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Trial record **1 of 1** for: CQAB149B2350

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A Study to Compare the Lung Effect of Indacaterol and Tiotropium in Chronic Obstructive Pulmonary Disease (COPD) (INTENSITY)

This study has been completed.

Sponsor:
Novartis Pharmaceuticals

Information provided by:
Novartis

ClinicalTrials.gov Identifier:
NCT00900731

First received: May 12, 2009
Last updated: July 22, 2011
Last verified: July 2011
History of Changes

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Results First Received: July 22, 2011

Study Type:	Interventional
Study Design:	Allocation: Randomized; Intervention Model: Parallel Assignment; Masking: Double Blind (Investigator, Outcomes Assessor); Primary Purpose: Treatment
Condition:	Chronic Obstructive Pulmonary Disease
Interventions:	Drug: Indacaterol 150 µg Drug: Tiotropium 18 µg Drug: Placebo to indacaterol Drug: Placebo to tiotropium

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
1598 participants were randomized. 3 participants in the Indacaterol group and 2 participants in the Tiotropium group did not receive study medication.

Reporting Groups

	Description
Indacaterol 150 µg	Participants received indacaterol 150 µg delivered via a single-dose dry-powder inhaler (SDDPI) plus placebo to tiotropium delivered via the manufacturer's proprietary inhalation device (HandiHaler®) once daily in the morning. Participants were permitted to take salbutamol/albuterol as a rescue medication.
Tiotropium 18 µg	Participants received tiotropium 18 µg delivered via the manufacturer's proprietary inhalation device (HandiHaler®) plus placebo to indacaterol delivered via a single-dose dry-powder inhaler (SDDPI) once daily in the morning. Participants were permitted to take salbutamol/albuterol as a rescue medication.

Participant Flow: Overall Study

	Indacaterol 150 µg	Tiotropium 18 µg
STARTED	**797** [1]	**801**
Safety Set: Received Study Drug	**794**	**799**
COMPLETED	**737**	**740**
NOT COMPLETED	**60**	**61**

Adverse Event	**31**	**27**
Withdrawal by Subject	**8**	**7**
Protocol Deviation	**8**	**11**
Administrative Problems	**5**	**4**
Abnormal Test Procedure Result(s)	**3**	**0**
Abnormal Laboratory Value(s)	**2**	**4**
Lost to Follow-up	**2**	**3**
Lack of Efficacy	**1**	**3**
Death	**0**	**2**

[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	Participants received indacaterol 150 µg delivered via a single-dose dry-powder inhaler (SDDPI) plus placebo to tiotropium delivered via the manufacturer's proprietary inhalation device (HandiHaler®) once daily in the morning. Participants were permitted to take salbutamol/albuterol as a rescue medication.
Tiotropium 18 µg	Participants received tiotropium 18 µg delivered via the manufacturer's proprietary inhalation device (HandiHaler®) plus placebo to indacaterol delivered via a single-dose dry-powder inhaler (SDDPI) once daily in the morning. Participants

	were permitted to take salbutamol/albuterol as a rescue medication.
Total	Total of all reporting groups

Baseline Measures

	Indacaterol 150 µg	Tiotropium 18 µg	Total
Number of Participants [units: participants]	**794**	**799**	**1593**
Age [1] [units: years] Mean (Standard Deviation)	**63.6 (8.60)**	**63.4 (8.29)**	**63.5 (8.45)**
Gender [units: participants]			
Female	**239**	**261**	**500**
Male	**555**	**538**	**1093**

[1] Baseline Measures used the safety population that consisted of all participants who received at least one dose of study drug.

Outcome Measures

Hide All Outcome Measures

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

Measure Type	Primary
Measure Title	Trough Forced Expiratory Volume in 1 Second (FEV1) at End of Treatment (Week 12)
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, FEV1 prior to and 1 hour post inhalation of ipratropium, and inhaled corticosteroid use at baseline as covariates.

Time Frame	End of treatment (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.
Per-protocol population included all participants who received at least one dose of study medication without any major protocol deviations. The endpoint was analyzed only for those participants who had data for this outcome measure. Missing data were imputed using last observation carried forward.

