected / at risk	**1/330 (0.30%)**	**0/333 (0.00%)**	**0/335 (0.00%)**
Cardiac disorders			
Acute myocardial infarction † [1]			
# participants affected / at risk	**1/330 (0.30%)**	**1/333 (0.30%)**	**0/335 (0.00%)**
Angina pectoris † [1]			

# participants affected / at risk	1/330 (0.30%)	1/333 (0.30%)	0/335 (0.00%)
Atrial fibrillation † [1]			
# participants affected / at risk	0/330 (0.00%)	1/333 (0.30%)	1/335 (0.30%)
Bundle branch block left † [1]			
# participants affected / at risk	0/330 (0.00%)	1/333 (0.30%)	0/335 (0.00%)
Cardiac arrest † [1]			
# participants affected / at risk	1/330 (0.30%)	0/333 (0.00%)	0/335 (0.00%)
Cardio-respiratory arrest † [1]			
# participants affected / at risk	0/330 (0.00%)	0/333 (0.00%)	1/335 (0.30%)
Cor pulmonale acute † [1]			
# participants affected / at risk	0/330 (0.00%)	0/333 (0.00%)	1/335 (0.30%)
Coronary artery disease † [1]			
# participants affected / at risk	0/330 (0.00%)	2/333 (0.60%)	0/335 (0.00%)
Myocardial infarction † [1]			
# participants affected / at risk	0/330 (0.00%)	1/333 (0.30%)	0/335 (0.00%)
Sick sinus syndrome † [1]			
# participants affected / at risk	1/330 (0.30%)	0/333 (0.00%)	0/335 (0.00%)
Tricuspid valve incompetence † [1]			
# participants affected / at risk	1/330 (0.30%)	0/333 (0.00%)	0/335 (0.00%)
Ear and labyrinth disorders			
Vertigo † [1]			
# participants affected / at risk	0/330 (0.00%)	1/333 (0.30%)	0/335 (0.00%)
Endocrine disorders			
Goitre † [1]			
# participants affected / at risk	1/330 (0.30%)	0/333 (0.00%)	0/335 (0.00%)

Gastrointestinal disorders			
Abdominal pain † [1]			
# participants affected / at risk	**0/330 (0.00%)**	**1/333 (0.30%)**	**0/335 (0.00%)**
Duodenal ulcer † [1]			
# participants affected / at risk	**0/330 (0.00%)**	**0/333 (0.00%)**	**1/335 (0.30%)**
Gastric ulcer † [1]			
# participants affected / at risk	**0/330 (0.00%)**	**0/333 (0.00%)**	**1/335 (0.30%)**
Gastritis † [1]			
# participants affected / at risk	**1/330 (0.30%)**	**0/333 (0.00%)**	**0/335 (0.00%)**
Inguinal hernia † [1]			
# participants affected / at risk	**0/330 (0.00%)**	**0/333 (0.00%)**	**1/335 (0.30%)**
Nausea † [1]			
# participants affected / at risk	**0/330 (0.00%)**	**1/333 (0.30%)**	**0/335 (0.00%)**
Pancreatitis † [1]			
# participants affected / at risk	**1/330 (0.30%)**	**0/333 (0.00%)**	**0/335 (0.00%)**
Rectal haemorrhage † [1]			
# participants affected / at risk	**1/330 (0.30%)**	**0/333 (0.00%)**	**0/335 (0.00%)**
General disorders			
Multi-organ failure † [1]			
# participants affected / at risk	**0/330 (0.00%)**	**0/333 (0.00%)**	**1/335 (0.30%)**
Hepatobiliary disorders			
Cholelithiasis † [1]			
# participants affected / at risk	**2/330 (0.61%)**	**0/333 (0.00%)**	**0/335 (0.00%)**
Infections and infestations			
Cellulitis † [1]			

# participants affected / at risk	1/330 (0.30%)	0/333 (0.00%)	0/335 (0.00%)
Diverticulitis † [1]			
# participants affected / at risk	0/330 (0.00%)	0/333 (0.00%)	2/335 (0.60%)
Gastroenteritis † [1]			
# participants affected / at risk	0/330 (0.00%)	1/333 (0.30%)	0/335 (0.00%)
Lower respiratory tract infection † [1]			
# participants affected / at risk	2/330 (0.61%)	2/333 (0.60%)	2/335 (0.60%)
Pneumonia † [1]			
# participants affected / at risk	0/330 (0.00%)	3/333 (0.90%)	0/335 (0.00%)
Sepsis † [1]			
# participants affected / at risk	0/330 (0.00%)	1/333 (0.30%)	0/335 (0.00%)
Sinusitis † [1]			
# participants affected / at risk	1/330 (0.30%)	0/333 (0.00%)	0/335 (0.00%)
Upper respiratory tract infection bacterial † [1]			
# participants affected / at risk	2/330 (0.61%)	2/333 (0.60%)	0/335 (0.00%)
Viral infection † [1]			
# participants affected / at risk	1/330 (0.30%)	0/333 (0.00%)	0/335 (0.00%)
Viral upper respiratory tract infection † [1]			
# participants affected / at risk	1/330 (0.30%)	0/333 (0.00%)	0/335 (0.00%)
Injury, poisoning and procedural complications			
Femoral neck fracture † [1]			
# participants affected / at risk	0/330 (0.00%)	1/333 (0.30%)	0/335 (0.00%)
Subdural haemorrhage † [1]			
# participants affected / at risk	1/330 (0.30%)	0/333 (0.00%)	0/335 (0.00%)
Traumatic intracranial haemorrhage † [1]			
# participants affected / at risk	1/330 (0.30%)	0/333 (0.00%)	0/335 (0.00%)