Reporting Groups

	Description
Indacaterol 150 µg	Participants received indacaterol 150 µg delivered via a single-dose dry-powder inhaler (SDDPI) plus placebo to tiotropium delivered via the manufacturer's proprietary inhalation device (HandiHaler®) once daily in the morning. Participants were permitted to take salbutamol/albuterol as a rescue medication.
Tiotropium 18 µg	Participants received tiotropium 18 µg delivered via the manufacturer's proprietary inhalation device (HandiHaler®) plus placebo to indacaterol delivered via a single-dose dry-powder inhaler (SDDPI) once daily in the morning. Participants were permitted to take salbutamol/albuterol as a rescue medication.

Measured Values

	Indacaterol 150 µg	**Tiotropium 18 µg**
Number of Participants Analyzed [units: participants]	**562**	**595**
Trough Forced Expiratory Volume in 1 Second (FEV1) at End of Treatment (Week 12) [units: Liters] Least Squares Mean (Standard Error)	**1.44 (0.010)**	**1.43 (0.010)**

No statistical analysis provided for Trough Forced Expiratory Volume in 1 Second (FEV1) at End of Treatment (Week 12)

2. Secondary: Forced Expiratory Volume in 1 Second (FEV1) Standardized (With Respect to Time) Area Under the Curve (AUC) From 5 Minutes to 4 Hours Post-dose at the End of Treatment (Week 12) [Time Frame: 5 minutes to 4 hours post-dose at the end of treatment (week 12)]

Measure Type	Secondary
Measure Title	Forced Expiratory Volume in 1 Second (FEV1) Standardized (With Respect to Time) Area Under the Curve (AUC) From 5 Minutes to 4 Hours Post-dose at the End of Treatment (Week 12)
Measure Description	Spirometry was conducted according to internationally accepted standards. FEV1 was measured at 5 and 30 minutes; and 1, 2, and 4 hours post-dose on Week 12. Standardized FEV1 AUC (5 minutes-4 hour) post-dose at week 12 was calculated based on the trapezoidal rule, and was adjusted for the area per time unit by using the scheduled time of measurements for FEV1. Mixed model used baseline FEV1, FEV1 prior to and 10-15 minutes post inhalation of salbutamol/albuterol, FEV1 prior to and 1 hour post inhalation of ipratropium, and inhaled corticosteroid use at baseline as covariates.
Time Frame	5 minutes to 4 hours post-dose at the end of treatment (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.
Full analysis set included all participants who received at least one dose of study medication. The endpoint was analyzed only for those participants who had data at week 12 for this outcome measure.

Reporting Groups

	Description
Indacaterol 150 µg	Participants received indacaterol 150 µg delivered via a single-dose dry-powder inhaler (SDDPI) plus placebo to tiotropium delivered via the manufacturer's proprietary inhalation device (HandiHaler®) once daily in the morning. Participants were permitted to take salbutamol/albuterol as a rescue medication.
Tiotropium 18 µg	Participants received tiotropium 18 µg delivered via the manufacturer's proprietary inhalation device (HandiHaler®) plus

	placebo to indacaterol delivered via a single-dose dry-powder inhaler (SDDPI) once daily in the morning. Participants were permitted to take salbutamol/albuterol as a rescue medication.

Measured Values

	Indacaterol 150 µg	Tiotropium 18 µg
Number of Participants Analyzed [units: participants]	**685**	**692**
Forced Expiratory Volume in 1 Second (FEV1) Standardized (With Respect to Time) Area Under the Curve (AUC) From 5 Minutes to 4 Hours Post-dose at the End of Treatment (Week 12) [units: Liter] Least Squares Mean (Standard Error)	**1.51 (0.010)**	**1.52 (0.010)**

No statistical analysis provided for Forced Expiratory Volume in 1 Second (FEV1) Standardized (With Respect to Time) Area Under the Curve (AUC) From 5 Minutes to 4 Hours Post-dose at the End of Treatment (Week 12)