Metabolism and nutrition disorders			
Diabetic ketoacidosis † [1]			
# participants affected / at risk	**0/330 (0.00%)**	**0/333 (0.00%)**	**1/335 (0.30%)**
Musculoskeletal and connective tissue disorders			
Intervertebral disc protrusion † [1]			
# participants affected / at risk	**1/330 (0.30%)**	**0/333 (0.00%)**	**1/335 (0.30%)**
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Adenocarcinoma pancreas † [1]			
# participants affected / at risk	**1/330 (0.30%)**	**0/333 (0.00%)**	**0/335 (0.00%)**
Bladder cancer † [1]			
# participants affected / at risk	**0/330 (0.00%)**	**0/333 (0.00%)**	**1/335 (0.30%)**
Diffuse large B-cell lymphoma † [1]			
# participants affected / at risk	**1/330 (0.30%)**	**0/333 (0.00%)**	**0/335 (0.00%)**
Rectal cancer † [1]			
# participants affected / at risk	**1/330 (0.30%)**	**0/333 (0.00%)**	**0/335 (0.00%)**
Nervous system disorders			
Brachial plexopathy † [1]			
# participants affected / at risk	**1/330 (0.30%)**	**0/333 (0.00%)**	**0/335 (0.00%)**
Cerebral infarction † [1]			
# participants affected / at risk	**1/330 (0.30%)**	**0/333 (0.00%)**	**0/335 (0.00%)**
Cerebrovascular accident † [1]			
# participants affected / at risk	**1/330 (0.30%)**	**0/333 (0.00%)**	**0/335 (0.00%)**
Epilepsy † [1]			
# participants affected / at risk	**0/330 (0.00%)**	**0/333 (0.00%)**	**1/335 (0.30%)**
Hemiparesis † [1]			

# participants affected / at risk	1/330 (0.30%)	0/333 (0.00%)	0/335 (0.00%)
Ischaemic stroke † [1]			
# participants affected / at risk	0/330 (0.00%)	0/333 (0.00%)	1/335 (0.30%)
Transient ischaemic attack † [1]			
# participants affected / at risk	0/330 (0.00%)	0/333 (0.00%)	2/335 (0.60%)
Psychiatric disorders			
Alcoholism † [1]			
# participants affected / at risk	1/330 (0.30%)	0/333 (0.00%)	0/335 (0.00%)
Renal and urinary disorders			
Nephrolithiasis † [1]			
# participants affected / at risk	0/330 (0.00%)	0/333 (0.00%)	1/335 (0.30%)
Renal failure chronic † [1]			
# participants affected / at risk	0/330 (0.00%)	0/333 (0.00%)	1/335 (0.30%)
Reproductive system and breast disorders			
Menorrhagia † [1]			
# participants affected / at risk	1/330 (0.30%)	0/333 (0.00%)	0/335 (0.00%)
Ovarian cyst † [1]			
# participants affected / at risk	1/330 (0.30%)	0/333 (0.00%)	0/335 (0.00%)
Respiratory, thoracic and mediastinal disorders			
Acute pulmonary oedema † [1]			
# participants affected / at risk	0/330 (0.00%)	0/333 (0.00%)	1/335 (0.30%)
Acute respiratory failure † [1]			
# participants affected / at risk	0/330 (0.00%)	0/333 (0.00%)	1/335 (0.30%)
Chronic obstructive pulmonary disease † [1]			
# participants affected / at risk	8/330 (2.42%)	4/333 (1.20%)	10/335 (2.99%)

Dyspnoea † 1			
# participants affected / at risk	**0/330 (0.00%)**	**0/333 (0.00%)**	**2/335 (0.60%)**
Lung infiltration † 1			
# participants affected / at risk	**0/330 (0.00%)**	**1/333 (0.30%)**	**0/335 (0.00%)**
Pleural effusion † 1			
# participants affected / at risk	**0/330 (0.00%)**	**1/333 (0.30%)**	**0/335 (0.00%)**
Vascular disorders			
Hypertension † 1			
# participants affected / at risk	**1/330 (0.30%)**	**1/333 (0.30%)**	**1/335 (0.30%)**
Hypertensive crisis † 1			
# participants affected / at risk	**0/330 (0.00%)**	**0/333 (0.00%)**	**2/335 (0.60%)**
Peripheral arterial occlusive disease † 1			
# participants affected / at risk	**1/330 (0.30%)**	**0/333 (0.00%)**	**0/335 (0.00%)**

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

Other Adverse Events

Hide Other Adverse Events

Time Frame	26 weeks
Additional Description	Safety population consisting of all participants who received at least one dose of study medication.