3. Secondary: Transition Dyspnea Index (TDI) Focal Score After 12 Weeks of Treatment [Time Frame: 12 weeks]

Measure Type	Secondary
Measure Title	Transition Dyspnea Index (TDI) Focal Score After 12 Weeks of Treatment
Measure Description	TDI focal score is based on three domains: functional impairment, magnitude of task and magnitude of effort. Each domain is scored from -3 (major deterioration) to 3 (major improvement) to give an overall TDI focal score of -9 to 9 with a negative score indicating a deterioration from baseline. A 1 unit difference in the TDI focal score is clinically significant. Mixed model used baseline dyspnea index, FEV1 prior to and 10-15 minutes post inhalation of salbutamol/albuterol, FEV1 prior to and 1 hour post inhalation of ipratropium, and inhaled corticosteroid use at baseline as covariates.
Time Frame	12 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.
Full Analysis Set included all randomized participants who received at least one dose of study drug. The endpoint was analyzed only for those participants who had data at week 12 for this outcome measure. Missing data were imputed using Last Observation Carried Forward.

Reporting Groups

	Description
Indacaterol 150 µg	Participants received indacaterol 150 µg delivered via a single-dose dry-powder inhaler (SDDPI) plus placebo to tiotropium delivered via the manufacturer's proprietary inhalation device (HandiHaler®) once daily in the morning. Participants were permitted to take salbutamol/albuterol as a rescue medication.
Tiotropium 18 µg	Participants received tiotropium 18 µg delivered via the manufacturer's proprietary inhalation device (HandiHaler®) plus placebo to indacaterol delivered via a single-dose dry-powder inhaler (SDDPI) once daily in the morning. Participants were permitted to take salbutamol/albuterol as a rescue medication.

Measured Values

	Indacaterol 150 µg	**Tiotropium 18 µg**
Number of Participants Analyzed [units: participants]	**729**	**737**
Transition Dyspnea Index (TDI) Focal Score After 12 Weeks of Treatment [units: Score on a scale] Least Squares Mean (Standard Error)	**2.01 (0.178)**	**1.43 (0.178)**

No statistical analysis provided for Transition Dyspnea Index (TDI) Focal Score After 12 Weeks of Treatment

4. Secondary: Quality of Life Assessment With St. George's Respiratory Questionnaire (SGRQ) Total Score After 12 Weeks of Treatment [Time Frame: 12 weeks]

Measure Type	Secondary
Measure Title	Quality of Life Assessment With 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 50 items in three domains: symptoms (frequency and severity), activity (that cause or are limited by breathlessness) and impacts (social functioning & psychological disturbances resulting from airway disease). The total score is 0 to 100 with a higher score indicating greater impairment of health status. Mixed model used baseline SGRQ, FEV1 prior to and 10-15 minutes post inhalation of salbutamol/albuterol, FEV1 prior to and 1 hour post inhalation of ipratropium, and inhaled corticosteroid use at baseline as covariates.
Time Frame	12 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.
Full Analysis Set included all randomized participants who received at least one dose of study drug. The endpoint was analyzed only for those participants who had data at week 12 for this outcome measure. Missing data were imputed using Last Observation Carried Forward.

Reporting Groups

	Description
Indacaterol 150 µg	Participants received indacaterol 150 µg delivered via a single-dose dry-powder inhaler (SDDPI) plus placebo to tiotropium delivered via the manufacturer's proprietary inhalation device (HandiHaler®) once daily in the morning. Participants were permitted to take salbutamol/albuterol as a rescue medication.
Tiotropium 18 µg	Participants received tiotropium 18 µg delivered via the manufacturer's proprietary inhalation device (HandiHaler®) plus placebo to indacaterol delivered via a single-dose dry-powder inhaler (SDDPI) once daily in the morning. Participants were permitted to take salbutamol/albuterol as a rescue medication.

Measured Values

	Indacaterol 150 µg	**Tiotropium 18 µg**

Number of Participants Analyzed [units: participants]	**743**	**753**
Quality of Life Assessment With St. George's Respiratory Questionnaire (SGRQ) Total Score After 12 Weeks of Treatment [units: Score on a scale] Least Squares Mean (Standard Error)	**37.1 (0.56)**	**39.2 (0.55)**

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

5. Secondary: Change From Baseline in the Mean Number of Puffs Per Day of Rescue Medication Over the Study Duration (From Day 1 to Week 12) [Time Frame: Baseline, up to 12 weeks]

Measure Type	Secondary
Measure Title	Change From Baseline in the Mean Number of Puffs Per Day of Rescue Medication Over the Study Duration (From Day 1 to Week 12)
Measure Description	Participants recorded the number of puffs of rescue medication taken in the previous 12 hours each morning and evening in an electronic diary. The number of puffs per day over the 12 weeks of treatment was divided by the number of days to derive the mean number per day of puffs of rescue medication for each participant. Mixed model used baseline number of puffs per day of rescue medication, FEV1 prior to and 10-15 minutes post inhalation of salbutamol/albuterol, FEV1 prior to and 1 hour post inhalation of ipratropium, and inhaled corticosteroid use at baseline as covariates.
Time Frame	Baseline, up to 12 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.
Full analysis set included all participants who received at least 1 dose of study medication. The endpoint was analyzed only for those

participants who had data at baseline and at week 12 for this outcome measure.

Reporting Groups

	Description
Indacaterol 150 µg	Participants received indacaterol 150 µg delivered via a single-dose dry-powder inhaler (SDDPI) plus placebo to tiotropium delivered via the manufacturer's proprietary inhalation device (HandiHaler®) once daily in the morning. Participants were permitted to take salbutamol/albuterol as a rescue medication.
Tiotropium 18 µg	Participants received tiotropium 18 µg delivered via the manufacturer's proprietary inhalation device (HandiHaler®) plus placebo to indacaterol delivered via a single-dose dry-powder inhaler (SDDPI) once daily in the morning. Participants were permitted to take salbutamol/albuterol as a rescue medication.

Measured Values

	Indacaterol 150 µg	Tiotropium 18 µg
Number of Participants Analyzed [units: participants]	**740**	**747**
Change From Baseline in the Mean Number of Puffs Per Day of Rescue Medication Over the Study Duration (From Day 1 to Week 12) [units: Puffs] Least Squares Mean (Standard Error)	**-1.40 (0.097)**	**-0.85 (0.097)**

No statistical analysis provided for Change From Baseline in the Mean Number of Puffs Per Day of Rescue Medication Over the Study Duration (From Day 1 to Week 12)

6. Secondary: Change From Baseline in the Mean Number Per Day of Daytime Puffs of Rescue Medication Over the Study Duration (From Day 1 to Week 12) [Time Frame: Baseline, up to 12 weeks]

Measure Type	Secondary
	Change From Baseline in the Mean Number Per Day of Daytime Puffs of Rescue Medication Over the Study Duration

Measure Title	(From Day 1 to Week 12)
Measure Description	Participants recorded the number of puffs of rescue medication taken in the previous 12 hours each evening in an electronic diary. The number of daytime puffs per day over the 12 weeks of treatment was divided by the number of days to derive the mean number per day of daytime puffs of rescue medication for each participant. Mixed model used baseline number of daytime puffs per day of rescue medication, FEV1 prior to and 10-15 minutes post inhalation of salbutamol/albuterol, FEV1 prior to and 1 hour post inhalation of ipratropium, and inhaled corticosteroid use at baseline as covariates.
Time Frame	Baseline, up to 12 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.
Full analysis set included all participants who received at least 1 dose of study medication. The endpoint was analyzed only for those participants who had data at baseline and at week 12 for this outcome measure.

Reporting Groups

	Description
Indacaterol 150 µg	Participants received indacaterol 150 µg delivered via a single-dose dry-powder inhaler (SDDPI) plus placebo to tiotropium delivered via the manufacturer's proprietary inhalation device (HandiHaler®) once daily in the morning. Participants were permitted to take salbutamol/albuterol as a rescue medication.
Tiotropium 18 µg	Participants received tiotropium 18 µg delivered via the manufacturer's proprietary inhalation device (HandiHaler®) plus placebo to indacaterol delivered via a single-dose dry-powder inhaler (SDDPI) once daily in the morning. Participants were permitted to take salbutamol/albuterol as a rescue medication.