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
Indacaterol 150 µg	Indacaterol 150 µg once daily in the morning, inhaled via a single dose dry powder inhaler (SDDPI). Placebo to Salmeterol delivered twice daily via a proprietary dry powder inhaler in the morning and in the evening. Daily inhaled corticosteroid treatment (if applicable) was allowed to remain stable throughout the study. The short acting (beta) β2-agonist (SABA) salbutamol/albuterol was available for rescue use throughout the study.
Salmeterol 50 µg	Salmeterol 50 µg twice daily delivered via a proprietary dry powder inhaler in the morning and in the evening. Placebo to Indacaterol daily in the morning, inhaled via a single dose dry powder inhaler (SDDPI). Daily inhaled corticosteroid treatment (if applicable) was allowed to remain stable throughout the study. The short acting (beta) β2-agonist (SABA) salbutamol/albuterol was available for rescue use throughout the study.
Placebo	Placebo to Indacaterol once daily in the morning, inhaled via a single dose dry powder inhaler (SDDPI). Placebo to Salmeterol delivered twice daily via a proprietary dry powder inhaler in the morning and in the evening. Daily inhaled corticosteroid treatment (if applicable) was allowed to remain stable throughout the study. The short acting (beta) β2-agonist (SABA) salbutamol/albuterol was available for rescue use throughout the study.

Other Adverse Events

	Indacaterol 150 µg	Salmeterol 50 µg	Placebo
Total, other (not including serious) adverse events			
# participants affected / at risk	**69/330 (20.91%)**	**68/333 (20.42%)**	**71/335 (21.19%)**
Infections and infestations			
Nasopharyngitis † 1			
# participants affected / at risk	**24/330 (7.27%)**	**29/333 (8.71%)**	**21/335 (6.27%)**
Respiratory, thoracic and mediastinal disorders			
Chronic obstructive pulmonary disease † 1			
# participants affected / at risk	**52/330 (15.76%)**	**48/333 (14.41%)**	**58/335 (17.31%)**

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

Limitations and Caveats

Hide Limitations and Caveats

Limitations of the study, such as early termination leading to small numbers of participants analyzed and technical problems with measurement leading to unreliable or uninterpretable data
No text entered.

More Information

Hide More Information

Certain Agreements:

Principal Investigators are **NOT** employed by the organization sponsoring the study.
There **IS** an agreement between Principal Investigators and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.
The agreement is: ☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **less than or equal to 60 days**. The sponsor cannot require changes to the communication and cannot extend the embargo. ☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **more than 60 days but less than or equal to 180 days**. The sponsor cannot require changes to the communication and cannot extend the embargo. Other disclosure agreement that restricts the right of the PI to discuss or publish trial results after the trial is completed. ☑ **Restriction Description:** The terms and conditions of Novartis' agreements with its investigators may vary. However, Novartis does not prohibit any investigator from publishing. any publications from a single-site are postponed until the publication of the pooled date (i.e., data from all sites) in the clinical trial.

Results Point of Contact:

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

No publications provided by Novartis

Publications automatically indexed to this study:

Yelensky R, Li Y, Lewitzky S, Leroy E, Hurwitz C, Rodman D, Trifilieff A, Paulding CA. A pharmacogenetic study of ADRB2 polymorphisms and indacaterol response in COPD patients. Pharmacogenomics J. 2012 Dec;12(6):484-8. doi: 10.1038/tpj.2011.54. Epub 2011 Dec 13.

Jones PW, Mahler DA, Gale R, Owen R, Kramer B. Profiling the effects of indacaterol on dyspnoea and health status in patients with COPD. Respir Med. 2011 Jun;105(6):892-9. doi: 10.1016/j.rmed.2011.02.013. Epub 2011 Mar 11.

Worth H, Chung KF, Felser JM, Hu H, Rueegg P. Cardio- and cerebrovascular safety of indacaterol vs formoterol, salmeterol, tiotropium and placebo in COPD. Respir Med. 2011 Apr;105(4):571-9. doi: 10.1016/j.rmed.2010.11.027. Epub 2011 Jan 11.

Responsible Party:	External affairs, novartis
ClinicalTrials.gov Identifier:	NCT00567996 History of Changes
Other Study ID Numbers:	**CQAB149B2336**
Study First Received:	December 4, 2007
Results First Received:	July 22, 2011
Last Updated:	July 22, 2011
Health Authority:	Brazil: Ministry of Health Canada: Health Canada Colombia: INVIMA Instituto Nacional de Vigilancia de Medicamentos y Alimentos Czech Republic: State Institute for Drug Control Denmark: Danish Medicines Agency Germany: Federal Institute for Drugs and Medical Devices Hungary: National Institute of Pharmacy Iceland: Icelandic Medicines Control Agency India: Ministry of Health Italy: Ministry of Health Norway: Norwegian Medicines Agency Peru: Ministry of Health Russia: Ministry of Health of the Russian Federation

Slovakia: State Institute for Drug Control
Taiwan: Department of Health
Finland: Finnish Medicines Agency