Measured Values

	Indacaterol 150 µg	**Tiotropium 18 µg**
Number of Participants Analyzed		

[units: participants]	**722**	**732**
Change From Baseline in the Mean Number Per Day of Daytime Puffs of Rescue Medication Over the Study Duration (From Day 1 to Week 12) **[units: Puffs]** **Least Squares Mean (Standard Error)**	**-0.90 (0.063)**	**-0.59 (0.063)**

No statistical analysis provided for Change From Baseline in the Mean Number Per Day of Daytime Puffs of Rescue Medication Over the Study Duration (From Day 1 to Week 12)

7. Secondary: Change From Baseline in the Mean Number Per Day of Nighttime Puffs of Rescue Medication Over the Study Duration (From Day 1 to Week 12) [Time Frame: Baseline, up to 12 weeks]

Measure Type	Secondary
Measure Title	Change From Baseline in the Mean Number Per Day of Nighttime Puffs of Rescue Medication Over the Study Duration (From Day 1 to Week 12)
Measure Description	Participants recorded the number of puffs of rescue medication taken in the previous 12 hours each morning in an electronic diary. The number of nighttime puffs per day over the 12 weeks of treatment was divided by the number of days to derive the mean number per day of nighttime puffs of rescue medication for each participant. Mixed model used baseline number of nighttime puffs per day of rescue medication, FEV1 prior to and 10-15 minutes post inhalation of salbutamol/albuterol, FEV1 prior to and 1 hour post inhalation of ipratropium, and inhaled corticosteroid use at baseline as covariates.
Time Frame	Baseline, up to 12 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.
Full analysis set included all participants who received at least 1 dose of study medication. The endpoint was analyzed only for those participants who had data at baseline and at week 12 for this outcome measure.

Reporting Groups

	Description
Indacaterol 150 µg	Participants received indacaterol 150 µg delivered via a single-dose dry-powder inhaler (SDDPI) plus placebo to tiotropium delivered via the manufacturer's proprietary inhalation device (HandiHaler®) once daily in the morning. Participants were permitted to take salbutamol/albuterol as a rescue medication.
Tiotropium 18 µg	Participants received tiotropium 18 µg delivered via the manufacturer's proprietary inhalation device (HandiHaler®) plus placebo to indacaterol delivered via a single-dose dry-powder inhaler (SDDPI) once daily in the morning. Participants were permitted to take salbutamol/albuterol as a rescue medication.

Measured Values

	Indacaterol 150 µg	Tiotropium 18 µg
Number of Participants Analyzed [units: participants]	**729**	**742**
Change From Baseline in the Mean Number Per Day of Nighttime Puffs of Rescue Medication Over the Study Duration (From Day 1 to Week 12) [units: Puffs] Least Squares Mean (Standard Error)	**-0.52 (0.043)**	**-0.28 (0.042)**

No statistical analysis provided for Change From Baseline in the Mean Number Per Day of Nighttime Puffs of Rescue Medication Over the Study Duration (From Day 1 to Week 12)

8. Secondary: Percentage of Days With no Rescue Medication Use During the 12 Weeks of Treatment [Time Frame: Up to 12 weeks]

Measure Type	Secondary
Measure Title	Percentage of Days With no Rescue Medication Use During the 12 Weeks of Treatment
Measure Description	A day with no rescue medication was defined as any day in the diary that the participant used no puffs of rescue medication. The percentage of days with no rescue medication was calculated by dividing the number of days with no

	rescue medication over the 12 week treatment period by the number of evaluable days and multiplying by 100. Mixed model used baseline percentage of days with no rescue medication, FEV1 prior to and 10-15 minutes post inhalation of salbutamol/albuterol, FEV1 prior to and 1 hour post inhalation of ipratropium, and inhaled corticosteroid use at baseline as covariates.
Time Frame	Up to 12 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.
Full analysis set included all 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	Participants received indacaterol 150 µg delivered via a single-dose dry-powder inhaler (SDDPI) plus placebo to tiotropium delivered via the manufacturer's proprietary inhalation device (HandiHaler®) once daily in the morning. Participants were permitted to take salbutamol/albuterol as a rescue medication.
Tiotropium 18 µg	Participants received tiotropium 18 µg delivered via the manufacturer's proprietary inhalation device (HandiHaler®) plus placebo to indacaterol delivered via a single-dose dry-powder inhaler (SDDPI) once daily in the morning. Participants were permitted to take salbutamol/albuterol as a rescue medication.

Measured Values

	Indacaterol 150 µg	Tiotropium 18 µg
Number of Participants Analyzed [units: participants]	**725**	**738**
Percentage of Days With no Rescue Medication Use During the 12 Weeks of Treatment [units: Percentage of days] Least Squares Mean (Standard Error)	**46.1 (1.65)**	**41.4 (1.64)**

No statistical analysis provided for Percentage of Days With no Rescue Medication Use During the 12 Weeks of Treatment

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	12 weeks
Additional Description	Safety set consisting of all participants who received at least one dose of study drug.

Reporting Groups

	Description
Indacaterol 150 µg	Participants received indacaterol 150 µg delivered via a single-dose dry-powder inhaler (SDDPI) plus placebo to tiotropium delivered via the manufacturer's proprietary inhalation device (HandiHaler®) once daily in the morning. Participants were permitted to take salbutamol/albuterol as a rescue medication.
Tiotropium 18 µg	Participants received tiotropium 18 µg delivered via the manufacturer's proprietary inhalation device (HandiHaler®) plus placebo to indacaterol delivered via a single-dose dry-powder inhaler (SDDPI) once daily in the morning. Participants were permitted to take salbutamol/albuterol as a rescue medication.

Serious Adverse Events

	Indacaterol 150 µg	Tiotropium 18 µg
Total, serious adverse events		
# participants affected / at risk	**22/794 (2.77%)**	**30/799 (3.75%)**
Cardiac disorders		
Acute coronary syndrome † 1		
# participants affected / at risk	**1/794 (0.13%)**	**0/799 (0.00%)**
Angina pectoris † 1		
# participants affected / at risk	**1/794 (0.13%)**	**0/799 (0.00%)**

Arrhythmia † 1		
# participants affected / at risk	**0/794 (0.00%)**	**2/799 (0.25%)**
Atrial fibrillation † 1		
# participants affected / at risk	**0/794 (0.00%)**	**1/799 (0.13%)**
Cardiac arrest † 1		
# participants affected / at risk	**0/794 (0.00%)**	**1/799 (0.13%)**
Cardiac failure congestive † 1		
# participants affected / at risk	**0/794 (0.00%)**	**1/799 (0.13%)**
Coronary artery disease † 1		
# participants affected / at risk	**2/794 (0.25%)**	**1/799 (0.13%)**
Myocardial infarction † 1		
# participants affected / at risk	**1/794 (0.13%)**	**0/799 (0.00%)**
Myocardial ischaemia † 1		
# participants affected / at risk	**1/794 (0.13%)**	**0/799 (0.00%)**
Eye disorders		
Diabetic eye disease † 1		
# participants affected / at risk	**0/794 (0.00%)**	**1/799 (0.13%)**
Gastrointestinal disorders		
Abdominal pain † 1		
# participants affected / at risk	**1/794 (0.13%)**	**0/799 (0.00%)**
Flatulence † 1		
# participants affected / at risk	**1/794 (0.13%)**	**0/799 (0.00%)**
Gastrooesophageal reflux disease † 1		
# participants affected / at risk	**1/794 (0.13%)**	**0/799 (0.00%)**
Melaena † 1		

# participants affected / at risk	0/794 (0.00%)	1/799 (0.13%)
Subileus † 1		
# participants affected / at risk	1/794 (0.13%)	0/799 (0.00%)
Vomiting † 1		
# participants affected / at risk	0/794 (0.00%)	1/799 (0.13%)
General disorders		
Non-cardiac chest pain † 1		
# participants affected / at risk	0/794 (0.00%)	1/799 (0.13%)
Immune system disorders		
Hypersensitivity † 1		
# participants affected / at risk	1/794 (0.13%)	0/799 (0.00%)
Infections and infestations		
Acute sinusitis † 1		
# participants affected / at risk	1/794 (0.13%)	0/799 (0.00%)
Appendicitis † 1		
# participants affected / at risk	1/794 (0.13%)	0/799 (0.00%)
Ear infection † 1		
# participants affected / at risk	0/794 (0.00%)	1/799 (0.13%)
H1N1 influenza † 1		
# participants affected / at risk	2/794 (0.25%)	0/799 (0.00%)
Influenza † 1		
# participants affected / at risk	0/794 (0.00%)	1/799 (0.13%)
Lobar pneumonia † 1		
# participants affected / at risk	0/794 (0.00%)	2/799 (0.25%)
Lower respiratory tract infection † 1		

# participants affected / at risk	1/794 (0.13%)	0/799 (0.00%)
Pneumococcal sepsis † 1		
# participants affected / at risk	0/794 (0.00%)	1/799 (0.13%)
Pneumonia † 1		
# participants affected / at risk	3/794 (0.38%)	2/799 (0.25%)
Septic shock † 1		
# participants affected / at risk	0/794 (0.00%)	1/799 (0.13%)
Urinary tract infection † 1		
# participants affected / at risk	0/794 (0.00%)	1/799 (0.13%)
Viral upper respiratory tract infection † 1		
# participants affected / at risk	0/794 (0.00%)	1/799 (0.13%)
Injury, poisoning and procedural complications		
Anaesthetic complication pulmonary † 1		
# participants affected / at risk	1/794 (0.13%)	0/799 (0.00%)
Drug toxicity † 1		
# participants affected / at risk	1/794 (0.13%)	0/799 (0.00%)
Fall † 1		
# participants affected / at risk	1/794 (0.13%)	1/799 (0.13%)
Foot fracture † 1		
# participants affected / at risk	1/794 (0.13%)	0/799 (0.00%)
Humerus fracture † 1		
# participants affected / at risk	0/794 (0.00%)	1/799 (0.13%)
Lumbar vertebral fracture † 1		
# participants affected / at risk	1/794 (0.13%)	0/799 (0.00%)
Overdose † 1		

# participants affected / at risk	0/794 (0.00%)	1/799 (0.13%)
Rib fracture † 1		
# participants affected / at risk	0/794 (0.00%)	1/799 (0.13%)
Investigations		
Fibrin D dimer increased † 1		
# participants affected / at risk	0/794 (0.00%)	1/799 (0.13%)
Troponin increased † 1		
# participants affected / at risk	1/794 (0.13%)	0/799 (0.00%)
Metabolism and nutrition disorders		
Metabolic disorder † 1		
# participants affected / at risk	0/794 (0.00%)	1/799 (0.13%)
Musculoskeletal and connective tissue disorders		
Bursitis † 1		
# participants affected / at risk	0/794 (0.00%)	1/799 (0.13%)
Costochondritis † 1		
# participants affected / at risk	0/794 (0.00%)	1/799 (0.13%)
Rheumatoid nodule † 1		
# participants affected / at risk	1/794 (0.13%)	0/799 (0.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		
Colon cancer † 1		
# participants affected / at risk	0/794 (0.00%)	1/799 (0.13%)
Gallbladder cancer † 1		
# participants affected / at risk	0/794 (0.00%)	1/799 (0.13%)
Lung adenocarcinoma † 1		
# participants affected / at risk	1/794 (0.13%)	0/799 (0.00%)

Lung neoplasm malignant † [1]		
# participants affected / at risk	0/794 (0.00%)	1/799 (0.13%)
Nervous system disorders		
Cerebrovascular accident † [1]		
# participants affected / at risk	0/794 (0.00%)	2/799 (0.25%)
Cerebrovascular insufficiency † [1]		
# participants affected / at risk	1/794 (0.13%)	0/799 (0.00%)
Epilepsy † [1]		
# participants affected / at risk	0/794 (0.00%)	1/799 (0.13%)
Syncope † [1]		
# participants affected / at risk	1/794 (0.13%)	0/799 (0.00%)
Vagus nerve paralysis † [1]		
# participants affected / at risk	0/794 (0.00%)	1/799 (0.13%)
Psychiatric disorders		
Alcohol withdrawal syndrome † [1]		
# participants affected / at risk	1/794 (0.13%)	0/799 (0.00%)
Mental status changes † [1]		
# participants affected / at risk	0/794 (0.00%)	1/799 (0.13%)
Renal and urinary disorders		
Nephrotic syndrome † [1]		
# participants affected / at risk	0/794 (0.00%)	1/799 (0.13%)
Respiratory, thoracic and mediastinal disorders		
Chronic obstructive pulmonary disease † [1]		
# participants affected / at risk	7/794 (0.88%)	6/799 (0.75%)

Dyspnoea † 1		
# participants affected / at risk	**1/794 (0.13%)**	**3/799 (0.38%)**
Hypoxia † 1		
# participants affected / at risk	**1/794 (0.13%)**	**0/799 (0.00%)**
Pleural effusion † 1		
# participants affected / at risk	**1/794 (0.13%)**	**1/799 (0.13%)**
Pleurisy † 1		
# participants affected / at risk	**0/794 (0.00%)**	**1/799 (0.13%)**
Pulmonary haemorrhage † 1		
# participants affected / at risk	**1/794 (0.13%)**	**0/799 (0.00%)**
Respiratory distress † 1		
# participants affected / at risk	**0/794 (0.00%)**	**1/799 (0.13%)**
Vascular disorders		
Hypertension † 1		
# participants affected / at risk	**0/794 (0.00%)**	**1/799 (0.13%)**
Peripheral arterial occlusive disease † 1		
# participants affected / at risk	**0/794 (0.00%)**	**1/799 (0.13%)**
Peripheral vascular disorder † 1		
# participants affected / at risk	**0/794 (0.00%)**	**1/799 (0.13%)**

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

Other Adverse Events

Hide Other Adverse Events

Time Frame	12 weeks
Additional Description	Safety set consisting of all participants who received at least one dose of study drug.

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
Indacaterol 150 µg	Participants received indacaterol 150 µg delivered via a single-dose dry-powder inhaler (SDDPI) plus placebo to tiotropium delivered via the manufacturer's proprietary inhalation device (HandiHaler®) once daily in the morning. Participants were permitted to take salbutamol/albuterol as a rescue medication.
Tiotropium 18 µg	Participants received tiotropium 18 µg delivered via the manufacturer's proprietary inhalation device (HandiHaler®) plus placebo to indacaterol delivered via a single-dose dry-powder inhaler (SDDPI) once daily in the morning. Participants were permitted to take salbutamol/albuterol as a rescue medication.

Other Adverse Events

	Indacaterol 150 µg	Tiotropium 18 µg
Total, other (not including serious) adverse events		
# participants affected / at risk	**80/794 (10.08%)**	**61/799 (7.63%)**
Respiratory, thoracic and mediastinal disorders		
Chronic obstructive pulmonary disease † 1		
# participants affected / at risk	**80/794 (10.08%)**	**61/799 (7.63%)**

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

Limitations and Caveats

Hide Limitations and Caveats

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

More Information

Hide More Information

Certain Agreements:

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

Publications automatically indexed to this study:

Buhl R, Dunn LJ, Disdier C, Lassen C, Amos C, Henley M, Kramer B; INTENSITY study investigators. Blinded 12-week comparison of once-daily indacaterol and tiotropium in COPD. Eur Respir J. 2011 Oct;38(4):797-803. doi: 10.1183/09031936.00191810. Epub 2011 May 26.

Responsible Party:	External Affairs, Novartis Pharmaceuticals
ClinicalTrials.gov Identifier:	NCT00900731 History of Changes
Other Study ID Numbers:	**CQAB149B2350**
Study First Received:	May 12, 2009
Results First Received:	July 22, 2011
Last Updated:	July 22, 2011
Health Authority:	United States: Food and Drug Administration Slovakia: State Institute for Drug Control Belgium: Federal Agency for Medicinal Products and Health Products Norway: Norwegian Medicines Agency Switzerland: Ethikkommission United Kingdom: Medicines and Healthcare Products Regulatory Agency Austria: Federal Office for Safety in Health Care Colombia: INVIMA Instituto Nacional de Vigilancia de Medicamentos y Alimentos France: Afssaps - Agence française de sécurité sanitaire des produits de santé (Saint-Denis) Germany: Federal Institute for Drugs and Medical Devices Greece: National Organization of Medicines Hungary: National Institute of Pharmacy Israel: Ethics Commission Mexico: Ministry of Health Poland: Office for Registration of Medicinal Products, Medical Devices and Biocidal Products Russia: Ministry of Health of the Russian Federation Canada: Health Canada